TECHNICAL INFORMATION

DRUG REGULATION

30/09/08 from Alison Brunier, WHO/HQ:
Collaboration between WHO and drug regulators from the across the world enhanced at Berne conference - Described by WHO's Director for the department dealing with medicines policy as the "World Health Assembly for medicines regulators", the 13th International Conference of Drug Regulatory Authorities, held on 16-19 September in Berne, Switzerland, brought together over 300 participants from 102 Member States, WHO, UNICEF and European regulatory agencies. Topics discussed included preparedness for pandemic influenza; emerging regulatory issues concerning biosimilars and biologicals; the role of regulators in clinical trial approval; and crisis management. A number of key recommendations were made to WHO. These related to sustaining joint evaluation and oversight of clinical trials of new vaccines, especially in Africa; building the capacity of national regulators to undertake effective post-marketing surveillance and vaccine pharmacovigilance; providing more detailed information on the quality, safety and efficacy of WHO-prequalified vaccines; and improving international collaboration on the safety of pandemic vaccines and antivirals. For further information http://www.icdra.ch/index.php?page=827

JAPANESE ENCEPHALITIS

30/09/08 from Deborah Phillips, PATH:
Meeting recommendations advise development of new JE laboratory network: Preparations for the JE laboratory network in the Western Pacific region progressed at a WHO Polio, Measles and JE Laboratory Network meeting held in July in Manila, Philippines. Presentations from several countries informed plans for development of the network, which include distribution of standard guidelines, institution of a quality assurance programme, training, and capacity building. The Western Pacific JE laboratory network will build on existing vaccine-preventable disease networks in the region, as well as lessons learned from the JE laboratory network in the South East Asia region, and it is anticipated that participating laboratories will be identified later this year. International symposium presents advances in JE detection and prevention: A PATH-sponsored symposium at the 13th International Congress on Infectious Diseases in Kuala Lumpur, Malaysia, held on 22 June 2008, brought together global experts, as well as national and regional immunization officers, to discuss progress in JE control, surveillance and clinical research on JE vaccines. Complete proceedings from the symposium are under development and will be available on the PATH JE resource website in coming weeks: http://www.path.org/vaccineresources/japanese-encephalitis.php

MENINGITIS

30/09/08 from Alison Brunier, WHO/HQ:
African health ministers to introduce new meningitis vaccine to prevent deadly epidemics Meeting at the World Health Organization's 58th Regional Committee for Africa, held in Yaoundé from 1-5 September, Health Ministers from countries of the African Meningitis Belt committed themselves to introduction of a new meningococcal A conjugate vaccine designed to prevent periodic epidemics of the deadly disease in 25 sub-Saharan African countries.
Notably, they agreed to prepare comprehensive meningitis control plans, including the introduction of the new vaccine, once available; to implement meningitis control strategies; to undertake joint action vis-à-vis the threat; to improve information exchange for epidemic response and to contribute financially to activities to control epidemics.

The new vaccine is currently in the final stages of testing and is expected to be introduced starting in 2009-10 in Burkina Faso, followed by two dozen other countries in the period up to 2015.

Further information:
http://www.who.int/immunization/newsroom/declaration_meningococcal_conjugate_A_vaccine/en/index.html

POLIO
30/09/08 from Sona Bari, WHO/HQ:
**Polio workers killed in the line of duty: Attack in southern Afghanistan a reminder of the dangers faced by public health workers** - On 14 September, two doctors on WHO duty and their driver were assassinated by a vehicle-borne suicide bomber in Kandahar province of southern Afghanistan. Dr Shamsul Haq MH Kakar, Dr Mamoon Taher Taheri, along with their driver Azizullah Almas from the UN Assistance Mission in Afghanistan, were on their way to prepare logistics for a polio vaccination campaign in the region in late September when their convoy was attacked. This tragic incident, along with an armed attack in Somalia this summer which seriously wounded two polio workers, are stark reminders of the risks faced by those working for public health in many parts of the world.

The [Polio Eradication Heroes Fund](http://www.cdcfoundation.org/givenow/endowments.aspx) recognizes health workers and volunteers who have incurred serious injury or lost their lives as a direct consequence of their participation in polio eradication activities. The families of the workers receive a certificate recognizing the victim’s heroic commitment to polio eradication and a cash tribute. Those wishing to give may do so online ([https://www.logiforms.com/formdata/user_forms/9580_18629/27635/](https://www.logiforms.com/formdata/user_forms/9580_18629/27635/)) or by contacting the Polio Eradication Heroes Fund at the CDC Foundation, 50 Hurt Plaza – Suite 765, Atlanta, GA 30303, USA.

VACCINE SAFETY
30/09/08 from Alison Brunier, WHO/HQ:
**18th Meeting of the Global Advisory Committee on Vaccine Safety (GACVS)**

The Global Advisory Committee on Vaccine Safety (GACVS), an expert clinical and scientific advisory body, was established by WHO in 1999 to respond promptly, efficiently and with scientific rigour to vaccine safety issues of potential global importance. Issues described by the Committee during its 18th meeting, held on 18-19 June in Geneva, Switzerland, included the safety of yellow fever vaccine, mitochondrial diseases and vaccination, and thiomersal.

**Safety of yellow fever vaccine**

The Committee was updated on evidence regarding the safety of 17D yellow fever vaccines. It focused primarily on four fatal cases and one non-fatal case of vaccine-associated viscerotropic disease (YEL-AVD) occurring among 63 174 individuals vaccinated in the Ica Region of Peru following a yellow fever vaccination campaign conducted in September-October 2007 after a major earthquake. All five cases received vaccine from the same lot. The incidence of YEL-AVD (estimated as 11.7/100 000 vaccinated based on the number of people receiving the vaccine lot or 7.9/100 000 based on all those vaccinated in the Ica Region) was noted to be more than 20 times higher than the risk previously associated with 17D vaccines in general. The Committee reviewed the key clinical and virological findings of the case investigation, data on vaccine quality and production at the manufacturing facility, and the findings of an expert panel convened by the Pan American Health Organization and WHO. Members concluded that the cause of the cluster of cases was not clear. One of the cases presented a known risk factor; a second case presented a potential risk factor. Vaccine evaluation showed that the lot administered (as well as other lots from the same batch) met all quality specifications, and the yellow fever virus isolated from three confirmed cases was consistent with the vaccine virus and did not appear to have mutated. Approximately 72 000 doses of the vaccine lot common to the YEL-AVD cases was confirmed to have been used elsewhere in Latin America without additional cases of YEL-AVD.

The GACVS reiterated the need to obtain better estimates of rates of serious adverse events and to be better able to predict which individuals are at risk for such events. Members indicated support for the initiatives of WHO and other global partners in these areas, including ongoing efforts to enhance surveillance and to evaluate serious adverse events in mass yellow fever vaccination campaigns in endemic regions in Africa and Latin America.

**Mitochondrial diseases and vaccination**

The GACVS reviewed the limited data on mitochondrial disorders and vaccination available from the United Kingdom of Great Britain and Northern Ireland and the United States. The Committee concluded that there is no convincing evidence to support an association between vaccination and deterioration of mitochondrial
diseases (inherited disorders of energy metabolism that tend to affect tissues with high energy requirements such as the brain, heart and liver). The topic will be reviewed further if new findings become available. GACVS supports continued vaccination of children with mitochondrial diseases with the same vaccines as are given to healthy children.

**Thiomersal**

The Committee reviewed a recently-published pharmacokinetic study of mercury in premature and low-birth-weight infants who received a birth dose of hepatitis B vaccine containing thiomersal. The results suggest that exposure to thiomersal-containing vaccines does not result in accumulation of mercury in blood and that the blood half-life (2.9–4.1 days) of intramuscular ethyl mercury in infants following vaccination with thiomersal-containing vaccines is substantially shorter than that of oral methyl mercury in adults. The study concluded that exposure guidelines based on oral methyl mercury may not be appropriate for use in assessing the risk of thiomersal in vaccines at dosages consistent with standard vaccination regimens. Members also considered the results of a study conducted in Italy that examined neuropsychological performance 10 years after immunization in infancy with thiomersal-containing vaccines. The differences in mean scores were very small, detected only in girls, of doubtful clinical relevance, and not consistent with results from other studies of ethyl mercury.

On the basis of the presented data, GACVS remains of the view that there is no evidence to support a change in WHO’s recommendations for thiomersal-containing vaccines and the vaccination of low-birth-weight infants where indicated.

Other topics discussed during the meeting were: diphtheria-tetanus-pertussis (DTP) vaccine and asthma; non-specific effects of DTP vaccine on child mortality; and inadvertent administration of rubella vaccine to women shortly before or during pregnancy.

The report of the meeting was published in the WHO Weekly Epidemiological Record on 8 August and has been posted on the GACVS web site at [http://www.who.int/wer/2008/wer8332.pdf](http://www.who.int/wer/2008/wer8332.pdf)

**German site joins the Vaccine Safety Net**

The website [Impfbrief.de](http://www.impfbrief.de), which provides recent information for German-speaking health-care professionals, the media and general public on vaccine-preventable diseases, vaccine safety and vaccine scares, has become the latest site to join the Vaccine Safety Net, WHO's network of websites providing information on vaccine safety. The web site summarizes the latest scientific findings in the scientific literature or from conferences. Detailed reviews are provided by members of the web site's scientific board or guest authors. The Vaccine Safety Net was initiated by WHO in 2003 with the aim of facilitating access to reliable information on vaccine safety. IN order to join the network, websites must clearly indicate their purpose, disclose their ownership and information sources, reveal their sponsors, provide contact information, have a data protection policy, and provide quality information in sufficient quantity. The network includes web sites in Dutch, English, French, German, Italian, and Spanish.

Impfbrief.de web site - with link to [http://www.impfbrief.de](http://www.impfbrief.de)


**PUBLICATIONS**

**WHO PUBLISHED DOCUMENTS**

**30/09/08 from Mario Conde, WHO/HQ:**


The main purpose of this document which is published as a separate disease/vaccine-specific module, is to give vaccination professionals such as EPI managers, a brief and easy-to-understand overview of the scientific basis of vaccination regarding Varicella-zoster virus.

The document "Guidelines for the clinical evaluation of dengue vaccines in endemic areas", item code: WHO/IVB/08.12 is available online on: [http://whqlibdoc.who.int/hq/2008/WHO_IVB_08.12_eng.pdf](http://whqlibdoc.who.int/hq/2008/WHO_IVB_08.12_eng.pdf)

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

REVIEW PROCESS

Next Review Dates:

PROPOSAL REVIEWS - ISS, INS, New Vaccines & Measles 2nd Dose:

Third Review: The deadline for receiving applications was 25 September 2008. The applications will be reviewed from 23-31 October 2008.

HSS REVIEWS
Second Review: The deadline for receiving applications is 12 September 2008. The applications will be reviewed from 3-15 October 2008.

MONITORING REVIEW
Annual progress reports to GAVI were reviewed from 22-27 September 2008.

COUNTRY INFORMATION1 BY REGION

AFRO EAST & SOUTH

REGIONAL INFORMATION
30/09/08 from Hayatee Hasan, WHO/HQ:
Mobile health initiative expands to over 20 countries in Africa - The United Nations Foundation and Vodafone Foundation’s Technology Partnership (Technology Partnership) announced on 9 September 2008 the expansion of its mobile health (mHealth) programme in Africa. Working with the World Health Organization (WHO) and the non-profit DataDyne.org, the Technology Partnership will expand the use of EpiSurveyor, an open-source application that helps healthcare workers track health data, to 22 sub-Saharan countries by the end of 2008. EpiSurveyor, which was developed by the non-profit DataDyne.org, can be downloaded to handheld devices and is easily adaptable by workers in the field. WHO, DataDyne.org and the Technology Partnership piloted EpiSurveyor in Kenya and Zambia. Its successful implementation has greatly improved the timeliness and availability of healthcare data, making it easier to strengthen district level healthcare programmes involving interventions against malaria and other preventative programs aimed at improving public health. For more information, visit:

ETHIOPIA
30/09/08 from AFRO E&S:
• The cold chain inventory has been completed, and the report will be ready in October 2008.
• The RED strategy has been implemented in all districts in the country, and support is being provided to update microplans in selected districts.
• DQS implementation is ongoing in some regions following a national training.

KENYA
30/09/08 from AFRO E&S:
• The application for pneumococcal vaccine introduction support has been approved by GAVI.
• An MLM training is being conducted in 24 districts in liaison with Moi University, with funds from Merck Vaccines, Africa.

1 HSS= Health Systems Strengthening; ICP = Inter Country Programme; ISS = Immunization Services Support; INS = Injection Safety Support; NVS = New Vaccine Support; DQA = Data Quality Audit; DQS = Data Quality Self Assessment; FSP = Financial Sustainability Plan; RED = Reach Every District; cMYP = Fully costed multi-year plan;
LESOTHO
30/09/08 from AFRO E&S:
• A vaccine management assessment was conducted in September 2008.
• Following a training of trainers in implementing the RED strategy, three out of 10 districts have conducted training for health staff.

MALAWI
30/09/08 from AFRO E&S:
• The government plans to conduct an assessment of cold storage capacity at the central level before applying for the pneumococcal vaccine.
• All 26 districts in the country are now implementing the RED strategy.
• MLM training on the 12 modules adapted from the AFRO modules has been postponed from June to December 2008. UNICEF will provide funds for the training.

MOZAMBIQUE
30/09/08 from AFRO E&S:
• The RED strategy is being implemented in 33 districts.
• MLM training will be conducted in the three provinces of Sofala, Cabo Delgado and Tete.

* SOUTH AFRICA
30/09/08 from AFRO E&S: The Minister of Health launched the pneumococcal and rotavirus vaccines in Senqu sub-district in the Eastern Cape Province on 12 September 2008. The vaccines will be introduced in Senqu on 22 September 2008, and later in the other districts in Eastern Cape. It is expected that the vaccines will have been introduced country-wide by April 2009.

UGANDA
30/09/08 from AFRO E&S:
• An HPV demonstration project is taking place in two districts with support from PATH.
• Funds have been mobilized to implement RED in Karamoja and West Nile Regions in the last half of 2008.
• Following a review and adaptation of the AFRO MLM modules in February 2008, a training of trainers was conducted with support from IST in August 2008. Regional training will start in the first quarter of 2009.

30/09/08 from Issa Makumbi, Uganda: A comprehensive review and inventory of the cold chain system was recently conducted, and USAID has provided $1 million, through UNICEF, to support the country in addressing the gaps in the cold chain.

AFRO WEST & CENTRAL

REGIONAL INFORMATION
30/09/08 from AFRO West & Central:
Vaccine Management Workshop - This workshop was held from 8-12 September 2008 in Dakar, Senegal to discuss vaccine safety and management. The workshop was co-organized by UNICEF (WCARO and Copenhagen) and WHO West & Central AFR. Twenty-four countries from the sub-regions attended the workshop.

New Vaccines Introduction
A peer-review workshop was organized in Dakar, Senegal from 15-19 September 2008 for countries in the West and Central Blocks of Africa that are planning to apply for GAVI support to introduce new vaccines, as well as to assist countries responding to conditionalities set by the GAVI Independent Review Committee in previous reviews. The countries participating in the workshop include Benin, Burundi, Cameroon, Congo, Ghana, and Sao Tome & Principle.

Vaccine Financing
A workshop was organized by the WHO West & Central AFRO on 23-24 July 2008 in Douala, Cameroon in collaboration with the OCEAC (Organization for the Coordination of the fight against the great epidemics in Central Africa) and the BEAC (Bank of Central African States). The main purpose of this workshop was to discuss vaccine financing, following the PAHO methodology.
Data Quality - Introduction of an auto-evaluation tool for immunization data
A workshop was held in Mbalmayo, Cameroon from 16-20 June 2008 to discuss the DQS. A similar workshop on DFQS was held in Lambaréné, Gabon from 7-11 July 2008.

WESTERN PACIFIC

REGIONAL INFORMATION

30/09/08 from WPRO:
WHO/UNICEF Inter-Country Workshop on "Elimination of Maternal and Neonatal Tetanus (MNT)" - This joint workshop for countries of East Asia and the Pacific will be conducted in Bangkok, Thailand from 7-9 October 2008, and is targeted to Ministries of Health in countries where MNT remains endemic. In the East Asia and Pacific regions, this includes the countries of Cambodia, China, Indonesia, Lao PDR, Myanmar, Papua New Guinea, Philippines and Timor Leste.

HPV vaccine introduction in Fiji & New Zealand
New Zealand introduced HPV vaccine in June 2008, bringing the total number of countries that have done so to six (Australia and four Pacific island countries). HPV immunization was added to the immunization schedule for girls in school Year 8 (or age 12 if not delivered in a school-based programme) on an ongoing basis with a phased catch-up programme available for girls born on or after 1 January 1990. The school-based catch-up programme will be phased over 2009 and 2010. Fiji is planning to introduce HPV vaccine in late 2008 for 9-12 year-old girls with the help of 110,000 doses of vaccine donated by Merck. The implementation will be supported by the AusAID funded Health Sector Improvement Plan.

CAMBODIA

30/09/08 from WPRO: Cambodia decided to introduce Hib-containing pentavalent vaccine (DTP-HepB-Hib) from 2010, and will submit an application for support from GAVI in September 2008. WPRO provided technical assistance to develop the application for Hib and ISS support. With the country deciding to introduce Hib, the total number of countries and areas in the Western Pacific Region that have either introduced or are in the process of introducing the Hib vaccine is 26 out of 36. Four more Pacific Island countries are in the process of consultation to mobilize resources for introduction of Hib vaccine in 2009.

LAO PDR

30/09/08 from WPRO: Oral Poliovirus Vaccine (OPV) supplementary immunization activities (SIAs) are planned for high risk areas during the next Child Health Days (CHD) scheduled for 8-22 December 2008. During a joint WHO/UNICEF mission in early September 2008, support was provided to determine selection criteria for high risk areas, which include: international travel entry points; high population density; and population movements including tourist places and low coverage areas. Subsequently, 58 priority districts to be targeted in 12 provinces were selected (313,209 children under five years) as well as an additional 11 districts in seven provinces should additional resources become available (52,168 children under five years). The dates for the second OPV SIA round were set for the first week of February 2009. In addition, next steps were determined to finalize the draft "Proposal for Acceleration of MNTE Activities in LAO PDR 2009-2010". Selection criteria for high risk districts to be targeted with three rounds of tetanus toxoid (TT) SIAs were defined; 72 poverty districts were agreed upon to be included, and further selection will be done based on district core and surrogate indicators. These will include DTP1 and DTP3 coverage and drop out rates, TT2+ coverage for pregnant and child-bearing age women, antenatal care coverage, institutional delivery rate, and neonatal tetanus cases. It is also planned to use future CHDs to offer TT to women of child-bearing age.

VIETNAM

30/09/08 from WPRO: Vietnam has been approved to introduce the Hib vaccine from 2009. It will start meningo-encephalitis surveillance from November 2008 in two hospitals - National Paediatrics Hospital in Hanoi and National Children's Hospital #1 in Ho Chi Minh City. The surveillance will be supported by WPRO. In addition, the Hib Initiative will organize a case-control study with purulent meningitis and confirmed Hib meningitis as expected outcomes and a second study to assess the impact of pneumonia outcomes. This will provide comprehensive evidence of Hib vaccine on meningitis and pneumonia in the country, and will be useful in decision-making for other countries in the Region as well.
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<th>Title of Meeting</th>
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<th>Location</th>
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<td><strong>Oct-08</strong></td>
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<tr>
<td>GAVI Regional Working Group Meeting for East &amp; South Africa</td>
<td>01-Oct</td>
<td>02-Oct</td>
<td>Nairobi, Kenya</td>
<td>AFRO (E&amp;S)</td>
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<td>GAVI Independent Review Committee Meeting for HSS proposals</td>
<td>03-Oct</td>
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<td>PAHO Regional Meeting on Mumps</td>
<td>20-Oct</td>
<td>21-Oct</td>
<td>Washington DC</td>
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<td>EMRO EPI Managers Meeting</td>
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<td>22-Oct</td>
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<td>Cairo, Egypt</td>
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<td>EMRO 24th RTAG Meeting</td>
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<td>Dubai, UAE</td>
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<td>PAHO Meeting of the Network for New Vaccines Adverse Events (SANEVA)</td>
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<td>Mexico City, Mexico</td>
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<td>Strategic Advisory Group of Experts (SAGE) meeting</td>
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<td>06-Nov</td>
<td>Geneva</td>
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<td>EMRO Bacterial Meningitis and Pneumococcal Regional Surveillance Networks</td>
<td>11-Nov</td>
<td>13-Nov</td>
<td>Casablanca, Morocco</td>
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<td>Follow-Up meeting</td>
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<td>25th Meeting of the Caribbean Expanded Programme on Immunization Managers</td>
<td>17-Nov</td>
<td>21-Nov</td>
<td>Bahamas</td>
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<td>GAVI Eastern Mediterranean Regional Working Group Meeting</td>
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<td>Cairo, Egypt</td>
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<td>EMRO Measles Inter-Country Meeting for Priority Countries (GAVI Eligible,</td>
<td>22-Nov</td>
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<td>TechNet21 2008 Consultation Meeting</td>
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<td>Tunisia</td>
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<td>12-Dec</td>
<td>Asuncion, Paraguay</td>
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<td>14th Meeting of the Regional Commission for the Certification of</td>
<td>09-Dec - 10-Dec</td>
<td>Vientiane, Lao PDR</td>
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<td>10-Dec</td>
<td>Thimpu, Bhutan</td>
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<td>EMRO Rotavirus Regional Surveillance Network Follow-Up Meeting</td>
<td>16-Dec - 18-Dec</td>
<td>Amman, Jordan</td>
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<td>Global Immunization Meeting</td>
<td>17-Feb - 19-Feb</td>
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<td>PAHO Meeting of the Technical Advisory Group on Vaccine-Preventable</td>
<td>26-Jan - 29-Jan</td>
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<td>Strategic Advisory Group of Experts (SAGE) meeting</td>
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<td>PAHO Sub-Regional Meeting of the Central American Region, Mexico</td>
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<td>26th Meeting of the Caribbean Expanded Programme on Immunization</td>
<td>16-Nov - 20-Nov</td>
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<td>PAHO</td>
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<td>Managers</td>
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LINKS RELEVANT TO IMMUNIZATION

GLOBAL WEBSITES

Department of Immunization, Vaccines & Biologicals, World Health Organization
http://www.who.int/immunization/en/

WHO New Vaccines Hib website
http://www.who.int/nuvi/hib/

GAVI Alliance Website
http://www.gavi alliance.org/

IMMUNIZATIONbasics (JSI)
www.immunizationbasics.jsi.com

PATH Vaccine Resource Library
http://www.path.org/vaccineresources

UNICEF Supply Division Website
http://www.unicef.org/supply/index_immunization.html

UNICEF Supply Division Product Menu for GAVI Vaccines

Hib Initiative Website
http://www.hibaction.org/

Japanese Encephalitis Resources
http://www.path.org/vaccineresources/japanese_encephalitis-resources.php

Malaria Vaccine Initiative
http://www.malarialogies.org

Meningitis Vaccine Project
http://www.meningvax.org/index.htm

PneumoADIP
www.preventpneumo.org/

RotaADIP
http://www.rotavirusvaccine.org/

RHO Cervical Cancer (HPV Vaccine)
http://www.rho.org

WHO/ICO Information Center on HPV and Cervical Cancer
http://www.who.int/hpvcentre/en/

SIGN Updates
www.who.int/entity/injection_safety/sign/en/

Technet
http://www.technet21.org/

REGIONAL WEBSITES

New Vaccines in AFRO
http://www.afro.who.int/newvaccines/
PAHO’s website for Immunization
http://www.paho.org/english/ad/fch/im/Vaccines.htm

Vaccine Preventable Diseases in EURO
http://www.euro.who.int/vaccine

New Vaccines in SEARO
http://www.searo.who.int/en/section1226.asp

Immunization in WPRO
http://www.wpro.who.int/health_topics/immunization/

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