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WHO/HQ, Geneva, 23 September 2005

Immunization, Vaccines and Biologicals

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Copies may be requested from:
World Health Organization
Department of Immunization, Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
o Fax: + 41 22 791 4227 *o Email:* vaccines@who.int *o*

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Contents

Abbreviations and acronyms

AMP	Agence pour la Médecine Préventive (France)
CDC	Centers for Disease Control and Prevention (United States of America)
CERMES	Centre de Recherche Médicale et Sanitaire (Niger)
DFID	Department for International Development (United Kingdom)
IPTi	Intermittent Preventive Treatment of infants
LSTM	Liverpool School of Tropical Medicine (United Kingdom)
MCC	meningococcal serogroup C conjugate
Men	meningococcal
MVP	Meningitis Vaccine Project
NIPH	Norwegian Institute of Public Health (Norway)
N.	*Neisseria*
Nm	*Neisseria meningitidis*
PATH	Program for Appropriate Technology in Health
PCR	Polymerase Chain Reaction
ST	sequence-type
USAID	United States Agency for International Development (United States of America)
WAIFW	Who acquires infection from whom
WHO	World Health Organization
WHO/MDSC	World Health Organization Multi-Disease Surveillance Centre

1. Background

The development of conjugate vaccines (capsular polysaccharides conjugated to protein antigens) offers hope for a more effective prevention strategy against meningococcal disease in Africa. The Meningitis Vaccine Project (MVP), a partnership between WHO and PATH, is developing a Men A conjugate vaccine specifically targeted for the prevention of meningococcal epidemics in sub-Saharan Africa. Clinical studies in Africa will begin in 2006 and licensure for use in vaccine campaigns among persons 1-29 years of age is expected in 2009. Effective conjugate C vaccines have been introduced in Europe for the prevention of serogroup C disease. These vaccines were found to be immunogenic in infants, to induce immunological memory, and to decrease carriage such that non-vaccinees were protected (herd immunity). The meningococcal serogroup C conjugate (MCC) vaccine programme in the United Kingdom has resulted in control of meningococcal group C disease, as a result of direct protection and impressive herd immunity. Well designed carriage studies conducted before and after the vaccination programme showed that in addition to direct protection, the vaccine has contributed to a major reduction in serogroup C carriage rates.

Well-conducted meningococcal carriage studies in Africa could provide data that would be of great value in the introduction of the Men A conjugate vaccine. Studies could be conducted during clinical trials, but also in preparation of vaccine introduction. The UK experience with the Men C conjugate vaccine can guide data collection and study design for future carriage studies in Africa. The task is a large one as it concerns several countries in sub-Saharan Africa and encompasses a number of scientific questions. WHO could play an important role in helping to coordinate this work. This meeting was intended to be a first step towards meeting this goal. Its primary aim was to bring together a small group of experts to help define a scope of work and identify possible funding sources. Future meetings will be held in Africa to further refine the scope of work.

2. Objectives of the meeting

To review current knowledge on meningococcal carriage and to provide specific recommendations on:

- Scope of work for future meningococcal carriage studies in Africa before, during and after meningococcal conjugate vaccine introduction, particularly in light of the scheduled Men A conjugate vaccine introduction;

- Ways to take this initiative forward and potential funding sources.

3. Expected outcomes

Expert recommendations that will: (1) define a research agenda; (2) identify way forward and potential funding sources.

4. Minutes

4.1 Presentations

- Current status and timelines of the Meningitis Vaccine Project (MVP);
- Current knowledge on meningococcal carriage, particularly in Africa;
- The United Kingdom (UK) experience on carriage studies surrounding the introduction of Men C conjugate vaccines;
- Current studies surrounding meningococcal conjugate vaccine introduction in target groups in the United States of America (USA);
- Possible study designs for carriage studies in Africa.

Main questions, which will need to be tackled in designing carriage studies in Africa, include: carriage levels in endemic *vs.* epidemic situations, seasonality of carriage, and age and serogroup distribution of carriage, duration and dynamics of carriage, role of carriage in immunity against serogroup A disease (individual responses, transmission, and epidemic potential). The question of Who Acquires Infection from Whom (WAIFW) is high on the priority list as it will be a key element in determining appropriate target groups for vaccination (cf. the UK experience where high disease prevalence rates but also high transmission rates were found among adolescents). Carriage studies will need to be conducted in settings where good disease surveillance is available.

4.2 Discussion

The discussion was organized around the four following headings:

- research agenda;
- methodology;
- capacity building;
- organization.

Knowledge from recent carriage studies in Africa should be collected and compiled. Two Burkina Faso carriage studies were presented by participants during the meeting: a longitudinal carriage and seroprevalence study conducted in Bobo-Dioulasso during the 2003 epidemic season (Agence pour la Médecine Préventive (AMP) and Centre Muraz) and a cross-sectional carriage and seroprevalence study comparing an epidemic and a non-epidemic district conducted in 2003 as well, under the leadership of the Centers for Disease Control and Prevention (CDC). A cross-sectional study in Uganda conducted under the leadership of Epicentre/Norwegian Institute of Public Health (NIPH, 2004) was also presented. The participants were aware of studies performed in Niger under the leadership of the Centre de Recherche Médicale et Sanitaire (CERMES, 2003) and in Ethiopia under the leadership of the Liverpool School of Tropical Medicine (LSTM). All of these studies are soon to be published and will be reviewed. The studies presented highlighted two issues that need to be taken into account when planning *Neisseria meningitidis* A (NmA) carriage and seroepidemiological studies in the meningitis belt. NmA prevalence may be very low despite hyperendemicity of NmA disease and the interpretation of anti-A immunity may

be complicated because of repeated meningococcal mass vaccination with AC or ACW polysaccharide vaccines that occurred in those countries in recent years.

Under **Research Agenda**, the following topics were specifically discussed:

- overall carriage of the various serogroups */ N. lactamica;*
- age distribution of carriage;
- individual risk factors;
- epidemic *vs.* endemic levels of carriage;
- seasonality of carriage;
- dynamics of carriage;
- seroepidemiological studies;
- modelling.

It was noted that seroepidemiological studies and studies exploring the dynamics of carriage would require a longitudinal follow-up, although several cross-sectional studies on representative population samples may catch both seasonality and transmission, and answer these questions. However, information on transmission from cross-sectional studies is limited to identifying the population group with the highest prevalence. Although information on prevalence can be obtained from cross-sectional surveys, the prospective study design for carriage studies is deemed superior to the cross-sectional design.

Many studies have shown that, there is no direct relation between meningococcal carriage point prevalence and disease incidence, but the heterogeneity in disease incidence across countries and districts suggests that the situation regarding asymptomatic colonization might also be heterogeneous, and scenarios could be quite different according to the area. As carriage is a very dynamic process, highly variable colonization rates may render carrier studies very hard to plan, and it may be difficult to extrapolate from one place to another. Pre-test studies could help determining what kind of longitudinal studies might be designed with an appropriate sample size. The joint experience of the Navrongo Health Research Centre and Swiss Tropical Institute in terms of follow-up of the population of the Kassena-Nankana District in Northern Ghana could serve as a model in that respect. The question of interest will need to be extremely clear for careful power calculations. E.g. if the main question is whether the vaccine may lower NmA carriage rate by 50%, it will be appropriate to choose a population with well-demonstrated current NmA circulation. Thus, careful analysis of the situation across the belt could allow identifying adequate site(s) and timing for a demonstration vaccine introduction. Recent data from Burkina Faso, Ghana and Uganda suggest a low carriage rate of serogroup A meningococci during endemic periods.

The carriage studies should not be limited to the serogroup A meningococci; the situation for other serogroups need to be assessed as there are some pending questions regarding recolonization, change of antigenic properties of the strains or carriage of several strains at the same time. In the UK study, the overall carriage rate was 8605 /48 538 = 17.73%. The introduction of monovalent C conjugate vaccines was followed by the near disappearance of serogroup C strains of sequence-type (ST)-11 among carriers (from a prevalence of 0.31% in 1999 to 0.04% in 2001). The ST-11 clone in association with the serogroup C capsule is likely to be a transient colonizer and may not be fully representative of virulent meningococcal clones. The situation in Africa is quite different from that in Europe and North America. There is a very low background of colonization with few non-groupable meningococci and the situation is very dynamic with clones that come and go with waves of colonization and disease every few years, as found in the Kassena-Nankana District of Northern Ghana where 300 residents out of 143,000 have been followed up twice yearly since 1998. It might be also valuable to collect information on carriage of *Neisseria lactamica*.

Large cross-sectional datasets will be needed to look at age distribution. Carriage in all age groups will need to be investigated. Age data on carriage from recent studies need to be carefully reviewed to determine what still needs to be done. It is difficult to power studies for studying risk factors and those studies should target on factors relevant for vaccination strategy. Such studies could be conducted in a few specific sites.

An important area of research would be to study more closely the immune response acquired naturally from carriage through surrogates of protection, similar to the work done in initial studies by Goldschneider *et al.*, i.e. to get some measure of the protective antibody levels achieved by carriage. In that respect, it was noted that results from a recent carriage study conducted in Burkina Faso were contradictory (AMP). Because of the background of vaccination in some populations, it was proposed that only study sites without mass vaccination in the three preceding years could be appropriate for this research component, and that it should not be a distraction from the main effort. This would require at least two samples before and two samples after vaccination. Mucosal responses to nasopharyngeal carriage could also be studied, with measurement of antibodies against both capsular and protein antigens.

The need for seroepidemiological studies coupled with vaccine introduction should be carefully assessed in terms of what is needed, specifically for modelling purposes. Seroepidemiological analyzes in relation to the carrier study were not done in the UK, the main reason being to eliminate the risk for lower participation rate expected when blood samples are taken.

Under **Methodology**, the following topics were specifically discussed:

- representative sampling: geographical and epidemiological;
- longitudinal and/or cross-sectional design;
- sampling units, sample size;
- timing (between samples, between sites);
- sampling techniques and sample analysis;
- standardization;
- strain / serum bank.

The relatively low sensitivity of carriage studies is a problem and only few appropriate techniques are available to assess carriage. Therefore, some carriers colonized by a low number of bacteria are missed, and the detected number of individuals colonized may thus be underestimated. Indeed, serogroup A is seldom identified (see above); it was suggested to develop PCR assays on swab material to increase sensitivity of detection. This moderate sensitivity of the swab technique will be balanced with large sample sizes (cf. the UK experience), and does not affect the validity of pre-post comparison studies if the sensitivity of the technique is kept constant. A common protocol for sampling and cultivation should be agreed upon.

Laboratories constitute another limiting factor, the biggest challenge being to bring together enough good microbiologists to do the work. Currently, only a few centres have the capacity to undertake large carrier studies. It was estimated that an average laboratory can process ~1,000 swabs every 2-3 months.

Representativity is essential and conducting only one large study in one area of the belt would not be appropriate. It would be preferable to conduct studies in 4-5 sites, which could also help in the selection of sites with high serogroup A carriage levels for future demonstration projects prior to introduction of vaccines. A longitudinal design would be very powerful to evaluate the situation in this regard, although similar information could also be collected from large repeated cross-sectional studies.

The timing of the sampling will depend on the question of interest, which can roughly fall under two categories:

- if the objective is to anticipate what will be the situation in 2008-2009 in a population site with regard to serogroup A carriage, samples can be spaced (long-term trends);

- If the objective is to get more precise insights into the dynamics of carriage, a closer sampling is needed. It could however be difficult to sample people too often.

Sampling techniques are now well standardized, but harmonization across sites will be key.

The establishment of a centralized strain bank (and eventually a serum bank) would require a specific budget line. While the primary and essential information needed is the serogroup of the carried strains, such a strain bank will permit further work on the material, including molecular characterization of strains (determination of the clone), identification of capsule genes in non-serogroupable strains, etc…

Under **Capacity Building**, the following topics were specifically discussed:

- exchange of students;
- laboratory support and training;
- laboratory network;
- role of the WHO Multi-Disease Surveillance Centre (WHO/MDSC).

Capacity building will need to be appropriately budgeted. This initiative could facilitate consolidation of current efforts to enhance meningococcal surveillance and laboratory capacity in Africa.

Under **Organization**, the following topics were specifically discussed:

- timing;
- possible funding sources;
- establishment of a task force;
- common proposal / application;
- development of a project administrative support office.

It was noted that conditions which stimulated the undertaking of the large carriage studies conducted in the UK were very similar to those existing now for the meningitis belt. The sense of ownership of the project of a core group of individuals committed to make it happen was critical for the successful completion of the study.

Participants emphasized the importance of designing a main proposal with a protocol common to all sites as a core piece of research using a similar methodology, while allowing each individual site to develop their own proposal to conduct specific studies. Each proposal will have to be independently reviewed. The main focus of the project will be to facilitate future vaccine introduction and to strengthen capacity in about five partner sites across the African meningitis belt. Commitment from the sites to work together will be crucial. Advocacy for partnership of all laboratories is essential. It will be essential to define a core group of partners to work on a more structured proposal to get this process started. The Malaria IPTi project (currently funded by the Bill & Melinda Gates foundation) has successfully used a consortium approach with joint overall objectives and could be viewed as a potential model for the current initiative.

Seed funds required to develop a structured proposal were estimated around ~ $ 100,000 USD. Potential donors will be contacted in the coming weeks.

The next meeting will be planned once a working group of founding members has been constituted. Objectives for such a meeting will be to define a scope of work with a focus on vaccine introduction, to

establish a network of laboratories through an internal selection process, to define relevant training courses and a framework for capacity building. If carriage studies are closely linked to vaccine introduction, contacts with National Health Authorities of countries hosting research sites will need to be established at an early phase. MVP has agreed to take responsibility for following up on action points identified during the meeting pending the establishment of a more effective project office.

4.3 Action points and closure

- Gather and review upcoming publications on recent carriage studies, namely those conducted in Burkina Faso (CDC and AMP, 2003) and Niger (CERMES, 2003);

- Explore potential funding sources such as the Bill & Melinda Gates Foundation, the Wellcome Trust, the Norwegian Government, pharmaceutical companies, the Islamic Development Bank, the European Union, other bilateral potential funding sources such as the United States Agency for International Development (USAID), the Department for International Development (DFID), the Italian or the French Government;

- Explore the potential role of the WHO/MDSC in Ouagadougou in this initiative;

- Promptly circulate meeting minutes to serve as a basis for further initiatives;

- Prepare a short communication on the status of this initiative for the upcoming Niamey workshop on meningococcal meningitis (CHALLENGES IN THE AFRICAN MENINGITIS BELT, from Genomics to Surveillance, Control and Prevention Strategies; to take place in Niamey, Niger on 26-29 November 2005; organized by Institut Pasteur - Paris, France and CERMES - Niamey, Niger in partnership with the Fondation Mérieux – Lyon, France).

Annex 1 : Agenda

Chair:	Dr Dominique Caugant
Moderator:	Dr Marc LaForce
Rapporteur:	Dr Marie-Pierre Préziosi

Opening remarks, objectives and expected results of the meeting	Dr Teresa Aguado (Coordinator, Research on Bacterial Vaccines (BAC)
Introduction of participants	Dr Dominique A Caugant (Meeting Chair)
Meningitis Vaccine Project: update and timelines	Dr Marc LaForce (Director, Meningitis Vaccine Project (MVP), Meeting moderator)
Meningococcal carriage	Dr Dominique A Caugant (WHO Collaborating Centre for Reference and Research on Meningococci, Norwegian Institute of Public Health, Norway)
Carriage of serogroup C Meningococci and vaccination with MCC vaccines	Dr Martin C Maiden (University of Oxford, United Kingdom)
Transmission dynamic models for predicting direct and indirect effects of MCC vaccination	Dr Caroline Trotter (Health Protection Agency, United Kingdom)
Epidemiological studies in the USA in the era of meningococcal conjugate vaccine	Dr Rémy Teyssou (Sanofi Pasteur, France)
Studies of meningococcal carriage in Africa, a historical perspective	Dr Brian Greenwood (London School of Hygiene Tropical Medicine, United Kingdom)
Longitudinal meningococcal carriage studies in the Kassena-Nankana District of Northern Ghana	Dr Gerd Pluschke (Swiss Tropical Institute, Switzerland)
Meningococcal carriage, disease and vaccination in Africa: perspectives from the United Kingdom	Dr Caroline Trotter (Health Protection Agency, United Kingdom)
Discussion	All participants
Research Agenda, Methodology, Capacity Building, Tentative Organization	
Action points and closure	

Annex 2: List of participants

Temporary Advisers

Dr Dominique A. Caugant
WHO Collaborating Centre for Reference and Research on Meningococci
Norwegian Institute of Public Health
P.O. Box 4404, Nyadalen,
Oslo
NORWAY

Telephone No. : +47 220422 00/042311
Fax No. : +47 22 0425 18
Email address : dominique.caugant@fhi.no
Website: http://www.fhi.no/eway/

Dr Brian Greenwood
London School of Hygiene and Tropical Medicine
50 Bedford Square
London WC 1B 3DP
UK

Telephone No. : +44 20 7299 4707
Fax No. : +44 20 7299 4720
Email address : brian.greenwood@1shtm.ac.uk
Website: http://www.lshtm.ac.uk/

Dr Musa Hassan-King
Chiron Vaccines
TD-MAR, Clinical Serology
Emil-Von-Behring-Strasse 76
35041 Marburg
GERMANY

Telephone No. : +49 6421 39 4234
Fax No. : +49 6421 39 5826
Email address : musa_hassan-king@chiron.com
Website: http://www.chironvaccines.com/

Dr Abraham Hodgson
Navrongo Health Research Center
Ghana Health Service
P. O. Box 114
Navrongo
GHANA

Telephone No. : +233 244 577665
Fax No. : +233 742 22496
Email address : ahodgson@navrongo.mimcom.net
Website: http://www.navrongo.org/

Dr Betty LaFourcade
Association Pour la Médecine Préventive (AMP)
Institut Pasteur
25 rue du Dr Roux
75724 Paris
FRANCE

Telephone No. : +33 1 5386 8920
Fax No. : +33 1 5386 8939
Email address : blafourcade@aamp.org
Website: http://www.aamp.org/

Dr Marc F. LaForce
Director, Meningitis Vaccine Project (MVP)
Program for Appropriate Technology in Health (PATH)
13, Chemin du Levant, Bâtiment Avant-Centre,
01210 Ferney-Voltaire
FRANCE

Telephone No.: (+33) 4 5028 0819
Fax No.: (+33) 4 5028 0407
E-mail: fmlaforce@path.org
Website: http://www.meningvax.org/

Dr Martin C. Maiden
University of Oxford
Peter Medawar Building, South Park Road
Oxford, OX13SY
UK

Telephone No. : +44 1865 271284
Fax No. : +44 1865
Email address : martin.maiden@zoology.oxford.ac.uk
Website: http://www.medawar.ox.ac.uk/maiden/

Dr Judith Mueller
Association Pour la Médecine Préventive (AMP)
Institut Pasteur
25 rue du Dr Roux
75724 Paris
FRANCE

Telephone No.: +33-(0)153.86.89.-36/-20
Fax No. : +33 1 5386 8939
Email address : jmueller@aamp.org
Website: http://www.aamp.org/

Dr Gerd Pluschke
Molecular Immunology
Swiss Tropical Institute
Socinstr. 57, CH 4002 Basel
SWITZERLAND

Telephone No. : +41 61 284 8235
Fax No. : +41 61 271 8654
Email address : gerd.pluschke@unibas.ch
Website: www.sti.ch

Dr Djibo Saacou
Centre de Recherche Médicale et
Sanitaire (CERMES)
BP 10887 Niamey
NIGER

Telephone No. : + (227) 75 20 40/45
Fax No. : + (227) 75 31 80
Email address : sdjibo@cermes.ne
Website: http://www.cermes.net/cermes/

Dr Rémy Teyssou
Epidemiology Platform, Medical Affairs
Sanofi Pasteur
2 Avenue Pont Pasteur
69367 Lyon Cedex 07
FRANCE

Telephone No. : +33 4 3737 7326
Fax No. : +33 4 3737 7044
Email address : remy.teyssou@sanofipasteur.com
Website: http://www.sanofipasteur.com/

Dr Caroline L. Trotter
Health Protection Agency
11 Shorland House, Beaufort Road
Clifton, Bristol, BS8 2JT
UK

Telephone No. : +44 785 5405110
Email address : caroline_trotter@yahoo.co.uk
Fax No.+44 1453 829741
Website: http://www.hpa.org.uk/

Dr Simonetta Viviani
Meningitis Vaccine Project (MVP)
Program for Appropriate Technology in Health (PATH)
13, Chemin du Levant, Bâtiment Avant-Centre,
01210 Ferney-Voltaire
FRANCE

Telephone No.: (+33) 4 5028 0819
Fax No.: (+33) 4 5028 0407
E-mail: sviviani@path.org
Website: http://www.meningvax.org/

WHO Secretariat

Dr Teresa M. Aguado
Coordinator
Research on Bacterial Vaccines (BAC)
Initiative for Vaccine Research (IVR)
Department of Immunization,Vaccines and Biologicals (IVB)
World Health Organization
20 Avenue Appia CH-1211, Geneva 27
Switzerland

Telephone No.: (+41) 22 791 2644
Fax No.: (+41) 22 791 4860
E-mail: aguadom@who.int
Website: http://www.who.int/vaccine_research/en/

Dr Eric Bertherat
Medical Officer
Epidemic Readiness and Intervention (ERI)
Office for Alert and Response Operations (ARO)
Department of Communicable Disease Surveillance and Response (CSR).
World Health Organization
20, Avenue Appia CH-1211, Geneva 27
Switzerland

Telephone No.: (+41) 22 791 14608
Fax No.: (+41) 22 791
E-mail: bertherate@who.int
Website: http://www.who.int/csr/en/

Dr Kader M Kondé
Research on Bacterial Vaccines (BAC)
Meningitis Vaccine Project Focal Point
Initiative for Vaccine Research (IVR)
Department of Immunization, Vaccines and Biologicals (IVB)
World Health Organization
20 Avenue Appia CH-1211, Geneva 27
Switzerland

Telephone No.: +41 22 791 1869
Fax No : +41 22 791 4860
E-mail: kondek@who.int
Website: http://www.who.int/vaccine_research/en/

Dr Brehima Koumaré
Acting Director
Multi Disease Surveillance Centre (MDSC)
Regional Office for Africa (AFRO)
03 BP 7019, Ouagadougou
Burkina Faso

Telephone No. : +226 5034 3818
Fax No. : +226 5033 2541
Email address : koumareb@oncho.oms.bf
Website: http://www.afro.who.int/ddc/index.html

Dr Marie-Pierre Préziosi
Medical Officer
Research on Bacterial Vaccines (BAC)
Initiative for Vaccine Research (IVR)
Department of Immunization, Vaccines and Biologicals (IVB)
World Health Organization
20 Avenue Appia CH-1211, Geneva 27
Switzerland

Telephone No.: (+41) 22 791 3744
Fax No.: +41 22 791 4860
E-mail: preziosim@who.int
Website: http://www.who.int/vaccine_research/en/

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

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

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

The quality and safety of vaccines and other biological medicines is ensured through the development and establishment of global norms and standards *(Quality Assurance and Safety of Biologicals).*

The evaluation of the impact of vaccine-preventable diseases informs decisions to introduce new vaccines. Optimal strategies and activities for reducing morbidity and mortality through the use of vaccines are implemented *(Vaccine Assessment and Monitoring).*

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

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

Department of Immunization, Vaccines and Biologicals
Family and Community Health

World Health Organization
CH-1211 Geneva 27
Switzerland
Fax: +41 22 791 4227
Email: vaccines@who.int
or visit our web site at: http://www.who.int/vaccines-documents

World Health Organization