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Advocacy - A practical guide: with polio eradication as a case study

This guide outlines advocacy activities to build human, financial and political support for the Polio Eradication Initiative as a platform for strengthening preventive health services. It outlines four basic steps that are essential for an effective advocacy initiative – documenting the situation, packaging the message, working with the media and mobilizing communities and individuals. This practical guide uses specific examples and ideas from the Polio Eradication Initiative, and leaves it up to the user to decide how to apply them towards achieving their own advocacy goals.

HPV Vaccine Communication: Special considerations for a unique vaccine.

This report presents communication guidance and specific considerations for countries that plan to introduce human papillomavirus (HPV) vaccine into their national immunization programme. New vaccine introduction is a hallmark of the Decade of Vaccines, but HPV vaccine is unique for many reasons. This report aims to offer guidance in two main areas: The first is to offer advice on basic communication planning and implementation for immunization; the second is to discuss specific considerations for HPV vaccine.


The meeting serves as a forum for WHO and other partners of the Global Alliance for Vaccines and Immunization (GAVI) to discuss research and development issues and to update research agendas. Moreover, the meeting will serve as a forum for broader issues of vaccine policy and implementation. The report will provide a summary of the meeting presentations and discussions which focused on Pandemic Influenza vaccines, development of vaccines against Malaria, Measles and Rubella, Pharmaco-vigilance in LMICs, Project Optimize- immunization systems and technologies for tomorrow.

WHO immunization work: highlights 2008-09

This newsletter provides an overview of WHO’s main achievements in immunization for 2008-09. It covers a broad scope of activities, from global immunization policy; to research and development of vaccines and technologies; quality, safety and standards; access to immunization services; and communication, advocacy and media. It also describes the the framework and priorities for the Strategic Plan 2010-2015 of the Department of Immunization, Vaccines and Biologicals. The document will be of interest to all those who wish to learn more about the focus of WHO’s vaccine and immunization work.

WHO-UNICEF Joint Statement on Vaccine Donations

This joint statement is intended to provide guidance to achieve “Good Donations Practice” for both vaccine donors and recipients, and to serve as a basis for preparing national or institutional donations guidelines.
WHO: Working to ensure global quality, safety and standard in immunization

This document provides a general overview of the work carried out by the Quality, Safety and Standards Team of the WHO Department of Immunization, Vaccines and Biologicals. It briefly outlines the changing regulatory environment required to keep pace with demand for the introduction of new vaccines. It includes sections on: setting norms and standards and establishing reference preparation materials; assuring the quality of vaccines and immunization equipment; and monitoring, assessing and responding to vaccine safety issues of global concern. Information about the funding of this work is provided, as are links to sources of further information.
In February 2000, WHO organized a meeting with the aim of redefining the future directions for rotavirus vaccine research in these countries. A major recommendation of this meeting was that the global incidence and clinical presentation of intussusception among children in developing countries should be reviewed (WHO/V&B/00.25). The present report responds to the recommendations of the above-mentioned meeting. Based on an extensive review of published literature from 70 developing and developed countries. It aims to define the baseline incidence of acute intussusception in infants and children, the clinical presentation of the condition, and current trends in its management in these countries.

Comprehensive cervical cancer prevention and control: a healthier future for girls and women
This WHO Guidance Note advocates for a comprehensive approach to cervical cancer prevention and control and is aimed at senior policy makers and programme managers. It describes the need to deliver effective interventions across the female life course from childhood through to adulthood. These include community education, social mobilization, HPV vaccination, screening, treatment and palliative care. It outlines the complementary strategies for comprehensive cervical cancer prevention and control, and highlights collaboration across national health programmes (particularly immunization, reproductive health, cancer control and adolescent health), organizations and partners.

Generic protocol to estimate the burden of Shigella diarrhea and dysenteric mortality - Field test version, May 1999
This V&B protocol provides a general outline for a population-based study of the disease burden due to Shigella diarrhoea and dysenteric mortality. It will need to be adapted to the local setting, and details of field work and operational procedures should be added by local investigators experienced in conducting field studies of diarrhoeal diseases. The study requires collaboration with a laboratory experienced in isolation and identification of Shigella from fecal specimens and experienced in conducting antimicrobial susceptibility testing of isolates.

Generic protocol to examine the incidence of lower respiratory infection due to respiratory virus in children less than five years of age
Respiratory syncytial virus (RSV) plays a major role in childhood morbidity and mortality in industrialized countries. The same is suspected to be true in developing countries, although there have been only a limited number of population-based studies of RSV disease burden in these settings. Such information is of increasing importance, as vaccines against RSV are presently under development. This document provides a generic study protocol, which can be adopted by investigators interested in conducting a study of RSV disease burden.
(Cross reference: Section 2: Innovation: new and/or improved vaccines.)
Group A streptococcal vaccine development: current status and issues of relevance to less developed countries.

This is one of a series of papers that review the clinical importance of group A streptococcal diseases, possible control strategies, prevention by vaccination and a possible role of WHO. In light of the current lack of a clear strategy for primary prevention of GAS infections, there is a place for a safe, effective, affordable and practical GAS vaccine. Based on the epidemiology of GAS diseases in less developed countries, there is concern that the vaccine most advanced in development - a multivalent, type-specific vaccine - may not provide sufficient and long-lasting protection in countries with highly endemic GAS diseases. The review advocates for an assessment of the efficacy GAS vaccines in less developed country settings, for oversight and coordination of GAS vaccine development activities, and that a vaccine is made available for the prevention of GAS diseases in less developed countries.

Guidelines for WHO/EPI collaborative studies on poliomyelitis - standard procedure for determining immunity to poliovirus using the microneutralization test

The test procedure for polio neutralizing antibody tests is precisely presented so that laboratories conducting tests for polio studies can achieve consistent results, using standard cell line and media, international standard poliovirus antiserum and standard Sabin strains. The presentation of results in international units will permit comparison of results between different studies in different countries and different regions of the world. Annexes provide details on specific procedures and preparations and include a basic code of laboratory practice.

Immunological Basis for Immunization - Module 5: Tuberculosis

Module 5 of the series Immunological basis for immunization. This document may be used as a reference source, as part of training curricula or as a training aid. It contains clear descriptions of the following aspects of tuberculosis: the organism and the disease, the response to natural infection, characteristics of BCG vaccines, response to immunization, current practices and schedules, future prospects and needs, and implications for immunization programmes. (For a listing of the complete series, see Section 7.3.3.)

Manual for the laboratory diagnosis of measles virus infection

This manual aims to assist in effective measles virological surveillance by presenting information on the agent, the disease, the immune response and prevention strategies, discussing the role of the laboratory in measles control and prevention and the requirements for laboratory surveillance. Also presented are detailed descriptions of the laboratory procedures recommended for the diagnosis of measles infection. It is intended for use by virologists and technologists working in laboratories collaborating with measles control and elimination efforts. It may also be of interest to managers of measles control programmes and field staff, who will be better able to appreciate the role of the laboratory and use it appropriately. (Cross reference: Section 5.3: Assessment and monitoring/Accelerated disease control.)

Manual for the laboratory diagnosis of yellow fever virus infection

This manual provides guidelines on the establishment and maintenance of an effective laboratory network capable of reliability providing confirmation of YF infection.

Measles control in the 1990s: Measles serology

A review of serological assays to estimate protection against measles conferred by measles vaccines.
**Measles control in the 1990s: Minimizing nosocomial transmission**

This document reviews recent literature on the subject, quantifies the contribution of nosocomial transmission to overall measles incidence (where possible) and provides practical recommendations to national EPI programme managers on strategies to combat the problem.

**Measles control in the 1990s: Principles for the next decade**

An outline of the epidemiology of measles in the pre- and post-vaccine eras in industrialized and developing countries. This document includes a discussion on lessons learned from experience and gives recommendations for the improvement of measles control.

**Report of the meeting on the scientific basis for stopping polio immunization, Geneva, 23-25 March 1998**

The meeting was called to review current scientific knowledge relevant to stopping polio immunization after global eradication of polio. The objective was to define research that could be performed in the near future to permit a strategy for stopping immunization to be recommended, using the best scientific evidence available. The meeting concluded that, while it was unlikely that vaccine-derived polioviruses (VDPV) would circulate indefinitely after the use of oral polio vaccine was discontinued, there are considerable gaps in our knowledge. In particular, studies are needed to define the transmissibility of VDPV in the general population, to examine the potential for immunodeficient persons to re-seed VDPV into communities, to develop appropriate surveillance strategies for detecting VDPV and to evaluate potential strategies for stopping vaccination. This report is targeted towards epidemiologists, virologists, immunologists, vaccine manufacturers, regulators and researchers.
Standardization and validation of serologic assays for the evaluation of immune responses to Neisseria meningitidis serogroup A/C vaccines, Geneva, 8-9 March 1999

An important juncture has been reached in the development and licensing of meningococcal conjugate vaccines. Few, if any, countries experience sufficiently high levels of serogroup C disease to permit comprehensive prospective studies of vaccine efficacy in formal clinical trials. In the United Kingdom in October 1999, a serogroup C conjugate vaccine became the first vaccine to be licensed for use in infants for which efficacy was not determined by a phase III clinical trial but inferred from immunogenicity data. Having set this precedent, a similar approach may be adopted for the licensure of new meningococcal conjugate vaccines being developed for prevention of disease caused by the other serogroups. Since decisions on the licensure of novel vaccines and the wider implementation of existing vaccines are critically dependent upon serological data, it was essential to assess whether current serological assays provide appropriate data. A meeting was held in March 1999, under the auspices of the WHO in Geneva, to attempt to clarify and resolve issues relating to laboratory assays for the analysis of human serum for meningococcal serogroup A and C specific antibodies. The participants addressed: (i) whether the existing standardized serologic assays provide sufficiently unambiguous data to permit decisions for licensing and public health recommendations of meningococcal serogroup A and C vaccines, and (ii) what additional studies, if any, needed to be conducted in order to resolve the outstanding issues relating to current assays, and the need, if any, for development of improved assays.

The child, measles and the eye
A set of 20 coloured slides, designed to help workers in immunization, eye-care programmes, nutrition education, maternal and child health, and primary health care in general. The slide set shows the risks of damage to the eye and the steps recommended to save sight. Accompanying text describes each slide and includes test questions for use in training.

The diagnosis, treatment and prevention of typhoid fever.
This document contains general background information on the epidemiology, infection, diagnosis, treatment and prevention of typhoid fever. Data were updated by 22 experts from 14 countries.

Treating children with measles
A set of 20 coloured slides, plus a booklet containing information on averting deaths from measles and minimizing the severity of complications of the disease through proper case management. The aim of this slide set is to train health workers in measles case management, with emphasis on how to identify, assess and classify a case, and to prevent, recognize, treat and manage complications.

WHO guidelines for epidemic preparedness and response to measles outbreaks
Produced jointly by the Department of Vaccines and Biologicals and the Department of Communicable Disease – Surveillance and Response, this document focuses on three main areas: (i) the organism and the disease, (ii) prevention and control, and (iii) epidemic control. The annexes include case definitions, information on case management, measles vaccine suppliers, elimination strategies, useful forms and calculations, references and suggested further reading.
Yellow fever

This document was produced as a background document for a technical meeting held in March 1998 (Yellow fever technical consensus meeting, Geneva, 2-3 March 1998, WHO/EPI/GEN/98.08, described below). It is a literature review, providing background material for assessment of current strategies focusing on the epidemiology of yellow fever, particularly in Africa. It reviews (a) surveillance systems and their effectiveness, and (b) studies examining the cost-effectiveness of preventive versus emergency vaccination programmes. It is aimed at public health and international development workers and serves as a comprehensive basic reference for yellow fever, its epidemiology and history.

(Cross reference: Section 5.2: Assessment and monitoring/Immunization systems)
**Aide-Memoire: to ensure the efficiency and safety of mass immunization campaigns with injectable vaccines**

**Assessment of immunization services and the coordination of the GAVI activities at country level. Report of a meeting, Geneva, 3-5 May 2000**

In 1999 the new immunization services assessment guidelines were developed as a rapid assessment tool. They were also designed as a means of assessing the capacity of immunization services to integrate new vaccines and other innovations, and of aiding partners and governments to plan the efficient allocation of resources. It was agreed that the immunization services assessment guidelines could serve country managers and partners in the review process and provide the Global Alliance on Vaccines and Immunization (GAVI) with a useful decision-making tool in relation to the funding of immunization services, the introduction of new vaccines and infrastructure development.

**Creating national and regional frameworks to support HIV vaccine development in developing countries. Report from a WHO-UNAIDS consultation. Lausanne, Switzerland, 2-3 September 2004**

This report: review progress and discuss key scientific challenges relevant to HIV vaccine development and evaluation; discuss key issues/challenges for the development of National AIDS vaccine plans; discuss policies and mechanisms for reviewing and approving research protocols; discuss the regulatory, legal, and ethical framework; review and adopt the African AIDS Vaccine Program (AAVP) guidance document for national plans in Africa; share country experiences for the development of national plans; make recommendations for establishing regional networks in other regions.

**Fourth informal consultation on the polio laboratory network, Geneva, 1-2 October 1998**

The fourth informal consultation on the polio laboratory network was held from 1-2 October 1998 at WHO, Geneva, to review the status of the Global Polio Laboratory Network and to accelerate progress towards achieving the availability of the services of an accredited Network Laboratory to every country. This report summarizes the status of the Network and lists activities recommended to accelerate further development. Major recommendations include revision of the laboratory accreditation scheme to include the category of provisional accreditation; revision of the polio laboratory manual to include improved laboratory methods and procedures; establishment of standard laboratory data recording, management and reporting; and initiation of implementation of plans for containment of laboratory stocks of wild polioviruses.

**Global Immunization Vision and Strategy 2006-2015**

In response to challenges to immunization, including the need to protect more people and introduce new vaccines, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), in consultation with other partners, have developed the Global Immunization Vision and Strategy (GIVS) for the period 2006-2015. GIVS is a framework that offers policy-makers and other stakeholders a unified vision of immunization and a set of strategies from which countries can select those most suited to their specific needs.
Global Immunization Vision and Strategy Brochure
This colourful WHO/UNICEF brochure captures the essence of 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 document provides the four strategic areas of GIVS and immunization goals established therein.

Global Influenza Pandemic Vaccine Action Plan
This publication describes strategies for the short, mid and long term, aiming to increase influenza vaccine production and surge capacity before and during an influenza pandemic.

Global vaccine action plan 2011-2020
The Global Vaccine Action Plan (GVAP) endorsed by the 194 Member States of the World Health Assembly in May 2012 is a framework to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities. The Plan aims to strengthen routine immunization to meet vaccination coverage targets, accelerate control of vaccine-preventable diseases with polio eradication as the first milestone, introduce new and improved vaccines and spur research and development for the next generation of vaccines and technologies. The plan is expected to reduce global childhood mortality, surpassing the United Nations Millennium Development Goal 4 target to reduce by two-thirds the under-five mortality rate.

Global vaccine safety blueprint - The landscape analysis
Global vaccine safety blueprint is a WHO strategic document that proposes new approaches for strengthening vaccine pharmacovigilance systems in low- and middle-income countries. The Blueprint was written based on findings from a survey of global vaccine safety stakeholders, a report on SWOT analysis of ongoing global and inter-country vaccine safety initiatives, a survey of regulators from producing and procuring countries, a survey of vaccine manufacturers, a baseline assessment of the vaccine safety systems from in 11 countries participating in WHO's a global post-marketing surveillance network, an analysis of NRA assessment data and financial assessment of a sample of national vaccine safety systems and of existing vaccine safety initiatives. This landscape analysis was done in 2010-2011 to generate accurate, meaningful, up-to-date, and actionable information on current opportunities and challenges in vaccine safety across the world. The subject of this DPAF is to proposed a single publication summarizing the seven studies.

How to implement influenza vaccination of pregnant women
This manual serves as a primary resource to help users to decide, plan and implement maternal influenza vaccination strategies and to foresee and address potential challenges related to decision-making or implementation. The manual aims to guide countries by providing principles and considerations to support decision-making and introduction planning rather than prescribing introduction measures that may not be applicable in some country contexts.

Imaginative ways of raising immunization coverage
Imaginative ways of raising immunization coverage
Immunization costing and financing: A tool and user guide for comprehensive Multi-Year Plan (cMYP)

Estimating the costs and financing of immunization programmes is a key step in the development of a comprehensive Multi-Year Plan (cMYP). To help undertake the costing and financing of a cMYP a tool has been developed - the cMYP Costing and Financing Tool. This tool is accompanied by a User Guide which provides an overview of important immunization costing and financing concepts, methodologies and definitions, as well as step-by-step instruction on how to use the costing and financing tool, including how to analyse the data and findings.

Immunization costing and financing: A tool and user guide for comprehensive Multi-Year Plan (cMYP) - Update 2014

Estimating the costs and financing of immunization programmes is a key step in the development of a comprehensive Multi-Year Plan (cMYP). To help undertake the costing and financing of a cMYP a tool has been developed - the cMYP Costing and Financing Tool. This tool is accompanied by a User Guide which provides an overview of important immunization costing and financing concepts, methodologies and definitions, as well as step-by-step instruction on how to use the costing and financing tool, including how to analyse the data and findings.

Immunological Basis for Immunization - Module 3: Tetanus (Revision)

This module revises/replaces the document WHO/EPI/GEN/93.13

Immunological basis for immunization Series: Module 15: Meningococcal Disease

The main purpose of the modules of the series - which are published as separate/vaccine specific modules - is to give immunization managers and vaccination professionals a brief and easily-understood overview of the scientific basis of vaccination. This module focuses on meningococcal.

Immunological basis for immunization Series: Mumps

The main purpose of the modules of the series - which are published as separate/vaccine specific modules - is to give immunization managers and vaccination professionals a brief and easily-understood overview of the scientific basis of vaccination. This module focuses on Mumps.

Immunological basis for immunization: Cholera

The main purpose of these documents - which are published as separate disease/vaccine-specific modules - is to give vaccination professionals e.g. EPI managers, a brief and easy-to-understand overview of the scientific basis of vaccination.

Immunological basis for immunization: Japanese Encephalitis

The main purpose of the modules of the series - which are published as separate/vaccine specific modules - is to give immunization managers and vaccination professionals a brief and easily-understood overview of the scientific basis of vaccination. This module focuses on Japanese Encephalitis.

Immunological basis for immunization: Module 4: Pertussis - Update 2009

This module replaces the publication WHO/EPI/93.14. The main purpose of the modules of the series - which are published as separate/vaccine specific modules - is to give immunization managers and vaccination professionals a brief and easily-understood overview of the scientific basis of vaccination. This module focuses on Pertussis.
Immunological basis for immunization: Module 9: Haemophilus influenza type b vaccines
The main purpose of this document - part of the Immunological basis for immunization series- is to give vaccination professionals e.g. EPI managers, a brief and easy-to-understand overview of the scientific basis of vaccination regarding Haemophilus influenzae type b.

Immunological basis for immunization: Pneumococcal vaccine
The main purpose of this document is to give vaccination professionals e.g. EPI managers, a brief and easy-to-understand overview of the scientific basis of vaccination related to Pneumococcal.

Immunological basis for immunization: Rubella
The main purpose of these documents - which are published as separate disease/vaccine-specific modules - is to give vaccination professionals e.g. EPI managers, a brief and easy-to-understand overview of the scientific basis of vaccination.

Increasing immunization coverage at the health facility level
The major focus of this document is work carried out by immunization staff in order to improve access to immunization and increase coverage in their catchment areas. It includes a problem-solving approach through the use of local data, consultation with communities and re-establishing outreach.

Intermittent Preventive Treatment for Infants Using Sulfadoxine-Pyrimethamine (SP-IPTi) for Malaria Control in Africa: An Implementation Field Guide
SP-IPTi is the administration of a full therapeutic course of sulfadoxine-pyrimethamine (SP) delivered through the Expanded Programme on Immunization (EPI) at intervals corresponding to routine vaccination schedules for the second and third doses of DTP/Penta, and measles vaccination -- usually at 8-10 weeks, 12-14 weeks, and ~9 months of age -- to infants at risk of malaria in Sub-Saharan Africa. This implementation guide provides the necessary technical and operational information and tools for country-level policy-makers and programme managers to decide on how to include SP-IPTi with immunization services. This practical "how to" guide draws upon the experience and lessons learned from pilot implementation projects in Benin, Ghana, Madagascar, Malawi, Mali, Senegal and Tanzania.
Issues relating to the use of BCG in immunization programmes - a discussion document

Of all the infant vaccines in use today, bacille Calmette-Guérin vaccine (BCG) has been in use the longest. Yet controversy remains about its continued use. This document lays out clearly the arguments why BCG is likely to remain a vital part of immunization schedules for many countries well into the next decade. It describes the currently-used BCG vaccines and policies throughout the world. It covers practical aspects such as contraindications and administration as well as adverse effects. There is a chapter on how BCG fits into the ongoing search for a new vaccine that might protect against all forms of TB, or at least against pulmonary TB. Finally, these discussions are placed in the context of national policy for the use of BCG. The document supports the continued use of BCG while the search continues for a new generation of vaccine.

(Cross reference: Section 2: Innovation: New and/or improved vaccines)


This document is the report of a meeting convened by WHO on the impact of targeted programmes on health systems, focusing on the Polio Eradication (PE) Initiative as a case study. The meeting reviewed six recent studies assessing the effects of PE on immunization and broader health systems development. There is no debate that PE holds the potential for positive synergies and impact on health systems. Determining the extent to which this has been achieved has proven difficult. The studies presented at this meeting found no overwhelming evidence of either great positive benefit or serious negative impact on national health systems — however, there are missed opportunities to do more. The recommendations from the meeting summarize the next steps required to optimize the opportunities of PE to strengthen health systems while minimizing the threats. The findings of this report can help guide the planning of other health intervention programmes.

Meeting report: HPV Surveillance and Monitoring Meeting, 16-17 November 2009

The document summarizes the presentations and discussions of the HPV Surveillance and Monitoring Meeting held on 16-17 November 2009 at WHO Geneva in order to further delineating objectives and strategies for HPV vaccine impact monitoring and to discuss methods for HPV vaccine coverage monitoring.

Missed opportunities for immunization: Global review

Review of studies from developing and industrialised countries, with recommendations relevant to immunization programmes in all countries.

Options for a global fund for new vaccines

This document outlines desirable characteristics of various financing mechanisms, and assessed various global fund constructs against these characteristics. Some already existing funds and mechanisms are examined closely, including the meningitis International Coordinating Group, the Vaccine Independence Initiative, the PAHO Revolving Fund, and a proposed new global fund. The document is intended for donor organizations and policy planners in considering possible financing mechanisms and their implications. The annex include an extensive bibliography with sources for more information.

This document provides guidance for immunization managers and maternal child health partners seeking to introduce hepatitis B birth dose vaccination into their national immunization programmes, placing particular emphasis on the unique programmatic features of birth dose vaccination and the necessary integration with obstetric and post-natal care. This document will also be helpful for countries that have already introduced HepB-BD but would like to improve coverage.

Principles and considerations for adding a vaccine to a national immunization programme - From decision to implementation and monitoring.

This document reviews the principles and issues to be considered when making decisions about and planning the introduction of a vaccine into a national immunization program. Importantly, the document also highlights ways to use the opportunity provided by the vaccine introduction to strengthen immunization and health systems. This comprehensive resource document describes the latest references and tools related to vaccine decision-making, economic analyses, cold chain, integrated disease control and health promotion, vaccine safety, communications, monitoring, and more, and provides URL links to many of these resources. For more detailed information about a specific vaccine or aspect of immunization, decision-makers and planners should consult vaccine-specific position papers, vaccine-specific introduction guidance and other tools developed by WHO, UNICEF and other partners.


What future role do public sector vaccinology institutions envisage for themselves in the rapidly changing world of vaccines, and how can WHO help? This was the question addressed by representatives from public sector vaccinology institutions (PSVIs) and private industry participants were convened by the Access to Technologies Team of the World Health Organization (WHO/ATT). Ongoing work by public sector manufacturers in producing combination vaccines and vaccines against “neglected diseases” reflect the considerable contribution public sector can make to global vaccine supply. However, challenges such as the rising complexity of vaccine production, increasing regulatory demands and strengthened international patent enforcement exacerbate the already widening technology gap between the public and private sectors. Private–public sector partnerships and public–public sector collaborations in the form of technology transfers or joint ventures are of increasing interest to public sector manufacturers as a way to address these constraints and improve long-term viability. Experiences shared at this meeting illustrate how the ultimate goal must be carefully defined and planned. Foremost amongst the results of this meeting are recommendations for PSVIs and recommendations for WHO, which are summarized within this report.
Report of the Ad-hoc consultation on typhoid vaccine introduction and typhoid surveillance

This is a report of the ad-hoc consultation on typhoid vaccine introduction and typhoid surveillance organized by WHO/HQ/IVR and this report summarizes the outcome of this consultation. The tentative Table of content is attached as a separate sheet. The document presents the discussion and general consensus on the strategies for the introduction of and the choices for available typhoid vaccines. It also presents the issues around surveillance for typhoid and what needs further strengthening. It is an important outcome as it is the first of such consultation involving a broad range of people with diverse background, but all involved in either immunization or communicable diseases control and surveillance, including laboratory experts. It will be an important reference document for future typhoid vaccination programmes.

Report of the Immunization and Vaccines related Implementation Research (IVIR), Advisory Committee Meeting, Geneva, 26-28 June 2013

The Immunization and Vaccines related Implementation Research (IVIR) Advisory Committee (AC) meeting report summarizes the deliberations of the Committee on matters related to implementation research and their relevance to immunization policies and practices during the face-to-face meeting June 26-27 June 2014. The document highlight issues on hepatitis impact evaluation, malaria vaccine impact and cost-effectiveness, a measles investment case, burden of yellow fever estimation across Africa, varicella and zoster vaccination modeling and cost-effectiveness in low and middle income countries and the WHO implementation research priority setting framework.

Response to measles outbreaks in measles mortality reduction settings

This document is targeted for use in countries in measles mortality reduction settings. It provides guidance to public health workers at the national and regional levels on the appropriate measles outbreak prevention and response practices. More specifically, this document provides guidance on detecting and confirming a measles outbreak; investigating and managing an outbreak; and communications and public awareness during a measles outbreak (see table of contents for more details).

Review of existing documents on planning, performance and assessment of clinical studies on vaccines

This document reviews the major guidelines currently available on clinical trials on vaccines. It concludes that there are several essential features of clinical trials on vaccines that are not sufficiently covered in existing documents, because they do not give sufficient consideration to the distinct features of vaccines. It contains a review of most of the relevant guidelines in existence and provides a blueprint for the gaps still existing. It is intended as a reference document for national authorities involved in performance or evaluation of clinical trials on vaccines. It contains a number of annexes that reference key documents, including those of the EMEA and the FDA.
SAGE working group on vaccination in acute humanitarian emergencies: a framework for decision making

Vaccine preventable diseases constitute a significant proportion of infectious diseases of public health importance in humanitarian emergencies. The focus of this document is on humanitarian emergency settings and it aims to provide an approach for deciding which vaccines, if pre-emptively and properly delivered at the outset of an emergency, would constitute high priority public-health interventions and would reduce avoidable death and disease. It will assist the user to determine thoughtfully, deliberately, ethically and rationally whether or not the delivery of one or more vaccines to specific target populations during the acute phase of an emergency, would result in an overall saving of lives, a reduction in mortality and morbidity, a reduction in the burden placed upon already strained health services, and more generally a contribution to more favourable social outcomes.

Solar energy and health -- Report of the World Solar Summit Process

Outline of a strategy which focuses on the health sector as an entry point for large-scale introduction of solar energy technologies into the rural areas of developing countries. A report prepared by WHO/EPI, with the help of a panel of 15 specialists, and presented at the High Level Expert Meeting of the World Solar Summit at UNESCO in July 1993. It was planned that this proposal would be refined in light of comments and feedback for further review at subsequent meetings on the Solar Decade.

State of the art of new vaccine research and development

Although highly effective vaccines are available against a number of pathogens, the world's poorest are still suffering a heavy toll of premature death and disability from infectious diseases for which vaccines do not exist or else need to be improved. For these diseases, it is of crucial importance that vaccine R&D be considered as a priority. The present document represents an extensive analysis of the state of the art of vaccine R&D against infectious diseases of public health importance for which vaccines still are non-existent, or need substantial improvement.

State of the world's vaccines and immunization. Third edition. Executive summary - English version

Executive summary
Strategic Plan 2006-2009

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

Sub-national management of immunization services during health sector reform (HSR) - Fact sheet 3 of 3

Temperature Sensitivity of Vaccines

The first version of this document was developed by Artur Galazka in 1989, as a WHO publication (WHO/EPI/GEN/89.08) called Stability of vaccines. The current document is a revision of the classic document, also by Dr Galazka, with the assistance of Julie Milstien and Michel Zaffran, entitled Thermostability of Vaccines (WHO/GPV/98.07), which was based on that earlier work. It has been updated to include both new products and new strategic practices.

The Common Assessment Tool for immunization services (booklet1)

This booklet gives you the information you need to carry out an assessment of immunization services.

The Common Assessment Tool for immunization services (booklet2)

This booklet gives you the information you need to carry out an assessment of immunization services.

The Common Assessment Tool for immunization services (booklet3)

This booklet describes the activities the sub-team at the national level needs to carry out.

The Common Assessment Tool for immunization services (booklet4)

This booklet describes the activities the Sub-National Sub-Team needs to carry out.

The Common Assessment Tool for immunization services (booklet5)

This booklet describes the activities the Service Delivery Sub-Team needs to carry out.

The Immunological Basis for Immunization Series. Module 19: Human papillomavirus infection

Brief and easily-understood overview of the scientific basis of vaccination. Focus on human papillomavirus infection.
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The Immunological basis for immunization series - Module 22: Hepatitis B
The main purpose of the modules of the series - which are published as separate/vaccine specific modules - is to give immunization managers and vaccination professionals a brief and easily-understood overview of the scientific basis of vaccination. This module focuses on Hepatitis B.

The Initiative for Vaccine Research Strategic Plan 2010-2020
As the WHO entity for vaccine research, IVR has prepared a long-term Strategic Plan to address critical challenges in vaccine development and vaccination research over the period 2010-2020. The Plan will be aligned with WHO's strategy and policies to stimulate innovation in health research, as well as with the immunization agenda of the Organization, the Global Immunization Vision and Strategy.

The child, measles and the eye
This teaching aid is about measles, and its potentially harmful effects on the eyes of children. Understanding the risks of damage to the eye from measles is the first step before learning what action to take to save sight.

Treating measles in children
The aim of this booklet is to train health workers in measles case management, with emphasis on how to:
. identify, assess and classify a case
. prevent, recognize, treat and manage complications.

Vaccines and immunization update. A UNICEF-WHO quarterly technical bulletin for managers of immunization services and health professionals
An eight-page quarterly technical bulletin jointly published by UNICEF and WHO. It covers technical issues relevant to managers of immunization services and health personnel involved in immunization activities. It is an important tool for disseminating regular technical information to countries and regions, for example, schedules of meetings, workshops, training, new guidelines; regional facts and figures, etc. Country-specific technical issues will also be shared by managers of immunization services or other country-based staff whenever it is relevant to the "immunization community".

WHO manual for the establishment of national and other secondary standards for vaccines
Biological reference standards are used in qualifying or validating test procedures to ensure uniformity in the designation of potency of biologicals. WHO developed the Recommendations for the preparation, characterization and establishment of international and other biological reference standards. Feedback from the National Control Laboratories (NCLs) and vaccine manufacturers indicated that they had many questions concerning the establishment of national standards. A practical manual for the use by the NCLs and vaccine manufacturers would be of help. This manual will be primarily aimed at national and other secondary standards which will be used in the potency testing and other bioassays of vaccines. This document will explain in detail the issues which must be considered and the general principles in the preparation and calibration of such standards.
Working papers for solar energy and health report

A selection of working papers which form the basis for the strategy to introduce solar energy technologies into the health sector, as outlined in the report (Solar energy and health -- Report of the World Solar Summit Process (WHO/EPI/LHIS/93.02)). Prepared by a number of experts in the field of solar energy, the papers are included unabridged in their original language of submission,
State of the world’s vaccines and immunization. Third edition.

This report is a call to action to governments and donors to sustain and increase funding for immunization in order to build upon the progress made so far in meeting the global goals. It focuses on the major developments in vaccines and immunization since 2000.

Part 1 (Chapters 15) examines the impact of immunization on efforts to meet the MDGs, especially the goal to reduce deaths among children under five. It looks at the development and use of vaccines and at the safeguards that have been put in place to ensure their safety, efficacy, and quality. It sets out the progress and challenges in meeting the immunization-related global goals, and looks both at the cost of scaling up immunization coverage to meet these goals, and efforts to ensure that the achievements are sustainable in the long term. Finally, it looks beyond 2015 to likely changes in the immunization landscape.

Part 2 focuses on over 20 vaccine-preventable diseases and reviews progress since 2000 in efforts to protect populations against these diseases through the use of vaccines.

Vaccines and immunization update. A UNICEF-WHO quarterly technical bulletin for managers of immunization services and health professionals

An eight-page quarterly technical bulletin jointly published by UNICEF and WHO. It covers technical issues relevant to managers of immunization services and health personnel involved in immunization activities. It is an important tool for disseminating regular technical information to countries and regions, for example, schedules of meetings, workshops, training, new guidelines; regional facts and figures, etc. Country-specific technical issues will also be shared by managers of immunization services or other country-based staff whenever it is relevant to the "immunization community".
**Economics of immunization: a guide to the literature and other resources**

Within the context of the economics of immunization, this document identifies literature and web resources on costing, cost-benefit analyses, financing, policy issues, tools, and other related topics.

**GPEI Financial resource requirements 2004-2008**

**Guidance on the economic evaluation of influenza vaccination**

The purpose of this document is to outline the key theoretical concepts, best practice in methodologies, and to provide guidance on the economic evaluation of influenza vaccination in LMICs. The guidance is aimed at those seeking to conduct, commission, or critically appraise economic evaluations of influenza vaccination in LMICs. The document is not intended to be a step-by-step manual to produce an economic evaluation but to offer high-level guidance on influenza vaccination assessment which can be adapted to the setting of interest.

**Guidelines for estimating the economic burden of diarrhoeal disease**

These guidelines explain how to estimate the economics burden associated with diarrhoeal disease. The overall objective of the guidelines is to assess the economic savings from introducing a rotavirus vaccine into the national vaccination schedule. The guidelines are divided into 6 modules: 1) Cost of hospitalizations 2) Outpatient costs 3) Cost of treatment in the informal health sector 4) Caregiver and out-of-pockets costs 5) Analysis and presentation of results and 6) Cost-effectiveness analysis.

**How to monitor temperatures in the vaccine supply chain**

This module of the WHO Vaccine Management Handbook (VMH) focuses on temperature monitoring and provides updated implementation guidance on vaccine vial monitors, and various temperature monitoring tools for cold rooms and fridges, including the new devices which monitor and log temperatures electronically.

**How to use passive containers and coolant-packs for vaccine transport and outreach operations**

This module of the WHO Vaccine Management Handbook (VMH) provides guidance on how to develop a transport strategy that minimizes the risk of exposure to freezing through the correct use of passive containers and their associated coolant-packs. It covers vaccine transport down to health facility level and transport for outreach operations.

**Introducing solar-powered vaccine refrigerator and freezer systems - A guide for managers in national immunization programmes**

This document provides managers in national immunization programmes with guidance on how to implement successful solar-powered vaccine refrigerator and freezer systems. The guidance takes into account important new developments in refrigerator technology, and is based on lessons learned during the 30 years since solar refrigerator systems were first used in immunization programmes.
**Vaccine supply, Nigeria, July 1996**

This document provides an overview of the vaccine supply situation in Nigeria. It looks at demand-forecasting, vaccine receipt, distribution and financing, with a view to the potential production of vaccines and national quality assurance. The document is primarily intended for the use of national staff, WHO personnel and other bilateral or international donor partners working in Nigeria, but may also serve as a useful guide to other countries with similar challenges.

**WHO FLUtool for planning and costing user guide - pilot version**

The FLUtool allows the user to estimate the costs of activities that take place during the introduction of maternal influenza vaccination into a national immunization programme. These activities include the following: procurement of vaccines and injection supplies, micro-planning, training, social mobilization and IEC (information, education, communication), purchase of cold chain equipment, service delivery of vaccines to target population, monitoring and evaluation, supervision, and waste management. The FLUtool provides estimates of several cost measures: 1) total costs of adding the influenza vaccine to specific regions/provinces or at the national level; and 2) cost per immunized pregnant woman (IPW). It differentiates recurrent (operational) and capital costs as well as financial and economic costs. It also present expenditures required for initial investments required for the influenza vaccine introduction.

**WHO Manual for Estimating the Economic Burden of Seasonal Influenza**

This manual outlines key conceptual frameworks and best practice approaches to estimate the economic burden of seasonal influenza disease. It also provides practical guidance on how to estimate the economic burden associated with seasonal influenza.

The manual has been developed primarily for estimating economic burden in LMICs. It provides step-by-step approaches on how to estimate economic burden associated with seasonal influenza including direct medical costs, direct non-medical costs and indirect costs.
Adopting global vaccine management policies for national use

The document focuses on the process of a global policy adoption into national use with various case studies. The document is specifically developed to assist countries in adopting VVM and multi-dose vial policies. It is to be used for Vaccine Management Training Project, currently being carried out by WHO/AFRO in 14 countries with plans to expand the project to all regions in 2003.

Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification

As part of the WHO vaccine pre-qualification (PQ) process, product summary files (PSFs) are assessed by the WHO PQ Secretariat to determine the suitability of the vaccine for the immunization services where it is intended to be used (p.6, WHO/IVB/05.19). This document aims:
- To clearly describe the screening process and its set of rules by which all prospective vaccine prequalifications will be judged in terms of their programmatic suitability for developing country public sector immunization programmes. Also, it describes the consequences of not complying with these characteristics on the screening and PQ processes.
- To indicate very clear preferences for future vaccines that will result in greater compliance with developing country needs and that will facilitate universal immunization without requiring massive and unrealistic investment in additional cold chain capacity, human resources, waste disposal facilities, etc.

Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification (Revision 2014)

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- To indicate very clear preferences for future vaccines that will result in greater compliance with developing country needs and that will facilitate universal immunization without requiring massive and unrealistic investment in additional cold chain capacity, human resources, waste disposal facilities, etc.

Guidelines for standardization of economic evaluations in the field of vaccine-preventable diseases

The overall aim of these guidelines is to provide clear, concise, and practical guidance of a high standard for 'doers' of economic evaluations in the field of vaccine-preventable diseases. They have been developed in order to meet the needs of decision-makers for relevant, reliable and consistent economic information. These guidelines assume that the reader is technically literate about the basic methods of economic evaluation, so lengthy explanations have been avoided; the emphasis is on 'what to do' rather than 'how to do'. However, a number of examples have been provided to illustrate some of the more challenging aspects of economic evaluation with particular relevance to vaccines and vaccine-preventable diseases.
Options for linking adolescent health interventions and HPV vaccination
This short policy brief will clarify WHO’s position on the potential of linkages between adolescent health interventions and HPV vaccination, both from the vaccination and adolescent health perspectives. It will include the results of a systematic review into evidence based, short duration adolescent health interventions that can be linked to HPV vaccination.

Statement on vaccine quality
This statement was developed in response to numerous requests for information on WHO’s position on vaccine quality from national immunization services, manufacturers, national control authorities, and staff of international agencies, nongovernmental organizations and bilateral donors. Its purpose was to indicate how the World Health Assembly is implementing resolutions related to use of high-quality vaccines. It also describes the procedures used to prequalify vaccine suppliers who will respond to offers to purchase from UNICEF and other United Nations agencies.

WHO guidance note: Vaccine diluents, revision 2015
This policy brief revises and replaces Vaccines and Biologicals Update: Proper handling and reconstitution of vaccines avoids programme errors, Volume 34, December 2000. It is designed to be used in complement with the document, Policy Brief: Handling of Multi-dose Vaccine Vials after Opening.

WHO policy on the use of opened multi-dose vaccine vials (2014 Revision)
This revision to the multi-dose vial policy provides updated guidance on how to handle all opened multi-dose vials of WHO pre-qualified vaccines. It outlines the conditions under which opened multi-dose vials can be kept for 28 days and which must be discarded after 6 hours or at the end of the immunization session, whichever comes first, along with a description of the visual triggers that can be used to guide vaccine handling by vaccinators.

WHO-UNICEF statement on vaccine vial monitors implementation: Marking the 10 years of successful implementation and role of vaccine vial monitors in reaching every child and mother
The WHO-UNICEF statement focus on the future of VVM with the following: Inclusion of VVMs in all tender documents by self-producing countries, inclusion of VVBs in all vaccine donations and VVM based vaccine management for all countries.
"First, do no harm": Introducing auto-disable syringes and assuring injection safety in national immunization systems

This document aims to assist policy-makers and programme managers to plan the introduction of AD syringes as part of a comprehensive national policy and plan of action to improve injection safety - both for routine immunization and mass campaigns.

A WHO Guide to Good Manufacturing Practice (GMP) requirements - Part 3: Training

The guides presents the GMP requirements on training by WHO, EMEA and FDA, an overview of the training process and the Instructional System Design(ISD) Model, with considerations to make training more effective, as well as explaining how to prepare a training procedure. The specific types of training and different approaches to basic training needs have also been included as well as the different types of information that people learn with recommendations for organiseing the instructional content and events in each case. Different assessment methods are explained and how to evaluate the document training. Some documents contributed by vaccine manufacturers who cooperated in this project have been annexed.

A WHO guide to good manufacturing practice (GMP) requirements. Part 1: Standard operating procedures and master formulae

This guide, produced in two parts, has been developed for the Global Training Network as part of a curriculum on good manufacturing practices (GMP). The Network has been established for participants from national control authorities and selected vaccine manufacturers that meet the eligibility requirements. Participation in the Network is contingent upon a pledge to use the training to implement a system of GMP in each trainee's institution. Thus, these documents are designed to be used as part of an intensive training course. Part 1 deals with the development of standard operating procedures (SOPs), provides samples of generic SOPs as models, and includes a number of actual SOPs in use from three vaccine production facilities. Part 2 deals with the concept of validation, instruments, facilities and procedures, and includes sample validation protocols. (Cross reference: Section 7.1. General training or training-associated documents).

A WHO guide to good manufacturing practice (GMP) requirements. Part 2: Validation

These documents (Parts 1 and 2) have been developed for GPV's Global Training Network as part of a curriculum on good manufacturing practices (GMP). The Network has been established for participants from national control authorities and selected vaccine manufacturers who meet the eligibility requirements. Participation in the Network is contingent upon a pledge to use the training to implement a system of GMP in the trainee's institution. Thus, these documents are designed to be used as part of an intensive training course. Part 1 deals with the development of standard operating procedures (SOPs), provides samples of generic SOPs as models, and includes a number of actual SOPs in use from three vaccine production facilities. Part 2 deals with the concept of validation, instruments, facilities and procedures, and includes sample validation protocols.

Aide-Memoire (Fact sheet) Safety of mass immunization campaigns

Aide-memoire for the planning and management of safety during mass immunization campaigns with injectable vaccines.

Aide-memoire : Strengthening National Regulatory Authorities
Aide-memoire: Adverse events following immunization (AEFI): causality assessment
A two-page document intended as a guide to a systematic, standardized causality assessment process for serious adverse events following immunization (including clusters). It proposes a method for individual causality assessment of adverse events following immunization and will take the reader through the steps needed for its implementation. It follows the same format as that set for other aides-memoire done for safety related issues such as that for AEFI investigations. It is intended to be used by staff at national (or first sub-national level) level including staff from immunization programs, regulatory authorities and pharmacovigilance or surveillance departments.

Aide-mémoire for prevention of freeze damage to vaccines
Cold chain storage is necessary to prevent damage to vaccine due to heat exposure, but keeping vaccines too cold can be just as harmful as keeping them too warm - many vaccines are damaged by freezing. WHO guidelines recommend that many liquid vaccines should not be frozen. Freezing of these vaccines results in loss of potency which can never be restored. Use of the vaccine can result in decreased effectiveness in recipients. This aide-mémoire summarizes WHO guidance on prevention of vaccine freezing in a concise 2-page document that can be used as a reminder of previously published material and is ideally suited as a communications tool, job-aid or learning resource.

Biosafety guidelines for personnel engaged in the production of vaccines and biological products for medical use
These biosafety guidelines are provided for the protection of workers in the manufacture or preparation of vaccines and biological products for medical use.

Correlates of vaccine-induced protection: methods and implications
The document presents an overview of definitions and methods in the area of immune correlates of vaccine-induced protection. This subject has far-reaching implications for the evaluation of vaccine efficacy, for passive protection, e.g. maternal immunity and risk screening, e.g. tuberculin testing or rubella antibody testing of pregnant women, as well as for basic understanding of pathogenesis and immunity.

Ensuring quality of vaccines at country level - a guideline for health staff.
This document is aimed at providing guidance to health authorities in countries importing vaccines through United Nations agencies, on the correct procedures to check the shipments upon receipt for acceptance or rejection, to ensure correct storage conditions including implementation of appropriate stock control system at all levels, procedures for lot release before distribution, correct practices for distribution of vaccines, diluents, syringes and safety boxes, adequate reconstitution practices and waste disposal practices.
Global Routine Immunization Strategies and Practices (GRISP)

This document provides additional focus and detail on routine immunization strengthening and coverage improvement activities and strategies resulting from the Global Vaccine Action Plan 2011-2020 (GVAP), endorsed by the World Health Assembly in May 2012.

The document provides a cohesive delivery and advocacy platforms for routine immunization globally, an integral part to achieving the vision expressed in GVAP. It also provides a commonly agreed upon routine immunization mission statement within disease specific initiatives, to seek to emphasize the required systems strengthening and extension of the reach of routine immunization to support the disease specific and more child health aims. It finally describes nine key investments that are viewed as critical to building routine immunization systems and improving coverage in the next five years.

Guide for inspection of manufacturers of biological products

This document has been produced as the third in a series of instruction materials on Good Manufacturing Process for the Global Training Network (The previous publications in this series are the WHO guide to good manufacturing practice requirements, Parts 1 and 2 – described above). Unlike the first two documents, this guide can be used outside a training context and may be useful to manufacturers in strengthening their capacity to do self-audits, and to national control authorities in developing an inspectorate. It is written in the form of checklists covering 10 areas: personnel; premises; equipment; production and in-process control; laboratory control; documentation of processing and distribution; animals; labelling, packaging and distribution; containment practices; and sanitation and cleaning.

Guidelines for preparation of the product summary file for vaccine prequalification

This procedure is targeted to countries that are sourcing their vaccines either through UN agencies or directly from manufacturers, using the WHO prequalified list of products, and that wish to ensure that these products are under appropriate regulatory oversight, but that may lack the resources to carry out a regulatory approval procedure. Because in executing the prequalification process, WHO assures that the necessary regulatory functions are in place, countries that source their vaccines using the WHO prequalified list could expedite the regulatory process for these products by using an expedited approval (fast-track procedure). Such a procedure would recognize the contribution of the WHO prequalification process, while facilitating development of national regulatory capacity. The aim of the fast-track procedure is two-fold: a) to comply with national regulations and international standards of regulatory approval of products and b) to continue to provide timely access to vaccines used in national immunization programs that meet standards of assured quality.
Guidelines on the international packaging and shipping of vaccines (Revision)

The "WHO guidelines on the international packaging and shipping of vaccines" has been one of the most widely used documents in the field of immunization. It is being referenced by UNICEF and PAHO in all its invitations to bid for vaccine supply as well as by countries directly procuring their vaccines. This 2005 edition takes into account new developments in the field of vaccine stability, temperature monitoring and information on recently prequalified vaccines. In addition to the updated volume per dose of vaccines, this document provides data on the packed volumes of diluents and droppers. It also includes transport box bulking factors for countries where insulated packages are used for the storage of vaccines. A special section on temperature monitoring has been added to describe the temperature limits that should be complied with during international shipments.

Informal consultation of experts on national regulation of vaccines, Geneva, 21-22 January 1999

The document is the report of a meeting of experts in vaccine regulation. The meeting considered four separate topics: (a) the need for a “how-to” document on building a regulatory authority for vaccines, based on existing national agencies for pharmaceuticals regulation; (b) a review of such a document including indicators for assessment by countries of their own national regulatory authorities (published separately as WHO/V&B/99.10); (c) revisions and additions to the procedure for assessing acceptability, in principle, of vaccines for supply to United Nations agencies; and (d) review of current guidance available on clinical trials of vaccines, including a document specifically commissioned to summarize this information (published separately as WHO/V&B/99.09). The meeting report summarizes the discussions on these issues. The group of experts provided guidance on the potential use of indicators for assessment by national regulatory authorities, approved a new prequalification procedure for vaccines, including those not necessarily proposed for UN agency purchase, and recommended the need to prepare a “points to consider” type document to guide national regulatory authorities on special issues of vaccines for clinical trials. It is intended as a record of the meeting for the participants, but also to provide insight into the deliberations of the committee of experts regarding these key issues in procedures in vaccine regulation.

Juma and safe injections

A booklet from the Medical Strip-Cartoon collection produced jointly by the (former) WHO Global Programme for Vaccines and Immunization and the Action Programme on Essential Drugs and Vaccines. It is based on an original concept and design by Chadu, an organization which creates and edits health-education material. It is widely used and distributed at country level.

Post-marketing surveillance of rotavirus vaccine safety

The manual provides a review of current knowledge related to the safety of rotavirus vaccine and suggests approaches for monitoring it after vaccine introduction in a country.
**Procedure for expedited review of imported prequalified vaccines for use in national immunization programs**

This procedure is directed at countries that are sourcing their vaccines either through UN agencies or directly from manufacturers, using the WHO prequalified list of products, and that wish to ensure that these products are under appropriate regulatory oversight, but that may lack the resources to carry out a regulatory approval procedure. Because in executing the prequalification process, WHO assures that the necessary regulatory functions are in place, countries that source their vaccines using the WHO prequalified list could expedite the regulatory process for these products by using a fast-track procedures. Such a procedure would recognize the contribution of the WHO prequalification process, while facilitating development of national regulatory capacity. The aim of the fast-track procedure is two-fold: a) to comply with national regulations and international standards of regulatory approval of product and b) to continue to provide timely access to vaccines used in national immunization programs that meet standards of assured quality.

**Report on the meeting on national regulatory authority (NRA) networking for new regulatory pathways**

The NRA networking for new regulatory pathways meeting was held from 27 to 28 November 2002. The meeting included representatives from nine selected countries, representatives from three WHO regional offices, experts and WHO staff. Countries were selected because of implementation of the critical regulatory functions or the existence of a plan endorsed by the government and because of their potential impact in clinical trials of new vaccines. This document summarizes the deliberations of the meeting in order to document status of clinical evaluation functions in these countries and recommendations for the establishment of the network.

**Safety of injections - WHO-UNICEF joint statement on the use of auto-disable syringes in immunization services**

This joint policy statement revises and replaces the previous WHO–UNICEF policy statement for mass immunization campaigns, WHO/EPI/LHIS/97.04 Rev.1, and extends the concept of use of auto-disable syringes as the equipment of choice for administering vaccines in all situations. The document reaffirms the current policy on use of auto-disable syringes, vaccines and safety boxes and the recommendation that they be supplied as a bundle for all elective and emergency campaigns, and sets milestones for phase-out of standard disposable syringes in all immunization programmes. The document is issued by WHO, UNICEF and the United Nations Population Fund. The policy is also the adopted practice of the International Federation of Red Cross and Red Crescent Societies in their operations. The document is aimed at national immunization managers and other government officials involved in immunization and their donor partners.
Tool for the assessment of injection safety

The 'tool for the assessment of injection safety' provides a standardized and representative assessment of injection safety practices that allow the measurement of progress and comparison across countries/jurisdictions, for both immunization and curative care. This tool underwent extensive consultations between the Safe Injection Global Network, BASICS, V&B and the Statistical Department of the Ohio State University. It was successfully pilot tested and used in a number of countries/regions. The assessment tool is geared at assessing all three critical elements of injection safety i.e. the re-use of syringes or needles between patients without sterilization (risk of infection for the recipient), inappropriate waste collection (risk of infection for the health care worker), and inappropriate waste disposal (risk of infection for the community). The entire assessment is to take place over a three-week period. The sampling strategy involves a two-stage cluster sampling of a total of 80 health facilities. A standard data collection instrument includes a combination of interviews and structured observations of practices and available supplies. Assessments of injection safety are seen as an important part of ensuring the safety of immunization programmes. This tool is primarily aimed at immunization managers as well as at staff from ministries of health and whomever would like to conduct an assessment of injection safety practices. This tool can be adapted to specific country needs and situations. They are the initial step to introducing change and should be linked to advocacy activities. They help in developing a plan of action to improve injection safety. It is expected that the assessments will be conducted by the countries themselves, at the national or district level and that it will also be used in as a self-assessment tool at the health facility level (using the questionnaire).

aide-mémoire - AEFI Investigation

Aide-mémoire on the investigation of clusters of adverse events following immunization. This document builds on the various and more extensive WHO guidelines and propose a clear systematic approach to AEFI investigation.
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<td>A world without polio</td>
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<tr>
<td>18 minute video, VHS; PAL; SECAM; NTSC</td>
<td>(to be assigned)</td>
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<tr>
<td>This video looks at the successes of the global initiative to</td>
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<td>eradicate polio, explains the difficulties encountered in some</td>
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<td>countries and warns that, so long as the polio virus remains in this</td>
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<td>world, no country is safe from the risk of importation. To illustrate</td>
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<td>the dramatic history of the fight against polio, the video</td>
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<tr>
<td>combines footage of recent immunization campaigns in China, India,</td>
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<td>Peru and Sudan with archive footage from the 1950s when the USA</td>
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<td>was struggling against polio, prior to the development of a vaccine.</td>
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<td>[Also available on request is a B-role video of unedited clips on the</td>
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<td>polio initiative for press use.]</td>
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<td>the sixth meeting of the Global Commission for the Certification</td>
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<td>of the Eradication of Poliomyelitis, Washington, D.C., 28-29 March</td>
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<td>The report summarizes discussions and decisions from the 6th</td>
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<td>meeting of the Global Commission for the Certification of the</td>
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<td>Eradication of Poliomyelitis (GCC) in Geneva, May 2002. GCC</td>
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<td>discussions focused on continued certification activities, before</td>
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<td>global certification, in WHO regions who already have regional</td>
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<td>certification, as well as on the implications of the recent</td>
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<td>episodes of circulating vaccine-derived polioviruses for the global</td>
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<td>certification process.</td>
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<td>Clinical research on treatment of measles: report of a meeting.</td>
<td>WHO/EPI/GEN/95.07;</td>
<td>47</td>
<td>English</td>
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<td>Banjul, Gambia, 3-5 November 1993</td>
<td>WHO/CDR/95.15</td>
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<td>This paper is aimed primarily at clinical researchers wanting to</td>
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<td>discover the most appropriate treatment for measles cases. Despite</td>
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<td>extensive knowledge of the epidemiology of measles, including case</td>
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<td>fatality rates, many questions relating to treatment of cases remain</td>
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<td>unanswered. For instance, it is not clear whether every case of</td>
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<td>measles should be given prophylactic antibiotics to prevent the</td>
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<td>possible occurrence of bacterial complications. Research priorities</td>
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<td>in this area are identified precisely.</td>
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Communication for polio eradication and routine immunization - Checklists and easy reference guides
These checklists and guides cover communication and social mobilization aspects of supplementary immunization for polio eradication (national immunization days and mop-up campaigns), routine immunization and disease surveillance. Individual countries and programmes are strongly encouraged to adapt the checklists in order to bring them into line with their current strategies, plans and resources. The entries are grouped into three areas: planning and strategies, messages and media, and monitoring and supervision.

Conclusions and recommendations on solar energy and health
Recommendations of the High Level Expert Meeting for the World Solar Summit Process held at UNESCO from 5-9 July 1993, on the future role of renewable energies. Advantages, disadvantages, availability and potential of the proposed strategy are taken into consideration.

Consultation Technet, Harare, 6-10 December 1999

Diphtheria: Manual for the laboratory diagnosis of diphtheria

Disease eradication: friend or foe to the health system?
Synthesis report from field studies on the Polio Eradication Initiative in the Tanzania, Nepal and the Lao People's Democratic Republic
This document is the synthesis report of three country case studies commissioned by WHO in 1998 in order to develop a methodology for assessing the impact of polio eradication (PE) on health systems. The case studies were conducted in three countries: Tanzania, Nepal and the Lao PDR. This report outlines the methodology, the findings from the three country studies, discusses the major issues involved and give recommendations for action. The main operational conclusions are that:
? Most negative impacts of PE can be averted through better planning.
? Positive impacts can only be achieved by having clear objectives and instituting effective planning procedures to reach these objectives.
This document will be of interest to those implementing polio eradication activities, and donors and partners who wish to support a health systems approach.

Distribution of vitamin A during national immunization days - A
This document is for the use of committees and coordinators of polio national immunization days (NIDs). It provides technical information on the distribution of vitamin A during such days and is based on the experience of teams who have completed at least one round of vitamin A distribution during NIDs in 1996, 1997 or 1998. The document has been developed as an addendum to the Field guide for supplementary activities aimed at achieving polio eradication (WHO/EPI/GEN/95.01 Rev.1). It is available as a hard coy document and also in electronic form (Word for Windows 7) to allow countries to adapt it to meet local needs.
District guidelines for yellow fever surveillance
These guidelines focus on surveillance of yellow fever, early detection, laboratory confirmation, case investigation, and immunization response at the district level. They describe how to detect and confirm suspected cases of yellow fever, how to respond to an outbreak and prevent additional cases from occurring. The guidelines are intended for use by health personnel in surveillance training workshops and serve as reference materials at the district and national level on issues concerning yellow fever.
(Cross reference: Section 3.1.6: Immunization systems/Yellow fever)

Equipment performance specifications and test procedures: Annexes
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E10: Injection accessories
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E2: Motorcycles
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E3: Refrigerators and freezers
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E4: Insulated containers
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).
Equipment performance specifications and test procedures: E5: Icepacks
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E6: Temperature monitoring devices
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E7: Cold chain accessories
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E8: Injection devices
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Equipment performance specifications and test procedures: E9: Steam sterilizers
Laboratory test procedures for different categories of equipment used in the EPI. Produced primarily for use in testing laboratories, it is also an essential reference for manufacturers. New equipment must successfully pass these tests in order to qualify for inclusion in the EPI Product Information Sheets. This document should be consulted in conjunction with the EPI Equipment Performance Specifications (WHO/EPI/LHIS/91.01).

Estimating the local burden of Haemophilus influenzae type b (Hib) disease preventable by vaccination: A rapid assessment tool
The main objective of this tool is to provide a methodology for countries to rapidly assess the burden of Hib disease using as much local data as possible. This document includes information on how to collect data from locally available sources and criteria for judging the quality of that data. It then details two methods for calculating the burden of Hib disease using this data. This tool was designed to allow a rapid assessment of Hib disease burden, requiring approximately 7-10 days to complete.
Estimating the potential cost-effectiveness of using Haemophilus influenzae type b (Hib) vaccine. Field test version 1

The objective of this document is to provide guidelines for estimating the potential cost-effectiveness of using Hib vaccine, from a health sector perspective. It includes guidelines for estimating two major categories of costs: 1) costs of vaccine and its administration, and 2) treatment costs averted as a result of immunization. This document is intended for use with the WHO document: Estimating the local burden of Haemophilus influenzae type b (Hib) disease preventable by vaccination: A rapid assessment tool (WHO/V&B/01.27). Although this document is focused on costs associated with the introduction of Hib vaccine, the same principles can be applied when evaluating the cost-effectiveness of other vaccines, e.g. HepB, as well. The audience for this document includes ministries of health and other technical agencies who are involved with the evaluation and introduction of new vaccines.

Fact Sheet: User fees for immunization in developing countries

This fact sheet summarizes the findings of the background paper "Practice and policies on user fees for immunization in developing countries", commissioned by the Financing Task Force of the Global Alliance for Vaccines and Immunization.

Framework for national policy makers in OPV-Using countries

This document provides national health policy makers in OPV-using countries with an overview of the rationale, risks, prerequisites and potential timetable for the global cessation of OPV. Particular emphasis is given to those activities required at the country level during the ongoing 'OPV Cessation Preparation Phase'.

Getting started with vaccine vial monitors. Questions and answers on field operations

Document compiles questions and answers on how the vaccine vial monitor (VVM) works, advantages and costs involved, using a VVM, getting started with VVMs, training and impact on programme operations. New questions were added based on concerns raised by vaccine manufacturers.

Global Measles and Rubella Strategic Plan 2012-2020

This Strategic Plan explains how countries, working together with the Measles & Rubella Initiative and its partners, will achieve a world without measles, rubella and congenital rubella syndrome (CRS). The Plan builds on the experience and successes of a decade of accelerated measles control efforts that resulted in a 74% reduction in measles deaths globally between 2000 and 2010. It integrates the latest WHO policy on rubella vaccination which recommends combining measles and rubella control strategies and planning efforts, given the shared surveillance and widespread use of combined measles-rubella vaccine formulations. The Plan presents clear strategies that country immunization managers, working with domestic and international partners, can use as a blueprint to achieve the 2015 and 2020 measles and rubella control and elimination goals.

Global Polio Eradication Initiative - 2005 Annual Report

Global Polio Eradication Initiative 2004 Annual Report

Global Polio Eradication Initiative Strategic Plan 2004 - 2008
### Global action plan for laboratory containment of wild poliovirus

This document provides a systematic worldwide plan of action to prevent transmission from the laboratory into the community. The plan of action is linked to the major polio eradication objectives for implementation in three phases; pre-polio eradication, post-global eradication and post-OPV immunization. The role of countries and laboratory activities required for each of the phases of containment is well defined.

(Cross reference: Section 5.3. Assessment and monitoring/Accelerated disease control.)

**WHO/V&B/99.32**
33 pages
Available in [English](https://www.who.int), [French](https://www.who.int/fr), [Spanish](https://www.who.int/es)

### Global poliomyelitis eradication by the year 2000 -- Plan of action

This plan of action for polio eradication revises and replaces the previous plans published as WHO/EPI/POLIO/92.02 and WHO/EPI/GEN/93.02. It incorporates recommendations of the first meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, which met in 1995, and the 1996 Technical Consultation on the Global Eradication of Poliomyelitis.

(Cross reference: Section 5.3: Assessment and monitoring/Accelerated disease control)

**WHO/EPI/GEN/96.03**
22 pages
Available in [English](https://www.who.int), [French](https://www.who.int/fr)

### Guideline for establishing or improving national, regional and district stores

This guideline is intended to be read by senior managers responsible for logistics and by their professional advisers. It covers locating vaccine stores; estimating vaccine volumes and refrigeration capacity; choosing appropriate cold chain equipment and the procurement of this equipment; selection of suitable sites and buildings and the detailed planning of vaccine storage areas. The guideline includes worksheets to estimate vaccine storage volumes and to calculate the cold chain equipment needed in the store. A series of diagrams helps readers to plan store layouts. (This document revises and replaces the original 1980 document with the same title, WHO/EPI/CCIS/80.15 Rev.2.)

**WHO/EPI/LHIS/96.03**
49 pages
Available in [English](https://www.who.int), [French](https://www.who.int/fr)

### Guidelines for establishing or improving primary and intermediate vaccine stores

The document gives a comprehensive guidance to national EPI system workers with the choice of store location, choice of refrigeration equipment, site and building selection, space planning and equipment procurement. The document discusses the issues to be considered when planning a distribution system, how to estimate vaccine storage needs, covers the selection of suitable refrigeration equipment, discusses space planning within the vaccine store, including the space required for storage of injection and waste disposal equipment and the layout of ancillary spaces such as the vaccine packing area and the storekeeper's office, lists the key factors affecting the selection of a suitable store site, discusses power supply, building standards and covers the management of the procurement process.

**WHO/V&B/02.34**
66 pages
Available in [English](https://www.who.int)

### Guidelines for estimating costs of introducing new vaccines into the national immunization system

This document provides guidelines on how to estimate the costs of introducing a new vaccine. All relevant cost items are described, including vaccines, syringes, distribution system, surveillance, social mobilization, etc.

**WHO/V&B/02.11**
43 pages
Available in [English](https://www.who.int), [Russian](https://www.who.int/ru)
Guidelines for introducing motorcycles into a PHC programme

The advantages of using motorcycles for transport in a health programme and the procedure to follow in introducing this type of transport are described. Topics include advance preparations, the type of motorcycle to choose, budget, supervision, ownership agreements, training for instructors and riders, assembly, servicing and repairs, spare parts and evaluation. Sample forms for suggested ownership and service agreements are contained as annexes.

Guidelines for planning training activities for immunization and disease control activities

A guide for training staff who are responsible for planning, managing and evaluating training at the national and/or provincial or district levels. Each chapter focuses on a major aspect of planning: assessment of training needs; training goals; principles and objectives; organizational structure for training; course schedule; action plan; training budget; and evaluation of the training plan.

Guidelines for the prevention of deformities in polio

An illustrated guide for health workers in polio-afflicted areas. Describes how to recognize polio and care for the child during different stages of paralytic polio, how to prevent deformities and motivate the family to participate. This document was produced jointly in 1995 by EPI and Rehabilitation.

Haemophilus influenzae type b immunization. Introducing Haemophilus influenzae type B conjugate vaccine into national immunization services

The objective of this fact sheet is to update health care workers and programme managers of immunization services on the background of diseases caused by Haemophilus influenzae type b (Hib), the characteristics of the Hib conjugate vaccine and the programme aspect of its introduction. The fact sheet summarizes the vaccine and its various formulations, the dosage, administration and the recommended schedules for infant immunization. It also deals with other programmatic issues such as cold chain requirement, vaccine storage, injection safety, phasing-in of the vaccine into existing immunization services, including monitoring and reduction of vaccine wastage. It is a concise reference for anyone wishing to learn more about Hib conjugate vaccine and its introduction into national immunization services.

Health sector reform (HSR): Fact sheet for national managers - Fact sheet 2 of 3

Health sector reform (HSR): the impact of health sector development on immunization services - Fact sheet 1 of 3

Hepatitis B immunization strategies

An overview of planning strategies for implementing immunization against hepatitis B.
Immunization service delivery and accelerated disease control continued

**Hepatitis B immunization. Introducing hepatitis B vaccine into national immunization services**

This fact sheet is a concise summary of hepatitis B virus infection prevention, primarily aimed at health workers and programme managers of immunization services. It summarizes the background information on hepatitis B virus infection worldwide and the recommended strategies for its prevention. The fact sheet provides information on the vaccine and its various formulations, the dosage, the administration and the recommended schedules for infant immunization. It also deals with other programmatic issues such as cold chain requirement, vaccine storage and shipping, injection safety, phasing-in of the vaccine into existing immunization services, training of health workers, advocacy, including monitoring and reduction of vaccine wastage.

**Hepatitis B vaccine**

**How to convert a refrigerator from kerosene to gas operation**

Instructions for a skilled technician on how to convert a kerosene refrigerator (Sibir K230T and Electrolux RAK100) to gas operation. Explains how to obtain and fit new parts and how to test the refrigerator before releasing it for use. (Note: For the conversion of Sibir V240KE to gas operation, a separate manual is available from the manufacturer.)

**Immunization and health reforms: making reforms work for immunization. A reference guide. Prepared for WHO/GPV/EPI by Rachel Feilden and Ole Frank Nielsen**

Concerns have been raised over the effects of health reforms upon immunization. This document has been prepared to provide some insights into how quality immunization services can be sustained in a reformed and decentralized health system, especially if integration involves disbanding the vertical EPI programme. There is no single model that encapsulates health reform, which sometimes involves radical constitutional and structural changes not only to health services but also in other sectors. This document presents two case studies of countries, which have approached reforms in very different ways, and highlights the lessons learned.

**Immunization in practice. A practical guide for health staff - 2015 update**

Immunization in Practice is designed for health workers who give immunizations. There are seven modules: target diseases, vaccines, cold chain, ensuring safe injections, planning to reach every child, organizing immunization sessions and monitoring and evaluation. The material may be used in whole or in part, for pre-service education in academic institutions, basic training for newly appointed health workers, refresher training, self-instruction and on-the-job reference.
Immunization supply chain and logistics - A neglected but essential system for national immunization programmes. A Call-to-Action

In this Call-to-Action, the WHO Immunization Practices Advisory Committee (IPAC) advocates greater action by both national programmes and the global immunization community to strengthen Immunization Supply Chain and Logistics. This Call-to-Action was approved by IPAC in October 2013 and endorsed by the WHO Strategic Advisory Group of Experts (SAGE) on Immunization in April 2013.

In response to a rapidly changing and increasingly complex vaccination landscape where existing Immunization Supply Chain and Logistics (ISCL) systems are not keeping pace, the IPAC calls on national immunization programmes to measure, monitor and invest in their ISCL systems, and to plan and implement improvements. In addition, the IPAC calls on the global community of partners to increase awareness and investment, to harmonize ISCL silos, to address ISCL when formulating immunization recommendations, and to identify and resolve knowledge gaps. The short Call-to-Action document provides some background evidence and proposes specific strategies.

Info polio 22
Informal consultation on the control of pertussis with whole cell and acellular vaccines, Geneva, 18-19 May 1998

This document summarizes the deliberation of an informal consultation on the global use of available whole-cell and acellular pertussis vaccines, convened by WHO and the Children’s Vaccine Initiative. The group concluded that the cost-benefit of the use of different vaccines will vary by country and by the whole-cell and acellular pertussis vaccines in question. Whole-cell vaccines will continue to be used for routine infant immunization for many years to come. The group recommended increased attention to vaccine quality, whichever product was used. The document summarizes known information on safety and efficacy of the various products, on pertussis epidemiology and diagnosis, and on possible immunization strategies. It recommended a WHO working group to consider further various points in pertussis epidemiology; a strong laboratory network to provide pertussis characterization services; and more information on the use of acellular pertussis vaccines as boosters. It noted the need for better systems in national immunization programmes to monitor and investigate potential adverse events following immunization. The current status of vaccine production and regulation in several countries was reviewed. The document is intended for immunization managers and policy planners to aid the decision-making process on choice of vaccines and immunization strategies, and to assist WHO in developing further actions for pertussis control.

Integrating Vitamin A with Immunization - An information and Training Package

This CD Rom resource contains the essential information for the administration of vitamin A supplements within routine immunization Days, and treatment of sick children. In addition of the main content, a number of resources and materials are available to be downloaded as PDF documents.

Intellectual Property Rights and Vaccines in Developing Countries: Proceedings of a WHO Meeting

The purpose of this document is to report on a technical meeting on Intellectual Property Rights and Vaccines, held in Geneva on 19-20 April 2004. The role of the meeting was to be forum for information exchange and evidence setting on the role of IP in access, R&D and technology transfer for most needed vaccines in developing countries. Ways to enhance access as well as promote innovation were also discussed.

Introduction of Haemophilus influenzae type B vaccine into immunization programmes

WHO recommends that Haemophilus influenzae type B (Hib) vaccine be included in routine infant immunization programmes for all children, as appropriate to national capacities and priorities. This manual provides managers with the information they need to implement a national decision to introduce Hib vaccine. Annexes provide recommendations for surveillance of Haemophilus influenzae type B disease and, in the form of questions and answers, give details for health workers and parents on introducing Hib vaccine into a child’s vaccination programme. (Cross reference: Section 2: Innovation: new and/or improved vaccines.)
Introduction of HepB vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

This field guide is primarily a management guideline for programme managers of immunization services and health workers who provide childhood immunization. The guideline provides a broad outline of the epidemiology of hepatitis B (HBV) virus infection and the global burden of disease. It outlines various immunization strategies a country may adopt to prevent HBV transmission. Apart from providing details of the vaccine and its formulation, the guideline also deals with the various management decisions that a programme manager must take in the introduction of the hepatitis B vaccine. Operational components such as vaccine procurement, cold chain needs, wastage reduction, immunization safety, etc., are dealt in great detail in the guideline. Finally, as an annex, the guideline provides additional information for both the health worker as well as the parents on hepatitis B and hepatitis B vaccine.

Key elements for improving supplementary immunization activities for polio eradication

This guideline is a supplement to the Polio Field Guide. Its purpose is to highlight the key elements for planning and implementing successful NID’s and mop-up campaigns.

Laboratory manual for the diagnosis of whooping cough caused by Bordetella pertussis-Bordetella parapertussis. Update 2014

This manual provides guidelines on laboratory diagnosis of whooping cough.

Logistics and Cold Chain for Primary Health Care - Module 01: How to estimate requirements for an existing store

Logistics and Cold Chain for Primary Health Care - Module 02: How to store supplies

Logistics and Cold Chain for Primary Health Care - Module 03: How to distribute supplies

Logistics and Cold Chain for Primary Health Care - Module 04: How to keep records and calculate wastage

Logistics and Cold Chain for Primary Health Care - Module 05: How to control quality of stocks

Logistics and Cold Chain for Primary Health Care - Module 06: How to estimate requirements for the first time
Logistics and Cold Chain for Primary Health Care - Module 07: How to estimate chloroquine requirements for the first time

WHO/EPI/LOG/84/07
14 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 08: How to estimate ORS packet requirements for the first time

WHO/EPI/LOG/84/08
12 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 09: How to estimate vaccine requirements for the first time

WHO/EPI/LOG/84/09
12 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 10: How to estimate contraceptive supply requirements for the first time

WHO/EPI/LOG/84/10
14 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 11: How to estimate essential drug requirements for the first time

WHO/EPI/LOG/84/11 Rev.1
18 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 12: The cold chain game

WHO/EPI/LOG/84/12
24 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 13.1: Annex to "How to improve communication"

WHO/EPI/LOG/84/13.1
4 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 13: How to improve communication

WHO/EPI/LOG/84/13 Rev.1
10 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 14: How to look after a compression refrigerator

WHO/EPI/LOG/84/14
11 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 15: User's handbook for compression refrigerators

WHO/EPI/LOG/84/15
27 pages
Available in
English
French

Logistics and Cold Chain for Primary Health Care - Module 16: How to look after a kerosene refrigerator

WHO/EPI/LOG/84/16
22 pages
Available in
English
French
Immunization service delivery and accelerated disease control continued

Logistics and Cold Chain for Primary Health Care - Module 17A: User's handbook for kerosene refrigerators, Electrolux RAK 1302

Logistics and Cold Chain for Primary Health Care - Module 18: How to look after a gas refrigerator

Logistics and Cold Chain for Primary Health Care - Module 19: User's handbook for gas refrigerators

Logistics and Cold Chain for Primary Health Care - Module 20: How to keep stocks of spare parts

Logistics and Cold Chain for Primary Health Care - Module 21: How to look after a cold store

Logistics and Cold Chain for Primary Health Care - Module 22: User's handbook for cold stores

Logistics and Cold Chain for Primary Health Care - Module 23: Instructor's guide

Logistics and Cold Chain for Primary Health Care - Module 24: Evaluation questionnaire

Logistics and Cold Chain for Primary Health Care - Module 27: How to use the vaccine cold chain monitor

Logistics for Health WorkSheets
A set of five blank worksheets to simplify recording data and/or making routine calculations required for the performance of standard logistics tasks:
Sheet 1: Calculate needs for disposable syringes and safety boxes
Sheet 2: Calculate vaccine storage volumes
Sheet 3: Refrigerator selection worksheet
Sheet 4: Spares and consumables needed per refrigerator/freezer
Sheet 5: Spares and consumables needed per vehicle
Making use of vaccine vial monitors - flexible vaccine management for polio supplementary immunization activities

The vaccine vial monitor (VVM), introduced on oral polio vaccine in 1997, has helped to reduce wastage and detect cold-chain failures during campaigns as well as routine programmes. However, the well-established traditional approach to cold-chain management has so far prevented the use of the VVM in a more proactive manner, in the sense of taking oral polio vaccine (OPV) out of the cold chain, while monitoring the VVM. This document explains how the VVM can be used for a more flexible cold chain management, allowing immunization of children often missed because of the limitations of the ‘traditional’ cold chain. It is based on the experience in a number of countries where it has been applied.

(Cross reference: Section 4.3: Accelerated disease control/Polio.)

Managing cold chain equipment: A guide for national logistics officers

This document, aimed at senior logistics managers, describes a system for managing equipment used in immunization programmes and focuses on information to be recorded for refrigerators, freezers, generators and cold rooms. (The range covered does not include equipment for which no individual records are kept, such as sterilizers and cold boxes.)

Manual of laboratory methods for testing of vaccines used in the WHO Expanded Programme on Immunization

This document is a revision of a manual designed for national control laboratories responsible for final product tests on the major vaccines used in the Expanded Programme on Immunization. (This version updates and expands the 1995 version, WHO/BLG/95.01.) Potency tests are emphasized, particularly those using methods which spare animal use. Part 1 deals with general principles of laboratory set up and maintenance, including the concept of laboratory quality systems. Part 2 covers viral vaccine tests and Part 3 bacterial vaccine tests. Part 4 describes statistical analysis of results. The new version is designed to be used with training curricula on quality control test methods and laboratory quality systems of the GPV Global Training Network, and as a reference for control laboratory staff.

Maternal and neonatal tetanus elimination by 2005

This joint UNFPA & UNICEF & WHO publication highlights the cornerstone strategies aimed at achieving elimination of maternal and neonatal tetanus by 2005, and at maintaining elimination status thereafter. The document summarizes the current status of the programme and identifies the 57 priority countries which account for the vast majority of all maternal and neonatal tetanus cases. The main strategies recommended for achieving elimination are the immunization of all women of childbearing age in high-risk areas and the promotion of clean delivery practices. Proper planning, monitoring and evaluation are key to high-quality implementation. Maintaining elimination status will depend on achieving high levels of routine coverage for children and pregnant women, and on further improvements of clean delivery practices. School-based immunization is suggested as a novel approach to ensure on-going high levels of immunity. The document also highlights the importance of surveillance and provides estimates on case load and on budget requirements for each of the 57 priority countries.

This report summaries the discussions, conclusions and recommendations concerning: action plans for accelerating measles control; improving routine and supplementary immunization; measles surveillance; defining and monitoring measles elimination; and providing vitamin A supplements to children at nutritional risk. The recommendations and conclusions of this meeting were also published in the Weekly Epidemiological Record, 15 December 2000 No. 50, 2000, 75, 409-416 (http://www.who.int/wer).

Meningitis due to Haemophilus influenzae type B: global review.

This document will report on a comprehensive global review of the scientific literature concerning meningitis due to Hib occurring prior to widespread vaccine introduction. The review included information from several hundred studies, including population-based, hospital-based, and surveillance data. Information on incidence in children 0-59 months of age, age patterns of disease, and case fatality rates will be provided, as well as information on antibiotic pre-treatment, where available. Analyses will focus on regional trends. Discussion will point out strengths and limitations of the data.

Microplanning for immunization service delivery using the Reaching Every District (RED) strategy

This guide provides a useful set of tools for health workers dealing with immunization. Research has shown that the RED strategy results in significantly more children being immunized, and this guide aims to enable many more health workers to employ the approach.

Module 17B: User's handbook for kerosene refrigerators, Sibir S2325

Module 26: User's handbook for photovoltaic refrigerators

Monitoring vaccine wastage at country level - Guidelines for programme managers

World Health Organization reports over 50% vaccine wastage around the world. Despite the availability of many tools to reduce vaccine wastage, countries still score high wastage rates. Increasing EIP vaccine cost during the last couple of years urges countries to take a more serious look at vaccine wastage, as well as to the introduction of new and under-used vaccines through GAVI. This document reviews the factors affecting vaccine wastage and discusses available tools and their relations to each other, with the aim of designing a prescription list for prevention/treatment of high vaccine wastage. The document also provides guidelines to calculate vaccine wastage and tools for conducting vaccine wastage studies.

Monthly immunization report/Daily tally sheet (to use with NNT protection calculator)

Two data recording sheets to be used in conjunction with the neonatal tetanus protection calculator.
Neonatal tetanus protection calculator
A child’s protection against neonatal tetanus at birth is determined by the number of doses of tetanus toxoid received by its mother, as well as the interval between those doses. When a child is brought in for its first DTP immunization, health workers have to estimate whether it has been protected or not. This recently developed calculator is a tool to help health workers make this estimate on the basis of two questions to the mother: the number of years since the mother’s last TT injection and the number of doses received. The calculator has been field tested and the feedback is that it is useful and easy to use.

Polio -- the beginning of the end
This book aims to give both the scientist and the interested layman an account of what has been achieved so far in global efforts to eradicate polio by the year 2000. It provides an overview of the scientific basis for polio eradication and the strategies that are being used to eradicate poliovirus. The book highlights the successful eradication of the disease in the Americas and its near eradication in WHO's Western Pacific Region. It also documents the reasons for recent outbreaks of the disease in Albania, Pakistan, and Sudan and highlights the growing threat to polio eradication posed by armed conflict. The book underscores the benefits of polio eradication, ranging from the reduction in human suffering to the global financial savings and the impact of polio eradication activities on health infrastructure development and primary health care.

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Polio laboratory manual, 4th edition
The document provides general information about the polio eradication initiative, the role of laboratories in surveillance for wild polioviruses, the structure and mechanisms for monitoring the performance of the WHO global polio laboratory of cell cultures, evaluating cell cultures for mycoplasma contamination and sensitivity for virus isolation. Protocols are provided for preparing and analyzing faecal samples for the presence of polioviruses. Serotyping poliovirus isolates in micro-neutralization assay is described as well as procedures for differentiating virus isolates as wild or vaccine like by enzyme linked immunosorbent assay (ELISA), probe hybridization and polymerase chain reaction (PCR). Guidelines are provided for the investigation of possible viral cross contamination of cell cultures; shipping of diagnostic samples and virus isolates; and laboratory data management.

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### Polio news 24

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### Poliomyelitis -- A guide for clinicians

A briefing on poliomyelitis which aims to enlist the support of medical staff in the global eradication initiative.

### Practices to improve coverage of the hepatitis B birth dose vaccine

This review summarizes and appraises the evidence from published and grey literature on improving coverage of the hepatitis B birth dose. Specifically, the review looks at implementation evidence in relation to two main questions:

- What practices improve coverage of the hepatitis B birth dose?;
- What are important facilitators and barriers to improving coverage of the birth dose?

### Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies.

The document provides guidance to manufacturers and regulatory authorities about the procedure in place at WHO to assess the acceptability, in principle, of vaccines purchase to UN Agencies. It provides the background information, the purpose of the service to UN agencies, and the details of the procedure followed. It details the steps to be followed, special considerations taken for vaccine fillers, for priority products, for products required on an emergency basis, etc. In addition, it provides in the annexes the required format and contents of the PSF, the model confidentiality agreement and non-conflict of interest form to be signed by experts participating of the assessment.
Product Information Sheets, 2000
Updated every two years, this is an essential reference guide on the selection and purchase of equipment for use in the Expanded Programme on Immunization and other primary health care initiatives. It includes information on equipment for use in EPI, the former WHO Programme for Acute Respiratory Infections (ARI) and the former Global Blood Safety Initiative (GBSI). Performance data and purchasing information is given for more than 180 items of equipment which meet established performance criteria. This is the first edition where cold chain refrigeration and freezer equipment will be classified by temperature zone. This edition revises and replaces all previous issues.

Protocol for a cold chain survey using cold chain monitors
Detailed guidelines on how to plan, set up and conduct a survey based on readings from cold chain monitors from the time the vaccine is initially packed to the time the last vial in the consignment is used. The results of this survey are analysed with the aid of two computer programmes which identify problem areas and enable management to focus on specific improvements. The recommended software, EPIC (and E-Mate) is listed below under Section 9.2. (Not in catalogue -The recommended software is described under "Software": EPIC (Cat. ID# 354) and E-Mate (Cat. ID#s 355).)

Quality of the cold chain - WHO/UNICEF policy statement on the use of vaccine vial monitors in immunization services
The vaccine vial monitor enables the immunization programme to improve the management of vaccine and reduce wastage. Vaccine vial monitors are now available for all vaccines, and their use for all routine and supplementary immunization activities is encouraged. This document is a joint UNICEF/WHO policy statement for all managers and users, outlining the potential benefits and advantages of the vaccine vial monitors.

Recognize the disease: A guide to the diagnosis of six target diseases
Instructional 4-panel foldout brochure for health workers. Photos depict typical signs of the six EPI target diseases and a brief summary tells how the diseases can be prevented. Similar text with photos available in poster form (Cat. ID# 57). Size: (20 x 32) cm. x 4

Recognize the disease: A guide to the diagnosis of six target diseases
A set of 30 coloured slides, accompanied by a bilingual (English and French) text, which can be used for training health workers at all levels. The slides show children with typical signs of measles, whooping cough, tetanus, poliomyelitis, diphtheria and tuberculosis at various phases during the progression of the illness.
Regulation of vaccines: building on existing drug regulatory authorities

This document was produced to guide national authorities involved in vaccine regulation how to develop the capacity to effectively regulate vaccines. It is based on publications of the Expert Committees on Biological Standardization, on Specifications for Pharmaceutical Preparations, and on the Use of Essential Drugs. The indicators contained in the document to help countries assess the performance of their vaccine regulatory system were developed with input from 38 countries by an informal consultation of experts. The major topics include an overview of drug regulatory authority functions, the essential features of a regulatory system for vaccines, and a stepwise plan for proceeding to develop such a system. It includes annexes on such topics as how to contract for laboratory support, how to get started, and indicators for essential regulatory functions for both drugs and vaccines.

Report of a meeting on priorities for pneumococcal and Hib vaccine development and introduction, Geneva 9-12 February 1999

This is a report of a meeting devoted to identifying priority activities that would accelerate the introduction of Hib and pneumococcal vaccines into developing countries. At the time of the meeting, the use of Hib vaccines in the developing world was largely limited to the Americas and western Europe, while pneumococcal conjugate vaccines were in a similar stage of development as that of the Hib conjugate vaccines 10 years ago. The meeting reviewed the situation in relation to both vaccines, identifying major obstacles to wider introduction, and developing a set of rational priorities for research and implementation activities in the near future.


During the last few years important results were obtained in studies related to measles control and elimination. In view of this, V&B, WHO arranged the meeting on 27-29 March 2000 with the objective to evaluate the progress in the measles research and recommend on further studies. The meeting developed an agenda on further research in the areas of 1) effectiveness and control of mass campaigns, 2) measles immunity and immunopathology, 3) alternative routes of vaccination and new products and 4) cost-effectiveness of measles control and elimination. These recommendations will form the basis to define and prioritize the WHO activities in the area concerned.


A summary of the basic criteria and procedures for certification of the eradication of poliomyelitis, as established by the Global Commission at its first meeting. It includes a description of the process for certification of polio eradication, the duties and composition of national committees and regional commissions, and an outline of activities to be undertaken before the next meeting.
This report summarizes proceedings and decisions of the March 2001 meeting of the Global Commission for the Certification of Poliomyelitis Eradication (GCC) in Washington, USA. Its content is of interest to everyone involved in the global polio eradication initiative, but specifically relevant to the work of specialized staff working on polio eradication in the remaining polio-endemic countries as well as staff of technical partner agencies, such as WHO offices at all levels and the CDC, Atlanta.

The WHO-UNICEF Global meeting for sustainable measles mortality reduction and immunization systems strengthening was held from 15-17 October 2003 in Cape Town, South Africa. The present report presents discussion main findings and issues.

This report documents discussions, conclusions and recommendations of the second meeting of the Global Commission for the Certification of Polio Eradication. The conclusions and recommendations are relevant for staff involved in the polio eradication initiative at national and regional level, because preparations for the certification of eradication have begun in all WHO regions. The Global Commission made specific recommendations on how regional certification commissions and national certification committees should be composed and how their work should be organized. The Commission also commented on a number of technical aspects of surveillance for acute flaccid paralysis (AFP), which are of relevance for regional and national staff involved in AFP surveillance.

Riders for health -- Manual for motorcycle instructors
A manual with a dual purpose: (i) it provides basic training for future instructors in the Riders for Health Scheme, and (ii) it serves as a course reference guide. The training starts with practical instructions on basic balance on the motorcycle and identification of its controls and proceeds to cover a range of on- and off-road riding techniques, repairs and daily maintenance.
(Cross reference: Section 7.1.1: General training or training-associated documents)
Standardization of interpretation of chest radiographs for the diagnosis of pneumonia in children, WHO Pneumonia Vaccine Trial Investigators Group.

Pneumonia is a major cause of childhood mortality in developing countries. Much of this mortality may be prevented by the use of appropriate vaccines. To determine the impact of vaccination on pneumonia a standardized method for identifying pneumonia is required. Radiological findings in the lungs are currently considered to be the “gold standard” for defining pneumonia. However, there may be considerable variability in how radiological findings may be interpreted. This document describes a standardized method for interpreting paediatric chest radiographs that may be used as an epidemiological tool to generate comparable data in studies to measure pneumonia disease burden and the efficacy or effectiveness of vaccines in preventing pneumonia.

Study protocol for temperature monitoring in the vaccine cold chain

In this revised version of the document, WHO/IVB/05.01 Study protocol for temperature monitoring in the vaccine cold chain, we refer to Tiny Talk data logger which is no longer prequalified. The document has been updated with the prequalified device alternative that is LogTag TRIX8 (WHO/PQS/06.06). In addition new video references on the shake test have been included. The protocol is designed to (1) document the level of freezing in the cold chain; and (2) identify specific problem areas where corrective actions are warranted. In this Protocol, temperatures are monitored continuously as vaccine shipments travel through the cold chain, from primary stores, to intermediate stores, to health centres and, finally, to the outreach delivery site/s. This Protocol can be tailored to meet the individual resources of any programme: either a simple, low-cost study can be conducted - without sophisticated monitoring tools - or a more comprehensive approach can be taken to provide more details. The target audiences for the protocol are national immunization programme managers, cold chain managers, national logisticians, UNICEF, WHO and partner organizations staff.

Study protocol for temperature monitoring in the vaccine cold store

This new protocol replaces the old protocol that was published in 1994 (Protocol for a cold chain survey - WHO/EPI/LHIS/94.09. The new protocol is designed to (1) document the level of freezing in the cold chain; and (2) identify specific problem areas where corrective actions are warranted. In this Protocol, temperatures are monitored continuously as vaccine shipments travel through the cold chain, from primary stores, to intermediate stores, to health centres and, finally, to the outreach delivery site/s. This Protocol can be tailored to meet the individual resources of any programme: either a simple, low-cost study can be conducted - without sophisticated monitoring tools - or a more comprehensive approach can be taken to provide more details. The target audiences for the protocol are national immunization programme managers, cold chain managers, national logisticians, UNICEF, WHO and partner organizations staff.
Sustainable outreach services (SOS). A strategy for reaching the unreached with immunization and other services

Health indicators currently report stagnating or deteriorating health conditions for large proportions of the population in many countries, with the poor or remote people bearing a disproportionate share of the burden. According to the principle of equity, every child has the right to basic health care, including protection against vaccine-preventable diseases. High-risk groups, such as remote populations, deserve special attention to fulfill this goal. It is within this context that WHO and the United Nations Children’s Programme (UNICEF) have developed a new vaccine-delivery strategy with the aim of reaching remote populations without access to health services. SOS is heavily based on lessons learned from polio campaigns and combines flexible strategies with micro planning and community involvement.
Template of a national plan of action for maternal and neonatal tetanus elimination

This template was created to minimize the workload of developing a plan of action for maternal and neonatal tetanus (MNT) elimination, and to ensure standardized baseline information. It is aimed at national staff who are responsible for developing such a plan. It includes the following sections: situation analysis, goal, objectives, strategies and planned activities, workplan and estimated needs. It also requests data for several tables included in the annexes. The information on the template should be incorporated into an overall plan of action to strengthen the immunization system.

Testing the correlation between vaccine vial monitors and vaccine potency

The purpose of this document is to provide information on a test for examining the correlation between vaccine vial monitors (VVMs) and the vaccine in the vials to which they are attached. The test was developed by an internationally-recognized laboratory and tried out on the VVMs of the four manufacturers that currently supply United Nations agency needs for oral poliovirus vaccine.

The current evidence for the burden of group A streptococcal diseases

This is one of a series of papers that review the clinical importance of group A streptococcal diseases, possible control strategies, prevention by vaccination and a possible role of WHO. This review conducts a systematic review into diseases caused by group A streptococcus and summarizes the global disease burden estimates. It looks into the quality of data, its limitations and advocates for better quality studies especially from neglected regions of the world.

The vaccine vial monitor -- Training guidelines

A one-hour lesson plan designed for the training of vaccinators and other immunization programme staff in the use of the vaccine vial monitor – how to read and interpret it. The document includes notes on advance preparation and the materials required and explains how to prepare the vaccine vial monitors for demonstration purposes. This document is complemented by WHO/EPI/LHIS/94.07 "Vaccine vial monitor: Questions and Answers" and the poster, CCPS/20, which illustrates the colour changes of the monitor.

Training evaluation: A guide to the evaluation of training courses on immunization and other disease control activities

Designed primarily for personnel responsible for planning, managing and evaluating training activities, this guide focuses on the collection, evaluation and application of feedback/data from training courses.
Training for mid-level managers (MLM) - Module 1. Cold chain, vaccines and safe-injection equipment management
Module 1 helps the mid-level manager determine how much vaccine and safe injection equipment is needed to run an immunization programme, how to manage its storage, distribution and replacement, how to monitor the system, and how to respond to changes when a new vaccine is introduced.

Training for mid-level managers (MLM) - Module 2: Partnering with the community
Module 2 describes how to work closely with the community to understand their needs, what roles can be successfully undertaken by community representatives, and how their involvement can help in managing a better service. This module can be used by mid-level managers to enhance their own skills, and with health workers and Non-Governmental Organization (NGO) partners to strengthen their work with communities.

Training for mid-level managers (MLM) - Module 4: Supportive supervision
Module 4 will help the mid-level manager to obtain the maximum benefit from every supervisory visit, from the training of supervisors, through managing a system of supervisory visits to following up and solving problems after the supervisory session.

Training for mid-level managers (MLM) - Module 5: Monitoring the immunization system
Module 5 encourages mid-level managers to measure the performance of all components of the immunization system, by a combination of passive data collection (monthly reports), and active data collection (supervisory visits). It describes how managers can use the data they collect to identify problems and take corrective action, in order to improve the quality and success of their immunization programmes.

Training for mid-level managers (MLM) - Module 6: Making a comprehensive annual national immunization plan and budget
Module 6 is written for national and provincial staff and is intended to take the mid-level manager through the necessary steps towards a comprehensive annual plan. It is organized by component of the immunization system rather than by immunization initiative. Interactive analysis and joint problem-solving are encouraged. There is a separate section on attaining hard-to-reach populations and a checklist from the Global Immunization Vision and Strategy to help ensure that the plan is sufficiently complete and forward-looking.

Training for mid-level managers (MLM) Module 3: Immunization safety
Module 3 describes how to ensure every vaccination is given safely, how to manage waste materials, and how to monitor the service sufficiently to be alert and responsive to any serious adverse event should it occur.
Training manual on the critical regulatory function for vaccines: 
Evaluation of clinical performance through authorized clinical trials

This document has been developed for the Global Training Network as part of the training curricula for strengthening the NRA's critical six functions. It is intended to provide general guidance for the evaluation of clinical data and to give guidance in the decision-making process for the licensing of vaccines new to the country, including new combination vaccines.

Training manual: licensing, lot release, laboratory access

This document has been developed and designed for use in conjunction with Global Training Network courses for countries that procure vaccines. It covers three of the four regulatory functions that a vaccine-procuring country must have in place to assure the quality of vaccines it buys. The fourth function, surveillance of vaccine performance, will be covered in a separate document. The document describes an ideal system, presents and comments on indicators of the functioning of such a system, and provides practical approaches to implementing each of the functions. (Cross reference: Section 7.1. General training or training-associated documents)

User's handbook for vaccine cold rooms and freezer rooms

This document teaches how to look after a modern cold room or freezer room.

Using immunization contacts as the gateway to eliminating vitamin A deficiency

A guide for the formulation of specific national plans of action to take advantage of contacts with immunization services to administer vitamin A supplements to infants as well as mothers, shortly after delivery. Vitamin A supplementation is highly cost-effective when combined with other on-going health interventions. Successful implementation depends on joint responsibility and a link with immunization and nutrition programmes. Revision 1, issued in 1997, includes revisions to (i) Appendix 1: Categorisation of countries revised on basis of updated information; and (ii) pages 14-15: re Indonesia.

Using national immunization days to deliver vitamin A

A short description of the situation and the problem with a proposed solution of including vitamin A delivery during polio national immunization days.

Using surveillance data and outbreak investigations to strengthen measles immunization programmes

Despite increased immunization coverage against measles and a significant fall in the number of reported cases worldwide, measles continues to cause considerable illness and death in children. This paper recognises the need to promote new tactics. It proposes that measles control strategies be expanded from immunization coverage targets to include surveillance-driven immunization activities and details appropriate surveillance and outbreak investigation strategies needed to support these activities.
**Vaccine management assessment**

This CD contains two modules: The Vaccine-management assessment tool (VMAT) and The Assessment-tool guidelines. They are developed by the Global Training Network (GTN) Vaccine Management Team to help countries to improve the quality of their vaccine management from national stores to service-delivery level. The original work on the tool was carried out by WHO Regional Office for Africa (AFRO) in 2001. After consultations, reviews and field trials it has developed into today’s document.

**Vaccine stock management: Guidelines for programme and store managers**

This manual is in support of the WHO-UNICEF EVSM initiative to help programme managers and responsible staff at primary and intermediate storage facilities with standard manual stock control tool. It reviews the necessity of information to be recorded and provides standard approaches in recording and reporting processes. It also provides examples on how to fill in forms recommended in the manual.

**Vaccine volume calculator - an aid for the introduction of new vaccines**

The vaccine volume calculator has been developed to assist countries in planning for space requirements when introducing new vaccines. It was published in collaboration with the Bill and Melinda Gates Children’s Vaccine Program at the Program for Appropriate Technology in Health (PATH). It consists of two spreadsheets in Microsoft Excel format. The calculator will be updated regularly on the V&B web site.

**WHO global action plan for laboratory containment of wild polioviruses. 2nd edition.**

This document provides a systematic worldwide plan of action to prevent transmission from the laboratory into the community. The plan of action is linked to the major polio eradication objectives for implementation in three phases: pre-polio eradication, post-global eradication and post-OPV immunization. The role of countries and laboratory activities required for each of the phases of containment is well defined.

**WHO policy statement: Ensuring the quality of locally produced vaccines and the viability of local production**

This document summarizes WHO policy on local vaccine production. It is aimed at ministries of health, ministries of finance and national decision-makers in countries which produce vaccines. By outlining the characteristics of sustainable vaccine production facilities and the need for strong, competent, and independent national regulatory authorities, it serves as a blueprint for partners and donors who might consider providing support to vaccine production and control activities. Finally, it defines the activities of the World Health Organization in this area.
WHO-UNICEF guidelines for developing a comprehensive multi-year plan (cMYP)

This updated document provides guidance to countries to make national comprehensive multi-year strategic plans (cMYP) for immunization, using the Global Vaccine Action Plan (GVAP) 2011-2020 as a guiding framework. It provides a new approach to planning that can be summarized as follows: 1. Ensuring that the strategies in the plan are sufficiently comprehensive using the GVAP as a guide. 2. Better alignment of immunization and health sector strategies to strengthen ownership, solve shared problems and ensure maximum utilization of resources. 3. Planning by immunization system components rather than by disease or initiative. 4. Including costing and financing strategies for the immunization programme. 5. Ensuring active participation of relevant actors at all levels. 6. Equity in access to immunization services, and monitoring and accountability for the results have been entrenched into the document. The document takes the reader through the process of planning with examples of each step for illustration and guidance. The seven steps for creating a comprehensive multi-year plan include: conducting situational analysis; setting national objectives and milestones; planning strategies and key activities by immunization system components; reviewing planned activities against GVAP activities; making an activity timeline and monitoring and evaluation framework; costing, financing and resource mobilization for the cMYP; then putting the cMYP into action through getting the necessary national level endorsements, developing an annual plan for the relevant year from MYP, integrating and consolidating activities for implementation. Additionally, there is guidance on summarizing the document into few pages to facilitate use for advocacy.

WHO-UNICEF joint policy statement for effective vaccine store management

The package includes WHO-UNICEF joint statement on effective vaccine store management and four modules. The purpose of this document is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The initiative provides countries with self-assessment tools, guidelines and model standards, focused specifically on vaccine storage and distribution.

WHO-UNICEF joint statement on effective vaccine store management

WHO/UNICEF Joint statement - reducing measles mortality in emergencies
Manual for quality control of diphtheria, tetanus, pertussis and combined vaccines

Manual of laboratory for testing vaccines (WHO/VSQ/97.04) was published in 1997 for the use in the WHO EPI. Taking into account recent developments in quality control methods and revision of WHO recommendations, the manual is to be revised to reflect the progress. The revision will cover the laboratory testing methods on potency, toxicity and identity tests of diphtheria, tetanus and pertussis vaccines and the statistical analysis of the test results as well as the design of a test. This document replaces WHO/VSQ/97.04 and provides guidance to the quality control staff of national control laboratories and vaccine manufacturers. It also assists the licensing authority in evaluating the quality control part of the application dossier.
Consensus meeting on assessment and monitoring of vaccine-preventable diseases, Geneva, 27-29 October 1999

This meeting reviewed issues of assessment and monitoring (including surveillance) for vaccine-preventable diseases. In particular, the meeting covered issues related to assessing the burden of disease related to new vaccines and cost-effectiveness, immunization safety monitoring, improving the quality of immunization coverage estimates, and surveillance for accelerated disease control initiatives.

Description and comparison of the methods of cluster sampling and lot quality assurance sampling to assess immunization coverage

This document has been prepared to provide national and subnational immunization staff with a brief description of the two most common methods for assessing immunization coverage levels. The document compares and contrasts the methods and provides guidance on which method is most appropriate depending on the objective and the context. A bibliography is also included.

Documenting the impact of hepatitis B immunization: Best practices for conducting a serosurvey

This document is specifically about impact assessment through serosurveys. This may be a standalone method or as part of a broader evaluation of hepatitis B control. Surveys of this kind have been carried out in a number of areas of the world. This document will be a resource for countries wishing to carry out a hepatitis B survey and is primarily aimed at the lead investigator(s) to assist them in designing the surveys.


This document provides background information and technical discussions of the WHO document: Estimating the local burden of Haemophilus influenzae type b (Hib) disease preventable by vaccination: A rapid assessment tool. (WHO/V&B/01.27). It is intended for use by personnel from the public health and clinical community who are involved with the evaluation and introduction of new vaccines and who have an interest in the technical bases of the rapid assessment tool.

Generic protocol for determining measles case fatality rates in a community

A protocol which addresses the practical issues involved in determining the acute case fatality rate in a measles outbreak.

Generic protocol for estimating the burden of Pertussis in young children

The primary objective of this protocol is to estimate the incidence and disease burden of pertussis in children under 5 years of age during periods of low to high (outbreak) disease activity. This will be achieved by a modular approach using three methodologies:- Ongoing enhanced passive surveillance - Community-based survey through cluster sampling - Outbreak investigation. The secondary objectives are to estimate 1. the incidence, hospitalization, and case fatality rates of pertussis in infants less than 12 months of age and 2. the efficacy any of a single dose of pertussis vaccine (given on time) to protect against death.
Generic protocol for hospital-based surveillance to estimate the disease burden of rotavirus gastroenteritis in children < 5 years of age. Field test version.

This document provides detailed guidance on how to conduct a prospective hospital-based surveillance study in order to estimate the disease burden due to rotavirus diarrhoea in young children. It includes guidance on choosing the study population, case definitions, laboratory procedures, data analysis, and how to monitor data quality. The document includes a survey of health care utilization patterns, which will provide baseline data on whether the proportion of the local population that seeks treatment for diarrhoea at the proposed study hospitals, which will be used as a criteria for proceeding with the study. The document also provides information on how to become part of a regional rotavirus laboratory network and how such networks might function.

Generic protocol for monitoring impact of rotavirus vaccination on gastroenteritis disease burden and viral strains

This generic protocol outlines a uniform approach to monitoring the impact of rotavirus vaccines that can be modified by countries to meet their specific needs. It provides background and justification for monitoring the impact of rotavirus vaccines once introduced in routine immunization schedules; describes assessment of vaccine impact by monitoring disease trends, using either existing data sources or active surveillance system; explain an approach for assessing vaccine effectiveness using a case control methodology; and describes the monitoring of the distribution of circulating rotavirus strains.

Generic protocol for population-based surveillance of haemophilus influenzae type B

Managers of immunization services need to consider whether Haemophilus influenzae type B (Hib) is a problem in their countries. This generic protocol provides detailed guidance on conducting population-based surveillance to assess the burden due to Hib-meningitis in children under five years of age. Laboratory methods are critical in this type of surveillance, and these are also discussed.

Global framework for immunization monitoring and surveillance

The Global Framework for Immunization Monitoring and Surveillance was developed by WHO and the United States Centers for Disease Control and Prevention (CDC), in response to the need for timely and valid epidemiological and programme information, which is crucial in measuring progress towards immunization goals and controlling vaccine-preventable diseases.

Global literature review of Haemophilus influenzae type b and Streptococcus pneumoniae invasive disease among children less than five years of age 1980-2005

This literature review updates and replaces the previous version (WHO/V&B/02.18). It is required for clearance of the disease burden figures (and publication of those in a peer-review journal) that underlying database be carefully described and made public.

Global vaccine safety blueprint

The Global Vaccine Safety Blueprint is a WHO strategic document that proposes new approaches to a consortium for strengthening vaccine pharmacovigilance systems in low-and middle-income countries.
**Guidelines for environmental surveillance of poliovirus circulation**

Acute flaccid paralysis (AFP) surveillance is the "gold standard" for surveillance in the polio eradication initiative. However, under certain circumstances valuable supplementary surveillance information can be obtained by evaluating environmental samples for the presence of wild polioviruses. The guidelines outline issues to be considered in planning for environmental surveillance, including: selection of target population and collection sites; sampling procedures and logistics of sample handling; laboratory procedures; theoretical considerations on sensitivity of the surveillance approach; and responding to wild virus detection in the environment.

**Guidelines for surveillance of congenital rubella syndrome (CRS) and rubella - Field test version, May 1999**

By December 1999, 105 countries reported use of rubella vaccine in their national immunization programmes. Many of these countries have not yet established surveillance for congenital rubella syndrome (CRS) and rubella. These guidelines were prepared to help countries meet that need. The guidelines include case definitions, nomograms for assessing suspected cases of CRS, rubella, and rubella in pregnancy, and information on laboratory aspects. In addition, information is provided for countries not yet using rubella vaccine that wish to assess the disease burden to CRS either through direct surveillance or indirectly using serosurveys.

**Human papillomavirus laboratory manual. First edition, 2009**

This manual was developed by the WHO HPV LabNet based on knowledge and experience gained through its international collaborative studies towards international standardization of HPV laboratory testing over the past several years. It aims to assist in establishing the laboratory support required for implementation and monitoring of HPV vaccination programmes. The manual should be useful for all audiences involved in development and implementation of HPV vaccines, particularly those involved in generating or using HPV laboratory data.

**Immunization coverage cluster survey**

The manual provides a prescriptive approach to the coverage survey by specifying a sample of seven children from each of 30 clusters. It provides guidance for identifying a starting household and subsequent households using what were considered simple methods that could be easily followed. The original Expanded Programme on Immunization (EPI) coverage survey was designed based on the assumption that immunization coverage was 50% to allow for maximum sample size with a precision of ±10%, in line with the low coverage levels at the time.

**Information for action - Developing a computer-based information system for the surveillance of EPI and other diseases (IFA manual)**

The information for action (IFA) system is a software tool developed for the computerization of surveillance data for the Expanded Programme on Immunization. IFA has been developed using EpiInfo and EpiMap. This manual is intended for those who need to make changes to IFA to include specific requirements before they can implement it. It may also be useful in providing a framework for developing a surveillance information system.

(Cross reference: Section 9.2: Software)
Laboratory methods for the diagnosis of meningitis caused by Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae, 2nd edition

The major focus of this document is to assist laboratories in identifying the causative organisms of bacterial meningitis (Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae) and deliver clinicians with the information required to deliver appropriate treatment to their patients. Laboratory surveillance guide Ministries of Health when responding to epidemics as well as making decisions regarding the introduction of vaccines, and provides the public health community with information regarding the impact of vaccination.

Making surveillance work: Module 4: Data management

This module is aimed at persons in charge of the immunization system or epidemiologist responsible for the disease surveillance system. The module focuses on managing data in an existing surveillance system – the routine activities that must be undertaken to ensure that data are available in a timely manner, without any loss, duplication or unnecessary modification. Details on what can and cannot be expected of a data manager are provided. The final section contains a sample handbook with instructions for the management of data on vaccine-preventable diseases, which can be adapted for other diseases as well.

Making surveillance work: Module 1: Rapid assessment of surveillance for vaccine-preventable diseases.

This module provides practical advise on conducting a rapid assessment of the quality of surveillance for vaccine-preventable diseases. The concepts and approach described are applicable to a wider range of diseases. Its target audience include national staff involved with surveillance and/or with immunization services, as well as consultants who may be part of a rapid assessment team. The module describes the steps of the assessment process including an agreement on the terms of reference, collection of background data, sites to be visited, the conduct of the assessment at each site, preparation of the summary and recommendation, presentation of findings, and the follow-up needed to ensure implementation of the recommendations. The module also provides a list of references and recommended reading.

Making surveillance work: Module 3: Logistics management

Implementation of effective surveillance is dependent upon good logistics in terms of data, specimens and human resources management for it and managing/transporting specimens safely. This guide is aimed at epidemiologists and logisticians who are setting up or improving surveillance operations. It reviews the elements of logistics for surveillance and the steps to ensure good logistics management, providing several field examples.

Manual of Rotavirus Detection and Characterization Methods

Comprehensive collection of methods for the detection and characterization of rotaviruses. The manual explains the most common procedures for rotavirus strain surveillance: present overviews of the methods and discusses implementation issues, describes each of the procedures in detail, including modifications to standard reagents or typing strategies that can be applied to achieve optimal results; provide additional information on reagents, suppliers, primers, and cloning and sequencing methods.
Measles control in the 1990s: Protocol for analysing the age distribution and age-specific incidence of measles cases in a given population or region

Intended to help programme managers investigate and understand age-related patterns of measles, this document is especially useful in situations where existing measles control appears inadequate. The information obtained from the analysis provides the basis for choosing the most appropriate strategies for measles control programmes in particular areas and communities.

Measuring impact of Streptococcus pneumoniae and Haemophilus influenzae type b conjugate vaccination

This manual describes approaches to measuring pneumococcal and Hib conjugate vaccine impact and a framework for determining the best methodology for measuring that impact for different country or epidemiologic settings. This document is divided into five sections that contain a brief description of pneumococcal and Hib disease and their associated conjugate vaccines, approaches to assessing their impact using surveillance data and vaccine effectiveness studies, and a framework for deciding the most appropriate method for the setting. The annexes provide protocols and data collection instruments that would accompany the studies described in the main body of the document, specifically a prototype protocol for a case-control study to assess pneumococcal conjugate vaccine effectiveness against invasive pneumococcal disease. This prototype protocol can be adapted for Hib vaccine, submitted to Institutional Review Boards and implemented following site-specific modifications.

Mesurer l'impact de la vaccination par les vaccins conjugués anti-Streptococcus pneumoniae et anti-Haemophilus influenzae type b

This is the version in French of the original document in English (WHO/IVB/12.08).

Module on best practices for measles surveillance

Measles is a highly infectious disease that causes mortality in both developing and industrialized countries. It is estimated that in 1998 about 30 million people contracted measles and that 875,000 of them died. Measles vaccine provides long-term immunity against the disease. Adequately chosen and implemented vaccination strategies not only reduce mortality and morbidity but also interrupt the transmission of indigenous measles virus. The WHO/UNICEF Measles Mortality Reduction and Regional Elimination Strategic Plan, 2001-2005 (WHO/V&B/01.13) outlines the following strategies for reducing measles mortality: providing the first dose of measles vaccine to successive cohorts of infants; insuring that all children have a second opportunity for measles vaccination; enhancing measles surveillance with integration of epidemiological and laboratory information; improving the management of every measles case. The objective of this document is to provide guidelines to public health workers at all levels on the best measles surveillance practices.

Monitoring immunization services using the Lot Quality Technique -- Answer sheets

Answers to the exercises set in the document "Monitoring immunization services using the lot quality technique" (WHO/VRD/TRAM/96.01).
Monitoring immunization services using the lot quality technique
The lot-quality (LQ) technique is designed to identify health centres or other health service units that are not meeting coverage targets or other standards. This manual focuses first on the LQ technique as an adjunct for supervision. A second focus of the manual is use of the LQ method to assess immunization coverage. An LQ immunization coverage survey is similar to a 30-cluster immunization coverage survey, but it has added benefits in that: it can be used in populations less than 30,000 persons; it has the ability to identify pockets of low performance; and it provides more precise overall estimates of coverage. The lot-quality technique may be modified to assess other health services such as antenatal care or vitamin A delivery, to conduct serologic studies, and to judge the quality of health records. (Cross reference: Section 7.1: General training or training-associated document)

New Vaccine Post-Introduction Evaluation Tool
This post-introduction evaluation tool is designed for immunization managers in countries that have introduced a new or underutilized vaccine to provide a systematic method for evaluating its implementation and impact on the existing immunization system in the country.

Practical guide for the design, use and promotion of home-based records in immunization programmes
Home based vaccination records, often in the form of vaccination cards or child health books, are a simple but effective way to capture an individual's vaccination status. It serves as a reminder for the caregiver for the next visit, provides information on the child's immunization status for health workers and caregivers and serves as a source of documented evidence on vaccination status for public health monitoring (including coverage surveys). This document will provide guidance to national immunization programmes on how to redesign home based records and promote their use among health workers and caregivers.

The number of cases of maternal tetanus and of neonatal tetanus (MNT) has been reduced by over 50% in the decade 1990–2000. The United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA) and the World Health Organization (WHO) are jointly targeting MNT for elimination by 2005. This document provides a protocol for countries wishing to validate that elimination status has been achieved. The protocol is based on a combination of two frequently used assessment techniques: cluster sampling and lot quality assurance.

Protocol for assessing prevalence of hepatitis B infection in antenatal patients
Strategies for use of hepatitis B vaccine differ according to endemicity of the disease in different parts of the world. This paper outlines a basic approach and includes a protocol to survey the prevalence of hepatitis B in pregnant women. (Cross reference: Section 3.1.2: Immunization systems/Hepatitis B)
Report of a global meeting on communicable disease surveillance, including epidemic-prone and/or vaccine-preventable diseases. Cairo, 24-25 Jan 2001

Strong surveillance and response systems are critical for effective disease control. The surveillance and monitoring of, and response to, epidemic-prone and vaccine-preventable diseases involve similar functions and very often use the same processes and personnel. In resource-poor countries, rational use of resources requires coordination and, where possible, synergies between different activities. This document summarizes a meeting that brought together participants from HQ, all the WHO regional offices, some intercountry teams and selected Member States to share experiences and lessons from multi-disease surveillance efforts; identify potential areas of common work to rationalize resources and strengthen surveillance and response for epidemic-prone and vaccine-preventable diseases.

Reporting on a meeting on preventing congenital rubella syndrome (CRS): immunization strategies, surveillance needs, Geneva, 12-14 January 2000

This report concerns the first international meeting on CRS and rubella held since 1984. CRS is an important cause of blindness, deafness, and mental retardation, and more than 100 000 cases are estimated to occur each year in developing countries. Rubella vaccine is now used by half of all countries and full details of their national immunization schedules are listed in an annex of this document. The primary use of rubella vaccine is to prevent CRS. The document describes appropriate target groups for rubella vaccine, surveillance needs (including the need to integrate measles and rubella surveillance), and research needs. It will be of interest to EPI managers using rubella vaccine, those considering its introduction, disease surveillance personnel, and research scientists interested in this disease.

Sample design and procedures for Hepatitis B immunization surveys: A companion to the WHO cluster survey reference manual

This document is designed to supplement the sample design, sample selection and sample size determination guidance provided by the World Health Organization (WHO) documents, Immunization Cluster Survey Reference Manual (WHO, 2005) and Assessing the impact of Hepatitis B vaccination: Strategies and overview of issues (WHO, 2006). This report is written as an aid to researchers and health professionals who are preparing to conduct a Hepatitis B vaccination program impact assessment or HBV sero-prevalence survey. The discussion emphasizes practical issues related to sample design choice, sample selection methods and procedures for minimizing both sampling and no sampling errors in the survey data.

School Vaccination Readiness Assessment Tool

The School Vaccination Readiness Assessment Tool provides a simple-to-use assessment of a country's overall capacity and specific strengths and weaknesses to implement school vaccination activities. Once the assessment is completed, it provides instructions on how to develop a readiness improvement plan and workplan.
Supplementary information on vaccine safety: Part 2: Background rates of adverse events following immunization

The objective of producing this document is to provide background information to programme managers and other technical staff dealing with vaccine adverse events. The review document provides rates for adverse events which may reasonably be expected, based on a thorough literature review. When faced with a suspected abnormal rate of reactions, the programme manager can compare the local rate with the background rates provided in the review. The majority of vaccines in use today are included.

Surveillance tools for meningitis sentinel hospital surveillance: field guide to rapidly estimate the hospital catchment population (denominator) and the annual rate of hospitalisations.

The document will provide information for Ministries of Health and hospital sentinel sites on why and how to determine the denominator of at-risk children <5 years of age and rate of meningitis hospitalizations for a sentinel hospital site conducting IB-VPD surveillance. Such a methodology is currently unavailable and this estimation is critical to enable interpretation of surveillance data, particularly pre- and post-vaccine introduction.

The Global Prevalence of Hepatitis A Virus Infection and Susceptibility: A Systematic Review

This report presents the results of a systematic review of the literature of the global prevalence of hepatitis A virus infection. This information is summarized by 21 regions as defined by the Global Burden of Disease Study (www.globalburden.org). The target audience includes researchers, health professionals, policy makers, and other experts. The work will contribute to an understanding of the global burden of disease from hepatitis A virus infection when the information is used to inform later models.

The global prevalence of hepatitis E virus infection and susceptibility: A systematic review

This report presents the results of a systematic review of the literature of the global prevalence of hepatitis E virus infection. This information is summarized by 21 regions as defined by the Global Burden of Disease Study (www.globalburden.org). The target audience includes researchers, health professionals, policy makers, and other experts. The work will contribute to an understanding of the global burden of disease from hepatitis E virus infection when the information is used to inform later models.

The immunization Data Quality Self-Assessment Tool (DQS)

The DQS is a flexible tool book of methods to evaluate different aspects of reported numbers of immunization, and the quality of the immunization monitoring system. The final goal of the DQS is to integrate the options that are most relevant for one country into routine practice.

The immunization data quality audit (DQA) procedure

The DQA was conceived as a means to verify reported performance as well as assess immunization monitoring and reporting systems. It reviews both the numbers of children reported to have received a DTP3 injection and the accuracy of the EPI reporting system. The document describes the standard DQA methodology as conducted by auditors external to the country audited.
Training for Mid Level Managers (MLM) - Module 7: The EPI coverage survey
Module 7 is intended to lead the mid-level manager through the process of conducting an EPI coverage survey from the effective organization of staff, to planning and conducting the survey, and analysing the results. The module follows the method that has been used successfully worldwide, for at least two decades, but makes it simpler to use and more practical for the mid-level manager. There are step-by-step instructions which can be used for learning activities, and blank forms which can be adapted for field use.

Training for mid-level managers (MLM) - Module 8: Making disease surveillance work
Module 8 explains in practical terms the basic concepts of surveillance and how to manage a surveillance system for vaccine-preventable diseases. It is hoped that the participant, after reading this module and discussing the concepts with the facilitator, will have a fair idea of how to start, run and monitor a surveillance system.

WHO vaccine-preventable diseases: monitoring system - 2007 global summary
A global summary of data pertaining to vaccine-preventable diseases. It covers disease incidence of diphtheria, measles, mumps, pertussis, polio, rubella and CRS, neonatal and total tetanus, and yellow fever, as well as vaccination coverage for BCG, DTP, hepatitis B, Hib, measles, polio, tetanus toxoid and yellow fever. It also includes recommended immunization schedule for those countries which have reported it. This data is reported on annual basis to the WHO regional offices by countries. The data is presented both by member states and in regional summary.

WHO vaccine-preventable diseases: monitoring system - 2008 global summary
A global summary of data pertaining to vaccine-preventable diseases. It covers disease incidence of diphtheria, measles, mumps, pertussis, polio, rubella and CRS, neonatal and total tetanus, and yellow fever, as well as vaccination coverage for BCG, DTP, hepatitis B, Hib, measles, polio, tetanus toxoid and yellow fever. It also includes recommended immunization schedule for those countries which have reported it. This data is reported on annual basis to the WHO regional offices by countries. The data is presented both by member states and in regional summary.

WHO vaccine-preventable diseases: monitoring system - 2009 global summary
A global summary of data pertaining to vaccine-preventable diseases. It covers disease incidence of diphtheria, measles, mumps, pertussis, polio, rubella and CRS, neonatal and total tetanus, and yellow fever, as well as vaccination coverage for BCG, DTP, hepatitis B, Hib, measles, polio, tetanus toxoid and yellow fever. It also includes recommended immunization schedule for those countries which have reported it. This data is reported on annual basis to the WHO regional offices by countries. The data is presented both by member states and in regional summary.
**WHO vaccine-preventable diseases: monitoring system - 2010 global summary**

A global summary of data pertaining to vaccine-preventable diseases. It covers disease incidence of diphtheria, measles, mumps, pertussis, polio, rubella and CRS, neonatal and total tetanus, and yellow fever, as well as vaccination coverage for BCG, DTP, hepatitis B, Hib, measles, polio, pneumococcal conjugate, rotavirus, tetanus toxoid and yellow fever. It also includes the latest reported recommended immunization schedule. This data is reported on annual basis to the WHO regional offices by 193 member states. The data is presented both by member states and in regional summary.

Please note: Due to the large file size of this document, it has been split into 3 sections to facilitate downloading. The sections are available below. Links to sections 2 and 3 are also available through the table of contents of section 1.

**WHO-recommended standards for surveillance of selected vaccine-preventable diseases'**

This document provides recommendations on the WHO surveillance standards for selected vaccine-preventable diseases. It reviews the rationale for surveillance of each disease, as well as recommended case definitions, types of surveillance, data elements to collect, data analyses, and uses of data for public health decision-making. The recommendations are aimed at national-level surveillance staff and should be adapted according to national priorities and needs. This document replaces WHO/EPI/GEN/98.02 Rev.2.
2006 Report of the Steering Committee on Dengue and other Flavivirus vaccines.
Summary of the presentations, discussion and recommendations of the meeting in relation to Japanese encephalitis and dengue vaccines. This report discusses the key recommendations to WHO in that area of work for the coming year.

Meeting report of the Global Vaccine Research Forum held from 26 to 29 June 2011, Geneva, Switzerland.

Report of the Meeting of the WHO Advisory Committee on Dengue and other Flavivirus Vaccines. Geneva 13-14 May 2009
The 2009 meeting of the Flavivirus advisory committee focused on a review of advanced stage vaccine candidates against Japanese encephalitis (JE) and dengue. Confidential sessions were held with the individual commercial vaccine developers. The public report provides a summary of the information provided, cleared for release by the manufacturers, and represents up-to-date information on the respective candidates. One manufacturer did not grant permission for public release. In addition, the report contains brief information on a new dengue case classification and considerations for safety evaluation of dengue vaccines.

The document reports on the fourth annual meeting of the WHO Quantitative Immunization and Vaccine-Related Research (QUIVER) advisory committee held in October 2010 in Geneva.

Report on the WHO Quantitative Immunization and Vaccines related Research (QUIVER) Advisory Committee meeting
The report covers the discussion and recommendations from the fifth meeting of the QUIVER advisory committee was held October 4-6, 2011 in Geneva, Switzerland. Briefly, QUIVER was set up as a technical committee advising the Strategic Advisory Group of Experts (SAGE) due to increasing demand for the use quantitative methods in evaluating vaccines.

Persistent infection of cervical epithelium with high-risk types of human papillomavirus (HPV) can lead to cervical intraepithelial neoplasia (CIN) and ultimately to invasive cervical cancer. Vaccines to render the viral infections innocuous or to eliminate established infections are under clinical evaluation. A group of experts met on April 18-19, in Geneva, to review progress in the field and draw conclusions for the future assessment of prophylactic and therapeutic vaccines in development. The meeting report will document progress in clinical trials and future research approaches. This report is available online only.
WHO Preferred Product Characteristics for Malaria Vaccines

The updated Malaria Vaccine Technology Roadmap outlines the two agreed priority unmet public health needs for malaria vaccine development (represented in the roadmap as two strategic goals). WHO has developed a document entitled Preferred Product Characteristics for Malaria Vaccines. The document provides guidance which vaccine manufacturers and funding agencies can take into account when refining product development plans for their malaria vaccine activities. The document clarifies WHO’s preferences with regard to many criteria that form part of Target Product Profiles, particularly indication, target populations and safety and efficacy data to be generated in clinical trials.

WHO consultation on oral cholera vaccine (OCV) stockpile strategic framework: potential objectives and possible policy options

The WHO Initiative for Vaccine Research organized a meeting jointly with the WHO Global Task Force on Cholera Control to examine the feasibility of a global stockpile for OCVs. Having major stakeholders agree to the objectives and scope of an OCV stockpile is a critical first step towards its establishment. The objectives of this meeting were therefore to (1) Review and discuss potential objectives of an OCV reserve and stockpile and to explore questions related to the motivation for creating a stockpile; (2) Provide a landscape of the cholera vaccines currently available and those in the pipeline cholera vaccines; (3) Discuss key concepts and issues policymakers must address prior to actual development of an OCV reserve and stockpile.
A Guide to Introducing a 2nd Dose of Measles Vaccine into Routine Immunization Schedules

This document is for national immunization programme managers and immunization partners involved in operational support. Its objectives are:
- To guide the policy discussions and operational aspects of the introduction of a second dose of measles vaccine into the routine immunization schedule.
- To provide up-to-date references on the global policy, the technical justification, and the strategic issues relating to the introduction and provision of a second dose of measles vaccine in the routine immunization programme.

Introducing Rubella Vaccine into National Immunization Programmes. A step by step guide

This document is for national immunization programme managers and immunization partners involved in operational support. Its objectives are:
- To guide the policy discussions and operational aspects of the introduction of rubella vaccine into the routine immunization schedule.
- To provide technical guidance, up-to-date references on global policy, technical justification and strategic issues related to the introduction and provision of rubella vaccine in the routine immunization programme.

Introduction of pneumococcal vaccine PCV10, two dose presentation - A handbook for district and health facility staff

This handbook has been developed for countries introducing Synflorix (TM), PCV10 and PCV13 to guide and train health workers on administration of pneumococcal vaccines (PCV10 and PCV13).

Introduction of pneumococcal vaccine PCV13 - A handbook for district and health facility staff

This handbook has been developed for countries introducing Synflorix (TM), PCV10 and PCV13 to guide and train health workers on administration of pneumococcal vaccines (PCV10 and PCV13).

Introduction of rotavirus vaccines - Information for policy makers, programme managers, and health workers

The document provides policymakers with information to assist national decision-making when considering rotavirus vaccine introduction and provides immunization programme managers and health workers with key technical information to facilitate smooth introduction of rotavirus vaccine into a national immunization programme, once the decision to introduce has been made.

Report of the HPV Vaccine Delivery Meeting: Identifying Needs for Implementation & Research

Global experience with HPV vaccine delivery and health service delivery to 9-13 year old girls has been limited, particularly in resource-poor settings. This meeting brought together immunization, adolescent health, cancer, and education programme specialists from a range of international agencies, NGOs, and academic institutions to review the current state of knowledge on delivering HPV vaccine, health services, and school health services to 9-13 year old girls. As a result of this review and from plenary and workshop discussions, short, medium, and long-term priorities for action related to HPV vaccine delivery were identified.
Use of MenAfriVac (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns: Adaptation guide and Facilitators guide

The need to keep vaccines in a 2°C to 8°C cold chain is a constraining factor for many immunization campaigns due to limited storage capacity and/or limited ice pack freezing capacity; supplementary immunization activities planned across sub-Saharan Africa to introduce MenAfriVac are a good example. In 2012, the license for the Serum Institute of Indias meningitis A vaccine, MenAfriVac®, was changed based on a thorough review of scientific data by regulatory authorities and the World Health Organization (WHO) to allow for the use of the vaccine for a period of up to 4 days at temperatures of up to 40°C in a controlled temperature chain (CTC). This document provides countries with guidance on when and how to take advantage of this flexibility.

Use of MenAfriVac (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns: Guidance for immunization program decision-makers and managers

The need to keep vaccines in a 2°C to 8°C cold chain is a constraining factor for many immunization campaigns due to limited storage capacity and/or limited ice pack freezing capacity; supplementary immunization activities planned across sub-Saharan Africa to introduce MenAfriVac are a good example. In 2012, the license for the Serum Institute of Indias meningitis A vaccine, MenAfriVac®, was changed based on a thorough review of scientific data by regulatory authorities and the World Health Organization (WHO) to allow for the use of the vaccine for a period of up to 4 days at temperatures of up to 40°C in a controlled temperature chain (CTC). This document provides countries with guidance on when and how to take advantage of this flexibility.

Use of MenAfriVac (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns: Training module for organizing immunization sessions

The need to keep vaccines in a 2°C to 8°C cold chain is a constraining factor for many immunization campaigns due to limited storage capacity and/or limited ice pack freezing capacity; supplementary immunization activities planned across sub-Saharan Africa to introduce MenAfriVac are a good example. In 2012, the license for the Serum Institute of Indias meningitis A vaccine, MenAfriVac®, was changed based on a thorough review of scientific data by regulatory authorities and the World Health Organization (WHO) to allow for the use of the vaccine for a period of up to 4 days at temperatures of up to 40°C in a controlled temperature chain (CTC). This document provides countries with guidance on when and how to take advantage of this flexibility.

The African AIDS Vaccine Programme (AAVP) Forums provide ground for discussions between all interested parties working in the area of HIV vaccines in Africa, including scientists, community representatives, national decision-makers, international research agencies, vaccine industry and donors. The third AAVP forum focused on implementation of recommendations made by previous AAVP forums and addressed challenges in the current changing international environment for HIV vaccine development, under the following overall theme: “Africa's contribution to the global efforts for the development, evaluation and future access to HIV vaccines: the development of common policies and strategies for the conduct of multiple HIV clinical trials in Africa”. The forum culminated with the development of the "Yaoundé Statement” calling for a comprehensive and effective support for AAVP from international, regional and national policy makers within Africa.

Assessing the global needs for vaccine research and development: results of a joint GAVI/WHO IVR meeting, Geneva, 4-5 November 1999

One of the fundamental objectives of the Global Alliance for Vaccines and Immunization (GAVI) is to accelerate the research and development efforts for vaccines and related products specifically needed by developing countries. This document reports on the joint GAVI/WHO IVR meeting on Research and Development, held in November 1999. The group attempted to define the type of vaccines (in addition to AIDS, malaria and tuberculosis) that should be targeted by GAVI as a priority, identify the global obstacles which prevent or delay the development of these vaccines and prepare a preliminary strategy to address these issues.

Biotechnology and world health -- Risks and benefits of vaccines and other medical products produced by genetic engineering. Proceedings of a WHO meeting

This volume presents the findings of an international meeting convened by WHO to discuss the potential impact of DNA technology on the prevention and treatment of disease and the possible risks involved. The conclusions and recommendations of the meeting are aimed at establishing a framework for the worldwide application of DNA technology in health care, based on global standards designed to assure the safe, efficient, ethical and environmentally sound use of this technology. Priority is given to the provision of safe and effective vaccines for the prevention of infectious diseases, with particular emphasis on the needs of developing countries.
Control of rubella and congenital rubella syndrome (CRS) in developing countries

Congenital rubella syndrome (CRS) can lead to deafness, heart disease and cataracts, and a variety of other permanent manifestations. This document reviews various methods for assessing the disease burden due to CRS in developing countries. During rubella outbreaks seven studies in developing countries have documented rates of CRS per 1000 live births as high as those reported from industrialized countries prior to vaccine introduction. Special studies of rubella have been conducted in all WHO regions. Results are reported for rubella serosurveys of women of child-bearing age conducted in 45 developing countries. One section of the report discusses use of rubella vaccine reported to WHO in a survey conducted in 1996, and reviews various rubella immunization strategies.

See also: Guidelines for surveillance of congenital rubella syndrome (CRS) and rubella – field test version, May 1995

Ethical consideration arising in vaccine trials conducted in paediatric populations with high disease burden in developing countries

While many existing documents provide guidance on ethical issues in biomedical research and some specifically address vaccine research, few were drafted with a focus on the particular ethical issues posed by vaccine trials among children in developing countries. The document outlines some of the relevant considerations that might assist those involved in such trials, e.g. governments, communities, ethical committees, sponsors, funding agencies and investigators.

Global pandemic influenza action plan to increase vaccine supply: progress report 2008

In May 2005, the World Health Assembly requested WHO to seek urgent solutions with partners to address the global shortage of influenza vaccines for both epidemics and for pandemic preparedness. Months later, a landmark consultation brought together all stakeholders in the race against an influenza pandemic to identify the most promising ways to increase the availability of pandemic influenza vaccine. Participants adopted the Global Pandemic Influenza Action Plan (GAP), with a three-tiered agenda to (i) increase seasonal vaccine use; (ii) increase influenza vaccine production; and (iii) further research and development. This report summarizes WHO progress against to meet the overall objective of increased availability of pandemic influenza vaccine in the event of a pandemic.

Guidelines for Plaque-Reduction Neutralization Testing of human antibodies to Dengue viruses

The document provides guidance to do plaque-reduction neutralization (PRN) assays to assess dengue antisera. It is not a standard protocol, but a document that aims at the harmonization of assays. Based on a thorough review on the biology of the assay, it discusses its key variables and makes recommendations on how to control them. It also provides a suggested minimum protocol that is recommended to those who newly establish the assay. The protocol concludes with an outlook towards new assays, in particular those that can be automated for large sample processing.
Guidelines for the clinical evaluation of dengue vaccines in endemic areas

Dengue vaccines are now in clinical development phases. Dengue vaccine trials represent a major given the specific epidemiology and clinical manifestations of the disease. Moreover, there are theoretical safety concerns that require a careful, stepwise approach to vaccine evaluation. The goal is to inform and propose strategies for clinical evaluation that specifically address the challenges related to dengue. The guidelines should be sufficiently detailed to discuss the scientific rationale of the proposed strategies. Experiences gained with that document may facilitate the development of global written standards for dengue vaccine development as a next step.

IVR report 2006-2007

This report looks at the activities and achievements of the Initiative for Vaccine Research during 2006-2007 towards its mission to accelerate the development and effective use of optimal vaccines and technologies against infectious diseases of public health importance.

Meeting of the WHO Task Force on Clinical Trials of Dengue Vaccines. Atlanta, GA 11 November 2006

Summary presentation and discussions of new data from dengue vaccine candidates in clinical development; discussion of specific measures to facilitate development and evaluation of dengue vaccine candidates, recommendations to WHO on that subject.

Meeting on small-scale serosurveys to assess tetanus antibody levels among women of childbearing age in developing countries -- Unicef HQ, New York, 3 October 1995

This report contains minutes of the meeting and recommendations to (i) include tetanus serology testing with the competition ELISA in the multiple-indicator survey in two or three countries, (ii) conduct studies to assess the minimum tetanus antitoxin titer that reliably protects neonates in the developing world against neonatal tetanus, (iii) encourage further development of the 'double antigen' competition (ELISA) for tetanus antitoxin testing in order for it to be as inexpensive and easy to use as possible, and (iv), explore whether rapid diagnostic tests for tetanus should be pursued.

Meeting with International Partners on Influenza Vaccine technology Transfer to Developing Country Vaccine Manufacturers

This report looks at the purpose of the meeting to raise funds for the Flu Grantees project bringing together grantees, potential donors and development agencies.

Meeting with international partners on influenza vaccine production technology transfer to developing countries. 5-6 May 2010, Nha Trang Viet Nam

This report looks at the purpose of the meeting to raise awareness about WHO technology transfer project and potentially to attract funds for the Flu Grantees from potential philanthropic donors and development agencies.
Networking for new vaccine evaluation. Geneva, 13 June 2000
At the request of V&B's Strategic Advisory Group of Experts, a small meeting of experts in designing and evaluating clinical trial data was convened to consider guidance that could be provided to national regulatory authorities to assist them in reviewing documentation on safety and efficacy of new vaccine products. The group considered relevant topics that could be included in a training curriculum in this area and discussed ways that newer regulatory authorities could network with more established agencies to improve their abilities in this area. The document touches briefly on concepts of trial design as it relates to regulation. Its major purpose is to report the deliberations of the meeting.

New polio vaccines for the post-eradication era, Geneva, 19-20 January 2000
This document reports on a meeting which reviewed proposed contingency plans and current research on new candidate vaccines to determine the need for, and feasibility of, producing such vaccines, and to identify priorities for research. (Cross reference: Section 4.3: Accelerated disease control/Polio)

The meeting serves as a forum for WHO and other partners to discuss research and development issues, to exchange views on research agendas and to monitor progress of the R&D Task Force. Moreover, the meeting serves as a forum to discuss broader issues of vaccine policy and implementation. The report will provide a summary of the meeting presentations and discussions which focused on Pandemic Influenza vaccines, development of vaccines against HIV and Tuberculosis, access to immunization, therapeutic vaccines, vaccination of special groups, update on vaccines against GAVI priority diseases.

Proceedings of the Fifth IVR Global Vaccine Research Forum, 8-10 June 2004
The meeting serves as a forum for WHO and other partners of the Global Alliance for Vaccines and Immunization (GAVI) to discuss research and development issues, to update research agendas and to monitor progress of the GAVI R&D Task Force. Moreover, the meeting will serve as a forum for broader issues of vaccine policy and implementation. Particular focus will be placed on review and discussion of GAVI priority diseases, vaccines and/or technologies and/or vaccination strategies. Participants include leading scientists from major foundations and public sector institutions involved in vaccine research as well as high ranking representatives of vaccine industry from both developed and developing countries.

Proceedings of the Seventh Global Vaccine Research Forum, 3-6 December 2006, Bangkok, Thailand
The meeting serves as a forum for WHO and other partners to discuss research and development issues, to exchange views on research agendas and to monitor progress of the R&D Task Force. Moreover, the meeting serves as a forum to discuss broader issues of vaccine policy and implementation. The report will provide a summary of the meeting presentations and discussions which focused on Pandemic Influenza vaccines, Japanese Encephalitis, Dengue, Innovation, intellectual property rights and new vaccine production in the South East Asian region, Rabies in Asia, vaccines against Cervical Cancer, development of vaccines against HIV, Malaria and Tuberculosis, new vaccine presentations, update on vaccines against GAVI priority diseases.
Proceedings of the Sixth Global Vaccine Research Forum and parallel satellite symposia  
The meeting serves as a forum for WHO and other partners of the Global Alliance for Vaccines and Immunization (GAVI) to discuss research and development issues, to update research agendas and to monitor progress of the GAVI R&D Task Force. Moreover, the meeting serves as a forum for broader issues of vaccine policy and implementation. The report will provide a summary of the meeting presentations and discussions which focused on GAVI vaccine R&D projects, Hib introduction and challenges, Leishmaniasis, new regulatory approaches to vaccine licensing in developing countries, Influenza vaccines, adjuvants and immunomodulators, new vaccines against Shigella and ETEC, HIV, Malaria and Tuberculosis. Participants included leading scientists from major foundations and public sector institutions involved in vaccine research as well as high ranking representatives of vaccine industry from both developed and developing countries.

Proceedings of the first Global Vaccine Research Forum, Montreux, 7-9 June 2000  
This document reports on the first Global Vaccine Research Forum – a joint activity of the Global Alliance for Vaccines and Immunization (GAVI) and WHO’s Department of Vaccines and Biologicals. The Global Forum provides a discussion platform for public and private sector entities to exchange information, highlight gaps and develop joint approaches to accelerate the availability of new and improved vaccines/vaccination strategies in developing countries. This report is targeted at the vaccine community at large, ministries of health, research-sponsoring agencies and foundations, vaccine industry, regulatory agencies and academia. It provides an overview of issues and discussions related to the research and development of vaccines against three major killer diseases, HIV, malaria and tuberculosis, as well as vaccines against diseases that constitute major public health problems in developing countries but little elsewhere (“developing market vaccines”). The report also addresses the role of vaccine industry and public-private interactions in accelerating R&D on vaccines of limited economic interest. Finally, it highlights some of the consideration and interactions leading up to the establishment of the GAVI Task Force on Research and Development.

Proceedings of the second Global Vaccine Research Forum, Montreux, Switzerland, 10-12 June 2001  
The aim of this annual Forum is to bring together the major players in vaccine development and implementation, to communicate and discuss the activities and strategies adopted by the GAVI Research and Development Task Force, to explore what is new in the vaccine field, and to make recommendations. The 2001 annual Global Forum report focuses on “the big three”: AIDS, TB, malaria, and on the GAVI R&D Task Force projects: rotavirus, pneumococcus, meningitis and new immunization technologies. The GVRF is a forum used to discuss and exchange views of industry and the public sector and the economical incentives behind vaccine development with the aim of bringing to the forefront all the problems which vaccine manufacturers are facing in developed and developing countries.
REPORT ON THE IMMUNIZATION AND VACCINES RELATED IMPLEMENTATION RESEARCH (IVIR) ADVISORY COMMITTEE MEETING

The document contains the full meeting report of the IVIR-AC meeting organized 17-19 September 2014 around three themes:

1. Research to conduct impact evaluation of vaccines in use
2. Research to minimize barriers and improve coverage of vaccines currently in use
3. Research to improve methods for monitoring of immunization programs

Report of the Consultation on Human Papillomavirus Vaccines, WHO, April 2005

In this consultation, current knowledge on the epidemiology of HPV and cervical cancer, HPV vaccine trials, and the predicted cost-effectiveness of HPV vaccine was reviewed and plans for further data collection in these areas were presented. Programmatic issues related to future HPV vaccine introduction were discussed, and the outstanding information requirements for making evidence-based policy decision were identified.


The Immunization and Vaccines related Implementation Research (IVIR) Advisory Committee (AC) meeting report summarizes the deliberations of the Committee on matters related to implementation research and their relevance to immunization policies and practices during the face-to-face meeting June 9 - 11 June 2015. The document highlight issues on community vaccine acceptance, hepatitis impact evaluation, dengue vaccine impact and cost-effectiveness, pertussis resurgence modeling and data for immunization program monitoring.

Report of the Second meeting of the Advisory Group (AG): Global Action Plan (GAP) to increase supply of pandemic influenza vaccines

This report looks at the progression of the GAP since May 2006 and prepares recommendations for 2009 activities. It will serve as background for briefing the DG, to whom the GAP AG reports.


This report is the summary of the presentations and discussions carried out at this meeting.

Report of the ad-hoc Consultation on Ageing and Immunization. 21-23 March 2011, Geneva, Switzerland

An ad-hoc consultation on Ageing and Immunization was held at the World Health Organization combining expertise on populations and gerontology with molecular biology and immunology, to generate the bases for a future research programme to support vaccination of groups beyond infancy, particularly on developing countries. The consultation was jointly organized and conducted by the Initiative of Vaccine Research (IVR) of the Immunization, Vaccines and Biologicals department and the Ageing and Life Course (ALC) department.
Report of the meeting of the working group on clinical trials of new TB vaccines. WHO, Geneva, 19 April 1999
This meeting provided a think tank to generate ideas about the design of future efficacy trials of tuberculosis vaccine candidates in humans. The report is aimed at the tuberculosis vaccine development community at large. It has primarily a technical objective, i.e. offering guidance to vaccine developers and public health officials on the intricacies of future TB vaccine clinical trials. However, it is also meant to serve as an advocacy tool, providing decision makers in the public and the private sector with arguments on the feasibility of ‘simple’ clinical trial designs for TB vaccine candidates. The report presents 10 outline trial designs that were presented at the meeting, a commentary by the eminent vaccine trial expert, Dr J. Clements, as well as a synopsis resulting from a concluding round table discussion.

Further to the withdrawal of the rhesus reassortant tetravalent vaccine, due to suggested association between rotavirus vaccination and the development of intussusception, a meeting was convened to redefine research related to rotavirus in developing countries. Issues related to epidemiology, risk-factors, ethic, production are reported. Six major recommendations are expressed, including research activities regulation of production and evaluation of current and future rotavirus vaccines in developing countries.

Report of the meeting with international partners on prospects for influenza vaccine technology transfer to developing countries. 27-28 November 2008. Pune, Maharashtra, India
This report looks at the purpose of the meeting to raise awareness about WHO technology transfer project and potentially to attract funds for the Flu Grantees from potential philanthropic donors and development agencies.

Report on the Immunization and Vaccines related Implementation Research (IVIR) Meeting
The document reports on the deliberations and recommendations on implementation research related issues on vaccines and immunization programs by the WHO IVIR-AC.


The Global Action Plan (GAP) to Increase Supply of Pandemic Influenza Vaccines
This report looks at the progression of the GAP since May 2006 and prepares recommendations.

The Global Action Plan (GAP) to Increase Supply of Pandemic Influenza Vaccines - Report of the fourth meeting of the WHO Global Action Plan of the Advisory Group. 6 May 2010, Nha Trang, Viet Nam
This report looks at the progression of the GAP since May 2006 and prepares recommendations for 2010 activities. It will serve as background for briefing the DG, to whom the GAP AG reports
The Initiative for Vaccine Research Report 2008-2009
The biennial report 2007-2008 documents and evaluates the activities and achievements of IVR during this period against its stated objectives, and highlights its plans for the future in vaccine and immunization R&D.

The current status of development of prophylactic vaccines against human papillomavirus infection - Report of a technical meeting, Geneva, 16-18 February 1999
Human papillomaviruses (HPV) are associated with a number of diseases including cervical cancer, the second most common cancer occurring in women worldwide and the most common cancer in women in less developed countries. A number of studies are in progress to develop vaccines against HPV. Promising results obtained in the area prompted the World Health Organization to organize a technical meeting to review the current status of development of these vaccines. An important outcome of the meeting is that WHO will encourage testing of subunit HPV vaccines in clinical trials, with the aim of identifying an effective vaccine which could be used globally to reduce the disease burden of HPV.

WHO Informal workshop: development of international HPV reference reagents, 2-4 Sept 2001, Florianopolis, Brazil
This report documents the specific technical details discussed by the group, which should be respected while conducting the proposed collaborative studies.

WHO technical workshop on the role of the laboratory detection of human papillomavirus in global disease prevention and control
Acknowledging that HPV is a common infectious virus, with carcinogenic potential, that is strongly associated with cancer development, specially with cancer of the cervix in infected women, WHO convened a gathering of HPV experts to consider the role of the laboratory in the prevention of HPV-related cancers globally. The group considered the role of that laboratory work plays in the context of other important infectious diseases such as flu, poliomyelitis, measles, rubella and pneumococcal infections. The group of HPV experts recommended the establishment of a Global HPV Laboratory Network. The network would have as mission to contribute to improving quality of laboratory procedures for the evaluation of HPV vaccination. The operational mechanism and other specific recommendations in laboratory assessment were outlined.