Preface

**IVB Catalogue 2007** lists documents produced and distributed by the World Health Organization's Department of Immunization, Vaccines and Biologicals (IVB) since its establishment in 1998. The Catalogue also includes documents, training modules and communications materials printed prior to that time by the former Global Programme on Vaccines and Immunization and its component units - Expanded Programme on Immunization, Vaccine Supply and Quality, and Vaccine Research and Development.

**Languages**

The materials stocked by the IVB Document Centre are produced primarily in English. For each item in IVB Catalogue 2007 the language in which it is available is indicated. Some documents have been translated and produced by health authorities at country level for local use. The IVB Document Centre does not stock those translations although the Catalogue indicates if they exist. The IVB Document Centre can advise where such translations may be located.

**Availability of documents in electronic form**

All documents produced since Catalogue 2000 are available on the Internet. The documents posted on the IVB web site are available in PDF (portable document format) and/or Microsoft Word format at:

http://www.who.int/vaccines-documents

In this catalogue, you may gain direct access to documents available online by clicking on the links where available.

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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.

WHO's Immunization Work: 2005 Highlights

Summary of the main activities and achievements of WHO in the area of immunization in 2005 with regard to: innovation; quality, safety and standards; and improving access to immunization services. Recent changes to the structure of the immunization department at WHO headquarters will be highlighted. A summary of financial implementation for IVB in 2004-2005 will be provided, together with an indication of the budget and resource needs for WHO's immunization work in 2006-2007.

In February 2000, WHO organized a meeting with the aim of redefining the future directions for rotavirus vaccine research in these countries. A major recommendantion 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.

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 highy 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 3: Tetanus

Module 3 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 aspects of tetanus: tetanus toxin, the nature of immunity against tetanus, techniques to measure antibody response, protective level of tetanus antibodies, effectiveness of tetanus toxoid, development of immunity following immunization, placental passage of tetanus antitoxin, safety of tetanus toxoid and implications for immunization services. (For a listing of the complete series, see Section 7.3.3.)

Immunological Basis for Immunization - Module 4: Pertussis

Module 4 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 pertussis: antigens of pertussis organisms, antigens of whole cell pertussis vaccines, techniques for measuring antibody response, development antibodies due to natural stimulation, development of antibodies following vaccination with whole cell vaccine, the need to monitor pertussis vaccine efficacy, immunological aspects of acellular pertussis vaccine and implications for immunization programmes. (For a listing of the complete series, see Section 7.3.3.)

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.)

Immunological Basis for Immunization - Module 6: Poliomyelitis

Module 6 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 poliomyelitis: the virus; the nature of immunity against poliomyelitis; different techniques for measuring immunity; protective level of polio antibodies; sero-epidemiology in the prevaccine era; immunity induced by (i) oral polio vaccine and (ii) inactivated polio vaccine; combination schedules; and implications for immunization services. (For a listing of the complete series, see Section 7.3.3.)
Immunological Basis for Immunization - Module 7: Measles
Module 7 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 aspects of measles: the organism and the disease, the immunological response to natural infection, the response to immunization, current WHO recommendations and future prospect. (For a listing of the complete series, see Section 7.3.3.)

Immunological Basis for Immunization - Module 8: Yellow fever
Module 8 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 yellow fever: the virus and the disease, techniques to measure antibody response, response to natural infection, re-emergence of the disease, and implications for EPI managers. (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.

Manual for the virological investigation of poliomyelitis
Recommended practices and procedures for laboratory diagnosis of poliomyelitis, presented in a ring binder with guidelines on how to use the manual. The aim of this publication is to assure global consistency in reporting results and provide a basis for a global system of proficiency testing. (Note: A revision of this manual is in progress; scheduled for issue in late 2000.)

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.
Disease Specific continued

**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 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.
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.

Immunological basis for immunization - Module 3: Tetanus (Revision)
this module revises/replaces the document WHO/EPI/GEN/93.13

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.

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 is 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.

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.

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.

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.

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 World's Vaccines and Immunization - 2003 Revised Edition

State of the art of new vaccine 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-existant, or need substantial improvement.
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 on 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.

Strategies, policies and practices for immunization of adolescents: a review

Adolescence has been an age group not focused on before by the Department of Vaccines and Biologicals. Now, with the collaboration of the WHO Child and Adolescent Unit, a comprehensive review has been undertaken regarding the issues of immunizing the adolescent. The status of adolescent immunization in the WHO regions is also documented.

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.

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".

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

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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

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

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.
Immunization policy

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.

GPV policy statement: Vaccine donations
The policy statement (issued by the former Global Programme on Vaccines and Immunization, now the Department of Vaccines and Biologicals) on vaccine donations was developed in response to problems reported from countries receiving donations of vaccines which did not meet programme needs or caused disruptions in the immunization activity. It proposes guidelines to describe the approach to “good donation practice” on the part of both donor and recipient, to improve the management of donated vaccines. The policy statement is intended for: government officials working in the general fields of vaccines and immunizations; and for donors, both bilateral and multilateral.

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.

This policy statement on vaccine donations, based on a longer version developed by WHO (WHO/VSQ/97.05) was adopted by the partners of the Global Alliance for Vaccines and Immunization. It is aimed at prospective vaccine donors and to countries who may be potential recipients of donated vaccines.

WHO Policy Statement: The use of opened multi-dose vials of vaccine in subsequent immunization sessions (revision of WHO/EPI/LHIS/95.01)
Sufficient data have been collected on the safety and potency of vaccines recommended for use in immunization services to warrant a change in WHO’s policy on the use of multi-dose vials of vaccine. This document revises and replaces the 1995 policy statement, WHO/EPI/LHIS/95.01. The revised policy has the potential to reduce vaccine wastage rates by up to 30%, resulting in an annual savings worldwide of US$ 40 million in vaccine costs. The document summarizes the previous policy, describes the revisions, outlines the scientific rationale for the policy change and discusses operational implications for managers of immunization services.

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-produring 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 organising 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.

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 for the planning and management of safety during mass immunization campaigns with injectable vaccines.
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 pharmocovigilance or surveillance departments.

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.

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.

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.

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-memoire - 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 sytematic approach to AEFI investigation.
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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.

(Essence 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: E1: Cold rooms and freezer rooms
The document provides updated specifications for cold rooms and freezer rooms used in bulk storage of vaccines at national/regional levels.

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 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.)
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)

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.)

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.

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.

Guidelines for implementing the pre-eradication phase of the global action plan for laboratory containment of wild polioviruses
A practical guide to assist countries in successfully implementing the pre-eradication phase of laboratory containment of wild poliovirus. Implementation by all countries of the activities described in guidelines will be necessary before global eradication of polio can be declared. The guidelines include practical information for all levels involved with laboratory containment – from national coordinators to directors of laboratories. The guidelines include suggested strategies, sample national plans of action, letters to laboratories, and forms.
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. (Cross reference: Section 7.1: General training or training-associated documents)

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.
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.)


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. User's resource guide

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.

Immunological Basis for Immunization - Module 2: Diphtheria

Module 2 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 aspects of diphtheria: diphtheria toxin, the nature of immunity to diphtheria, techniques to measure antibody response, protective level of antibodies, development of antibodies due to natural stimulation, immunity due to immunization and implications for immunization programmes. (For a listing of the complete series, see Section 7.3.3.)

Info polio 22

WHO/V&B/01.28
2 pages
Available in
English
Arabic
Chinese
French
Russian
EPI Update 31 (Aug 1996)
6 pages
Available in
English
CCXT/02
69 pages
Available in
English
WHO/V&B/01.44
Available in
English
WHO/V&B/01.44
Available in
English
ISDN 9241546514
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12 pages
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English
French
ISSN 1727-3730
8 pages
Available in
English
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. It's purpose is to highlight the key elements for planning and implementing successful NID's and mop-up campaigns.

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

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

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

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

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

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

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

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

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

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

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

Logistics and Cold Chain for Primary Health Care - Module 19: User's handbook for gas refrigerators  
WHO/EPI/LOG/84/19 Rev.1  
51 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 20: How to keep stocks of spare parts  
WHO/EPI/LOG/84/20  
35 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 21: How to look after a cold store  
WHO/EPI/LOG/84/21 Rev.1  
15 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 22: User's handbook for cold stores  
WHO/EPI/LOG/84/22 Rev.1  
54 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 23: Instructor's guide  
WHO/EPI/LOG/84/23 Rev.1  
30 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 24: Evaluation questionnaire  
WHO/EPI/LOG/84/24  
4 pages  
Available in  
English  
French

Logistics and Cold Chain for Primary Health Care - Module 27: How to use the vaccine cold chain monitor  
WHO/EPI/LOG/84/27 Rev.1  
18 pages  
Available in  
English  
French

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  
WHO/EPI/LHWS/95.01-05  
5 pages  
Available in  
English
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#8211;UNICEF#8211;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.
Immunization service delivery and accelerated disease control continued

This report summarizes 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.

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.

Polio News 16

Polio News 21

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.

Polio News 22

Polio News 23

Polio News 24

Polio News 25
**Polio news 27**

**Poliomyelitis -- A guide for clinicians**
A briefing on poliomyelitis which aims to enlist the support of medical staff in the global eradication initiative.

**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 adition, 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.

**Proper handling and reconstitution of vaccines avoids programme errors**
National immunization programmes repeatedly find that peripheral staff have run out of correct diluent. The reasons are complex, and ways of correcting them are addressed in this update. As well, this very practical issues relating to the correct procedure for reconstitution and appropriate conditions to store vaccines that will need to be reconstituted are discussed.

**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.
Immunization service delivery and accelerated disease control continued


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.

WHO/V&B/00.31
31 pages
Available in English


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.

WHO/EPI/GEN/95.06
31 pages
Available in English


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.

WHO/V&B/00.34
16 pages
Available in English


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.

WHO/IVB/04.25
36 pages
Available in English

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.

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 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 fulfil 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.

**Technician's Handbook for Compression Refrigerators - Module A: Servicing and repair techniques**

**Technician's Handbook for Compression Refrigerators - Module B: Faults and fault-finding**

**Technician's Handbook for Compression Refrigerators - Module C: Repair work**

**Technician's Handbook for Compression Refrigerators - Module D: How to keep stocks of spare parts**

**Technician's Handbook for Compression Refrigerators - Module E/Add: Task sheets on solar refrigerators**

**Technician's Handbook for Compression Refrigerators - Module E: Task sheets and progress tests**

**Technician's Handbook for Compression Refrigerators - Module F/Add.1: Instructor's notes for photovoltaic refrigerators**

**Technician's Handbook for Compression Refrigerators - Module F: Instructors handbook**
Technician's Handbook for Compression Refrigerators - Module H: Fault-finding and repair of solar powered refrigerators

Technician's Handbook for Compression Refrigerators - Module I: Installation handbook for photovoltaic refrigerators

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 - Module 01: Introduction

IVB Catalogue 2007
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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 immuniation activities and details appropriate surveillance and outbreak investigation strategies needed to support these activities.

Vaccine introduction guidelines. Adding a vaccine to the national immunization programme. Decision and implementation.
Introduction guidelines to assist programme managers facing the choice of introducing new or under-utilized vaccines. These guidelines will address the decision-making and prioritization process for introducing a new vaccine, including the subsequent implementation of that introduction.
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 document provides guidance to countries to make national comprehensive multi-year strategic plans (MYP) for immunization, using the Global Immunization Vision and Strategy 2006-2015 (GIVS) 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 GIVS as a guide. 2. Integrating and consolidating activities with other health interventions and within the immunization programme to solve shared problems. 3. Planning by immunization system components rather than by disease or initiative. 4. Includes financial planning and costing. The document takes the reader through the process of planning with worked examples of each step for illustration and guidance. The 12 steps for creating a comprehensive multi-year plan include: conducting situational analysis, determining national priorities, setting national objectives and milestones, planning strategies and key activities by system components, reviewing planned activities against GIVS activities, making an activity timeline, costing the MYP, developing an annual plan for the relevant year from MYP, integrating and consolidating activities for implementation, prioritizing activities using district analysis, establishing the timeline, responsible units and financial resources for the annual plan, and putting MYP into action.

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

WHO/UNICEF joint statement - global plan for reducing measles mortality 2006-2010
This five year global plan, jointly sponsored by WHO and UNICEF outlines the activities necessary to sustainably reduce global measles deaths and covers the following areas: the current measles situation, the WHO/UNICEF comprehensive strategy to sustainably reduce measles deaths, the success achieved to-date, the new goal to reduce annual global measles deaths by 90% by 2010 compared to 2000 estimates, the challenges and ways to overcome them, and the important role of partnerships in technical coordination and resource mobilization.

Laboratory manual for the diagnosis of whooping cough caused by Bordetella pertussis-Bordetella parapertussis
This manual provides guidelines on laboratory diagnosis of whooping cough.
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.


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 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.

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.

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.
Immunization surveillance, assessment and monitoring continued

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)

WHO/EPI/GEN/98.15
117 pages
Available in English

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.

WHO/V&B/01.11
24 pages
Available in English French

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.

WHO/V&B/01.08
22 pages
Available in English French

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.

WHO/V&B/01.10
63 pages
Available in English French

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.

WHO/EPI/GEN/94.07
21 pages
Available in English
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 the 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)


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.

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 of adverse events following immunization (AEFI) -- Field guide for managers of immunization programmes

Guidelines for managers at the central, regional and district levels on monitoring adverse events following immunization (AEFIs) in disease surveillance systems. How to plan AEFI surveillance is described step-by-step. The appendix includes recommended standard case definitions and examples of essential forms for documenting and monitoring AEFIs. Originally issued in 1993, this document was revised and reissued in 1997 to make it more action oriented for programme managers. Especially important are the model reporting forms which have been added.

(The cross reference: Section 7.1: General training or training-associated documents)

The immunization Data Quality Self-Assessment Tool (DQS)

The DQS is a flexible toolbook 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 - Module 06: Monitor immunization coverage

Training for Mid Level Managers - Module 10: EPI coverage survey

WHO vaccine-preventable diseases: monitoring system 2006 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-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.


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 ridal 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.

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 1999

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.

Human papillomavirus and HPV vaccines: technical information for policy-makers and health professionals

This document reviews the evidence on the burden of HPV-related cervical cancer, the safety and efficacy of HPV vaccines and the cost-effectiveness of HPV vaccines. The document provides the technical information needed by decision-makers who may consider HPV introduction and complements the recently produced document "Preparing for the introduction of HPV vaccines. Policy and programme guidance for countries" (WHO/RHR/06.11), which lacks the scientific basis for decision-making.

Initiative for Vaccine Research Strategic Plan 2006-2009

This document outlines strategic plan, objectives and milestones for IVR work in 2006-2009.

Initiative for Vaccines Research: 2004-2005 Strategic Plan

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 titre 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.

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)

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 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 heath 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 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 focus of the consultation was to review current knowledge on meningococcal carriage, to provide specific recommendations on scope of work for future meningococcal carriage studies in Africa surrounding meningococcal A conjugate vaccine introduction, and to suggest ways to take this initiative forward and potential funding sources. Participants emphasized the importance of designing a main research protocol common to several sites across the African meningitis belt with the major focus of facilitating future vaccine introduction and strengthening capacity in about five partner sites.

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.

The Initiative for Vaccine Research. Report 2004-2005

The global vaccine research and development community is more than ever working together to put in place a sustainable pipeline delivering optimal vaccines for priority diseases, especially in developing countries. This has been hampered by the increasing challenge to respond rapidly to new threats such as severe acute respiratory syndrome (SARS) and avian influenza. This report looks at the activities and achievements of the Initiative for Vaccine Research during 2004-2005 towards its mission to accelerate the development and effective use of optimal vaccines and technologies against infectious diseases of public health importance.
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. (TOCs attached)