



Agenda
Meeting of the Strategic Advisory Group of Experts on Immunization (SAGE)
8 - 10 November 2011
CCV/CICG, Geneva

Tuesday, 8 November 2011

| Time | Session | Purpose of session, target outcomes and questions for SAGE | |
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| 08:30 | Welcome - introduction H. Rees, Chair of SAGE | | 20 min. |
| 08:50 | Report from Director, IVB - Session 1 Global report including key updates and challenges from regions, J.-M. Okwo-Bele, WHO, 30 min. Discussion: 1 hr 10 min. | FOR INFORMATION | 1 h 40 min. |
| 10:30 | Coffee/tea break | Break | 20 min. |
| 10:50 | Report from the GAVI Alliance Secretariat - Session 2 Report from GAVI Alliance, S. Berkley, GAVI Alliance, 20 min. Discussion: 20 min. | FOR INFORMATION | 40 min. |
| 11:30 | Reports from other Advisory Committees on Immunization - Session 3 Report of the Global Advisory Committee on Vaccine Safety (GACVS), M. Wharton, Chair of GACVS, 10 min. Discussion: 10 min. Report of the Immunization Practices Advisory Committee, (IPAC), S. Deeks, Chair of IPAC, 10 min. Discussion: 10 min. Report of the Quantitative Immunization and Vaccines Related Research (QUIVER), A. Hinman, Chair of QUIVER, 10 min. Discussion: 10 min. | FOR INFORMATION | 1 h 20 min. |
| 12:30 | Lunch | Break | 1 h |

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| 13:30 | Report of the Expert Committee on Biological Standards (ECBS), E. Griffiths, Chair of ECBS, 10 min. Discussion: 10 min. | | |
| 13:50 | Decade of Vaccines - Session 4 Update on the DoV Collaboration and presentation of the draft Global Vaccine Action Plan (GVAP), P. Alonso and C. Elias, co-Chair of the DoV Steering Committee, DoV Secretariat, 30 min. Discussion: 1 h 30 min. | FOR DISCUSSION Request SAGE inputs on the draft GVAP. Discuss plans for a special SAGE consultation to take place in February 2012. | 2 h |
| 15:20 | Coffee/tea break | Break | 30 min. |
| 15:50 | Decade of Vaccines - Session 4 (Contd.) | | |
| 16:20 | Global Vaccine Safety Blueprint - Session 5 Blueprint development process, P. Zuber, WHO, 15 min. Blueprint vision and strategic goals, questions to SAGE, J. Eskola, SAGE member, 15 min. Discussion: 1 h | FOR DISCUSSION This session aims at presenting SAGE with the 18-month process that led to the development of a global vaccine safety Blueprint including a September 2011 Global Vaccine Safety meeting. This Blueprint focuses on how national and international players can better collaborate in order to fill current gaps in vaccine pharmacovigilance, management and communication infrastructure. It attempts to define what needs to be accomplished in all countries and internationally to ensure effective vaccine pharmacovigilance. The specific purpose of the session is to: 1. present the Blueprint and development process to SAGE, 2. request SAGE's endorsement of the Blueprint vision and mission statements, and 3. request SAGE's advice on process for implementing the Blueprint. | 1 h 30 min. |
| 17:50 | Cocktail | | |

Wednesday, 9 November 2011

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| 08:30 | Monitoring national immunization coverage: WHO and UNICEF estimates of national immunization coverage - Session 6 Overview of data, methods and processes used for the WHO and UNICEF estimates of national immunization coverage, M. Gacic-Dobo, A. Burton, WHO, 30 min. Activities to improve immunization data quality in the American region C. Danovaro, WHO, 15 min. Discussion: 45 min. | FOR INFORMATION AND DISCUSSION Brief SAGE on: - Immunization data collection methods and WHO/UNICEF coverage estimation process. - the limitation of empirical data and the uncertainty of the estimates - activities to improve data quality in American regions and regional involvement of coverage estimation process Request SAGE's endorsement of the estimation method and SAGE's view on the appropriate use of the estimates. | 1 h 30 min. |
| 10:00 | Coffee/tea break | Break | 30 min. |
| 10:30 | Reinforcing surveillance - Session 7 Introduction to VPD surveillance coordinated by WHO, T. Cherian, WHO, 10 min. Progress and challenges with surveillance for rotavirus diarrhoea and invasive bacterial vaccine-preventable diseases (IB-VPD), M. Agocs, WHO, 20 min Regional perspective on improving the quality of IB-VPD surveillance, K. Fox, WHO, 15 min. Proposed next steps for improving quality of IB-VPD surveillance, A. von Gottberg, National Institute for Communicable Diseases, South Africa, 15 min. Discussion 1 h | FOR INFORMATION AND DISCUSSION Brief SAGE on general surveillance structure for VPDs. Update SAGE on the progress with rotavirus and IB - VPD surveillance (this includes meningitis sentinel surveillance). Discuss the challenges faced with IB -VPD surveillance and the proposed next steps to improve the quality of surveillance. | 2 h |
| 12:30 | Lunch | Break | 1 h |
| 13:30 | Review of serotype replacement in the setting of 7-valent pneumococcal conjugate vaccine (PCV7) use and implications for the PCV10/PCV13 era - Session 8 Methods & results for serotype replacement, D. Feikin, John Hopkins Bloomberg School of Public Health, 20 min. Methods & results for use of surveillance systems to evaluate PCV impact, M. Moore, US Centers for Disease Control and Prevention, 20 min. Summary of key findings with proposed next steps and recommendations, A. Reingold, SAGE member, 5 min. Discussion: 1 h | FOR DISCUSSION In March 2007, WHO issued recommendations on use of pneumococcal conjugate vaccine (PCV) in young children. Since then, in addition to expected reductions in vaccine serotype disease rates, evidence has emerged of some increases in non-PCV serotype invasive pneumococcal disease (IPD). These increases may be related to PCV introduction, a phenomenon known as "serotype replacement" or to non-PCV pressures. WHO convened an expert consultation in July 2010. The primary outcome of that meeting was a recommendation to conduct a systematic review of non-vaccine serotype IPD changes in countries that have introduced PCV. In September 2011, the findings of that review were presented at a meeting of co-investigators and experts in the field. The conclusions of that | 1 h 40 min. |

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| | | <p>meeting, including implications for monitoring non-vaccine serotype disease as 10- and 13-valent conjugate vaccines are introduced globally will be presented to SAGE.</p> <p>The purpose of this session is:</p> <ol style="list-style-type: none"> 1. To inform SAGE members of the process used for the systematic review of serotype replacement and conclusions drawn at the September 2011 meeting. 2. To request that SAGE to provide specific recommendations regarding pneumococcal disease surveillance to monitor possible serotype replacement in countries where PCV has been introduced. <p>Specific questions:</p> <ul style="list-style-type: none"> • Is SAGE in agreement that proper monitoring for the impact of PCV on both vaccine and non vaccine serotype IPD is an important activity? • Does SAGE agree with the key findings from the serotype replacement systematic review? • What is SAGE's advice on how to best disseminate recommendations for surveillance methodologies to monitor PCV impact (vaccine and non-vaccine serotypes) in countries where PCV has been introduced. | |
| 15:10 | Coffee/tea break | Break | 30 min. |
| 15:40 | <p>Optimizing immunization schedules for conjugate pneumococcal vaccines - Session 9</p> <p>Developing an approach to assess evidence on immunization schedules: the experience with PCV vaccines. P. Fine, London School of Hygiene and Tropical Medicine, 15 min.</p> <p>What is the available evidence on PCV schedule(s) for children in various areas of the world? C. Whitney, US Centers for Disease Control and Prevention, 30 min.</p> <p>Discussion: 1h 5 min.</p> | <p>FOR DECISION</p> <p>SAGE will be presented with a critical review of the evidence for various PCV schedule(s) and to compare them to the 3-dose primary schedule currently recommended.</p> <p>SAGE will be asked to:</p> <ul style="list-style-type: none"> • decide on optimal PCV childhood schedule(s). <ul style="list-style-type: none"> -Number of doses: 2 or 3 primary doses and interval between doses -Age at 1st dose -Need for a booster dose and if so recommended age -PCVs interchangeability Co-administration with other EPI vaccines. • identify data gaps and limitations of existing evidence to inform PCV schedules selection at country and regional level. • identify priority research questions to inform future PCV schedules policy. | 1 h 50 min. |
| 17:30 | End of day | | |

Thursday, 10 November 2011

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| 08:30 | <p>Polio eradication - Session 10</p> <p>Is it time for a new 'polio endgame': context, options & implications for SAGE, B. Aylward, WHO, 15 min.</p> <p>Discussion: 30 min.</p> <p>Operational priorities through mid-2012 for wild poliovirus eradication, C. Maher, WHO, 15 min.</p> <p>Discussion: 30 min.</p> <p>Could a combination of OPV & IPV accelerate wild poliovirus eradication? N. Grassly, Imperial College, UK, 20 min.</p> <p>Discussion: 40 min.</p> | <p>FOR DISCUSSION AND DECISION</p> <p>SAGE's comments on, and potential endorsement of the new strategic approach to the endgame that would combine the eradication of residual wild polio viruses (WPVs) and elimination of vaccine derived polio virus (VDPV) type 2.</p> <p>SAGE's comment on the operational priorities and any potential adjustments.</p> <p>SAGE's opinion as to what role IPV might play in the context of wild poliovirus eradication and which, if any, additional research studies or evaluation projects should be undertaken to guide strategy in this regard.</p> | 2 h 30 min. |
| 10:30 | Coffee/tea break | Break | 30 min. |
| 11:00 | Polio eradication - Session 10 (Contd.) | | |
| 11:30 | <p>Tuberculosis vaccines - Session 11</p> <p>The value of new tuberculosis (TB) vaccines in reducing burden of disease, C. Dye, WHO, 10 min.</p> <p>TB Vaccine Pipeline, Clinical Trials and Challenges, H. Mahomed, South African Tuberculosis Vaccine Initiative (SATVI), 15 min.</p> <p>Critical activities and strategies for advancing and introducing TB vaccines, M. Brennan, Aeras, 15 min.</p> <p>Planned WHO activities related to TB vaccine development, U. Fruth, WHO, 5 min.</p> <p>Discussion: 45 min.</p> | <p>FOR INFORMATION AND DISCUSSION</p> <p>Two preventative TB vaccine candidates are in phase IIb test-of-concept trials and preliminary efficacy results from the first of these trials are expected in early 2013. Before starting planning pivotal phase III trials, the TB community has expressed the desire to obtain initial SAGE feedback and endorsement on its current strategy which is based on (a) the Global Plan to Stop TB 2011-2015 and (b) the Blueprint for TB Vaccine Development.</p> <p>The main purpose of the session is to:</p> <ul style="list-style-type: none"> • Update SAGE on status of TB vaccines in pivotal trials and issues/bottlenecks in TB vaccine development • Ensure that current plans for developing vaccines meet the needs of SAGE for providing global policy recommendations on the use of novel TB vaccines • Request SAGE concurrence with the current TB vaccine development strategies for reducing disease in infant and adolescent/adult populations | 1 h 30 min. |
| 13:00 | Lunch | Break | |

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| 14:00 | Evidence and recommendations for use of hepatitis A vaccines - Session 12 Overview of disease burden, evidence and GRADE tables, S. Wiersma, WHO, 30 min. Draft recommendations for use of hepatitis A vaccines in global immunization programmes, A. Reingold, SAGE member and Chair of the SAGE hepatitis A working group, 20 min. Discussion: 1 h 10 min. | FOR DECISION For review of evidence and decision on recommendations for use of hepatitis A vaccines in global immunization programmes to prepare for the updating of the 2000 hepatitis A WHO position paper Specific expected output: <ul style="list-style-type: none"> • Request endorsement of proposed recommendations for updated vaccine policies and for the expanded use of hepatitis A vaccines in general populations as well as in specific risk populations. • Request endorsement of proposed recommendation to continue to monitor safety and long-term protection of hepatitis A vaccines. | 2 h |
| 16:00 | Closing | | 20 min. |
| 16:20 | End of meeting | | |