



**Meeting of the Strategic Advisory Group of Experts,  
WHO Vaccines and Immunizations  
Geneva, November 20-22, 2006**

Attended on behalf of IPA by Jane Schaller Executive Director; President Adenike Grange was also invited but could not attend.

A full accounting of the agenda and the background documents for this meeting can be found on its website <http://www.who.int/vaccines/meetings/sage>.

On the first day of the meeting Jean-Marie Okwo-Bele, Director of Immunization, Vaccines and Biologicals reviewed the recommendations from the two SAGE committee meetings this past year, and the progress on each of the recommendations. The SAGE guides the policy and activities of WHO concerning immunizations and vaccines. In 2006 there were SAGE recommendations concerning immunization financing, treatment for malaria in infancy, Japanese encephalitis vaccination, mumps vaccination, pneumococcal vaccines, optimization of immunization schedules, pandemic influenza vaccine, measles mortality reduction, global DPT3 coverage, reach every district (RED) strategy for routine immunization strengthening, the vaccines pipeline, current status of rotavirus vaccine, rotavirus clinical trials in Africa, quality safety and standards for vaccines and immunization, review of published immunization policies, and review of SAGE restructuring policies. This report is contained on the website. SAGE has now produced a catalogue of policy statements on immunizations which is also posted on their website.

Julian Lob-Levyt reviewed 2006 activities of the Global Alliance for Vaccine and Immunizations. IPA has a seat on the GAVI board, represented by our President Adenike Grange. This board will be meeting in Berlin the week of November 27<sup>th</sup>. A report will follow after that meeting. Of interest to pediatricians, Dr. Lob-Levyt commented that GAVI will be pursuing its activities concerning Hib vaccine, investment cases for rotavirus and pneumococcal vaccines, and will ask its board to approve investment in both rotavirus and pneumococcal vaccines. GAVI activities are related to making vaccines available to countries in the developing world; GAVI activities are now broadening to include health strengthening systems in the developing world. A fuller report of GAVI activities will follow the board meeting next week.

Next there were reports on immunization and vaccines from the various WHO regions; these are all posted on the website; pediatricians can check the reports of their particular regional WHO offices.

There were prolonged discussions of influenza pandemic vaccine development. Briefly; there is felt to be a race against time to provide vaccine for an anticipated epidemic of "Asian" influenza. There is much activity in this regard with 17 companies currently planning to begin 23 vaccine trials this year. This attention to influenza vaccine will also have some spin-off in stimulating research for new vaccines in general. A very large amount of vaccine may be needed in a very short period of time. Uncertainties remain, including the likelihood that influenza vaccines would have a significant impact on morbidity and mortality during the first wave of any pandemic, and whether immunization would in fact reduce spread. WHO also presented information on a global action plan

which involves joint efforts with other key partners and stakeholders from governments, the research community, foundations, and the pharmaceutical industry.

The Global Advisory Committee on Vaccine Safety presented an interesting report. This group is charged with vaccine safety issues related to current and new vaccines. One pediatrician, Dr. Greg Hussey from Cape Town South Africa, is on this committee. Concerning fears (often from parents) that “immune overload” from multiple vaccines would overtax an infant’s immune system: “The available evidence reviewed by the committee does not support the hypothesis that vaccines as currently used weaken or harm the immune system”. There was also a report from the WHO expert committee on biological standardization.

Representatives from WHO and GAVI discussed the current status of immunization financing and advanced market commitments. They noted that in order to reach the goals of the Global Immunization and Vaccine Strategy which was launched last year, there is currently a \$10-15 billion funding gap for immunizations between 2006 and 2015. As might be expected this occurs particularly in the poorest countries. The status of advanced market commitments to provide incentives for vaccine production and development, and the respective roles of WHO and GAVI in this endeavour were discussed.

On the second day of the meeting, November 21<sup>st</sup>, a number of discussions were of interest to pediatricians:

- Pneumococcal vaccine: Pneumonia is now considered the leading cause of preventable child death in the developing world. Two of the major bacterial causes of acute pneumonia in children are pneumococcus and haemophilus influenza. Hib vaccine was not discussed at this SAGE meeting. However there was extensive discussion of the situation with pneumococcal vaccine. The SAGE recommends that given the importance of pneumococcal disease in serious illness and death among infants and young children, particularly in underserved populations from poor countries that WHO support introduction of the currently licensed 7-sero type pneumococcal conjugate vaccine (PCV7). It is estimated that some 500,000 child deaths in GAVI-eligible countries would be prevented annually by this vaccine. Pneumococcal vaccines addressing more sero-types of the bacteria may become available in the future. The position paper on pneumococcal vaccine and immunization is posted on the SAGE website.
- Polio eradication update: The current status of global polio was presented, along with discussions of eradication, policies concerning handling of vaccine, and the future roles of oral and parenteral i-m or intradermal polio vaccines. There are currently two countries of major concern regarding polio: Nigeria and India, both of which have a significant burden of indigenous polio. These situations are the result of non-immunization of children. The burden is greatest in Nigeria, where a new approach of the polio eradication campaign involves more engagement of communities and delivery of a broader array of health services (Immunization-Plus) including measles vaccine, DPT, deworming medications, and bed nets. A need was expressed for social mobilization, and for reaching unreached children. Perhaps our member societies from Nigeria and India would be interested in joining in this effort. There are also cases of endemic polio in two other countries: Afghanistan and Pakistan, and there had been re-infection cases in 12 other countries. Of interest in this regard is a new policy of Saudi Arabia that in order to obtain a Visa to visit Saudi Arabia for any reason including the Hag, proof of polio

- immunization must be presented. International health regulations will be establishing a new recommendation on oral polio vaccine for travelers from all infected areas. There is a shortfall in funding for polio eradication of \$50 million in 2006 and an estimated \$390 million in 2007-2008. There was a somewhat gloomy discussion about the polio issue: an eradication campaign which had seemed to be achievable has been derailed by under immunization in a few countries, illustrating the vulnerability of the world to the continuing threat of large epidemics. A number of people commented: "We are living in a dangerous time".
- A presentation described the development of a Global Framework on Immunization Monitoring and Surveillance (GFIMS). This is essentially a companion document to the Global Immunization of Vaccine Strategy of last year, operationalizing many aspects of GIVS. This discussion also included the threat of epidemics of vaccine preventable diseases and our continuing vulnerability to them, and the opportunities that might address these problems, including better disease surveillance systems at country and regional levels throughout the world, and an effective alert and response operations process.
  - Meningococcal vaccine and epidemic meningitis: An epidemic belt of meningococcal meningitis exists across Africa with 21 countries and 400 million people at risk of epidemics. Fatality rates are between 10-50%, and 20-50% of survivors will suffer permanent brain damage. There is some evidence that the frequency of epidemics is increasing. A tetravalent vaccine exists but is in short supply. There was prolonged discussion, based on the results of one study with 763 volunteers of ages from childhood to adulthood, of whether in an impending health emergency it would be acceptable to use 1/5 dose of the meningococcal vaccine for mass immunizations. There was no resolution of this point, but general agreement that meningococcal vaccine is in short supply and all possible measures should be taken to increase its availability. If an epidemic occurs this year, it is not clear what the policy or outcome will be at this point. Representatives of pharmaceutical companies who were present are meeting to discuss increased vaccine production.
  - On the third day of the meeting, the SAGE measles working group presented its findings. This working group includes two pediatricians: Dr. Jose Santos from Mexico City and Dr. George Peter of Boston (formerly of Brown University). The SAGE committee supported the measles working group recommendations that measles vaccines should be given to any child (12 months to 15 years) who lacks evidence of at least one dose of measles vaccine administered at the age of nine months. The matter of increasing the age of first measles immunization from 9 to 12 months was discussed; there is evidence that the response at 12 months is somewhat better than at 9 months; however no position was taken on whether this should become a SAGE recommendation.
  - There were interesting discussions of optimization of immunization schedules. Studies of timing of infant vaccination in the developing world have shown a wide range of actual times of immunization which vary greatly from country to country. 25% of DPT3 vaccines were found to be delivered more than five months late. The possibility that "high coverage" is not necessarily the most effective coverage was raised. Delayed vaccination times are associated with rural residence. It was suggested that timeliness of actual delivery of vaccines should be looked at as a factor which might have greater impact than shifting immunization schedules, and that timeliness of vaccine delivery should be considered an important factor in evaluating the program.
  - A number of informational papers concerned current research and development efforts of vaccines for HIV, tuberculosis, and malaria. There is a considerable

- effort in all of these fields. Of particular interest to pediatricians is the question of whether adolescents should be included in HIV vaccine studies in Africa. A recent meeting in Botswana discussed this; it is not clear whether any pediatricians were included in that meeting. A number of clinical trials of HIV vaccines are ongoing and more are planned. It should be noted that the age groupings of populations for AIDS reporting statistics include the age group 15-24 years, with 0-14 years being considered "childhood". It was suggested that even if a vaccine has only partial efficacy in preventing infection with HIV or development of AIDS, partial efficacy could have a positive public health benefit.
- Concerning tuberculosis vaccines, there are a number of initiatives in the works seeking a vaccine that will more effectively prevent infection and/or dissemination of mycobacterium tuberculosis. There was nothing of particular reference to children in this report, although the presence of a vaccine that would prevent infection with tuberculosis would be a great boon to child and later adult health.
  - There is considerable excitement about progress with a vaccine against malaria. A trial in Mozambique (Lancet: 364:1411-20, 2004) has shown that this vaccine significantly lessened clinical malarial episodes and their severity by 35-49% in children ages 1-4 years with an 18 month follow-up. Interestingly this vaccine also confers some protection against Hepatitis B as a function of the vaccine production. A double blinded study involving 12,000-16,000 African children is now planned. As malaria is a leading killer of children in Sub-Saharan Africa, this is good news indeed.
  - A brief presentation concerned conjugate vaccines: Hib, meningococcal and pneumococcal, discussing vaccine schedules, whether vaccines caused herd immunity, and the monitoring of the various aspects of these vaccines including safety.

The meeting was closed at noon on November 22<sup>nd</sup>.

#### **Recommendations for IPA:**

- Immunization is clearly basic to child health, and we pediatricians should optimize our efforts in this regard. Immunization is now being used with broader packages including other basic health interventions, and will also be a factor in health strengthening systems. These matters are all critical to pediatrics and child health.
- The SAGE website is a useful site of information on immunizations and one that our members should find of interest.
- Concerning polio eradication: the pediatric societies of countries still at risk for polio should become involved with WHO, GAVI and their Ministries of Health to reach unreached children and promote public education.
- The endorsement of introduction of vaccines for pneumococcus, rotavirus, and Hib are most welcome. Pediatricians should become advocates at country level for the necessity of these vaccines for child health and for achievement of the Millennium Development Goals.

Submitted by J Schaller, Executive Director  
December 1, 2006