

**Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 11-14 March 2024  
Hybrid Meeting  
WHO HQ  
Agenda**

<b>Day 1: Monday, 11 March 2024 (time is Central European Time)</b>			
<b>Time CET</b>	<b>Session</b>	<b>Purpose of session, target outcomes and questions for SAGE</b>	<b>Duration</b>
<b>9h00</b>	<b>Closed SAGE meeting</b>	Preparation of the sessions of the day.	<b>1h15</b>
<b>10h45</b>	<b>Break</b>	<b>Break</b>	<b>15 min</b>
<b>11h00</b>	<b>Opening and welcome – introduction of participants</b> R. B. AYLWARD. ADG/UHL. WHO. 10 min  H. NOHYNEK, SAGE chair. 5 min  J. HOMBACH. SAGE Secretariat. WHO. 5 min.		<b>20 min</b>
<b>11h15</b>	<b>Global and regional reports – Session 1</b>  Report from the Director of IVB. K. O'BRIEN. WHO. 30 min.  Update from Gavi. A. NGUYEN. GAVI. 20 min.  Discussion. 30 min.	<b>FOR INFORMATION</b>	<b>1h30</b>
<b>12h45</b>	<b>Break</b>	<b>Break</b>	<b>1h00</b>
<b>13:45</b>	<b>Global and regional reports – Session 1 Continue</b> Regional reports focused on the "Big catch up" theme  Introduction. F. OLAYINKA. SAGE member. 5 min.  Presentations from AFRO, EMRO, EURO. 10 min each. Discussion. 20 min.  Presentations from PAHO, WPRO, SEARO. 10 min each. Discussion. 20 min.  Overall discussion. SAGE members. 15 min.	<b>FOR DISCUSSION</b>	<b>2h</b>
<b>15:45</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>16:00</b>	<b>IA2030 deep dive – Session 2</b>  Introduction. F. OLAYINKA. SAGE member. 5 min.  The Big Catch-Up: Overview, Progress, and Plans for 2024. A. LINDSTRAND. WHO. 10 min.  Monitoring and Learning for the Big Catch-Up: Approaches and Considerations. C. DANOVARO. WHO. 15 min.  Country Presentation: BCU implementation strategy and monitoring approach. S. TCHOKFE NDOULA, EPI manager Cameroon. 15 min.  Discussion. 45 min.	<b>FOR DISCUSSION</b>  The purpose of this session is to provide an informational overview of the status of Big Catch-Up and a detailed insight into the monitoring, evaluation, and learning (MEL) plan for the Big Catch-Up.  SAGE members are requested to provide feedback on the MEL plan and its limitations and to provide inputs into how to ensure that this time-limited initiative can have long-term impacts to strengthen program resilience.	<b>1h30</b>

<b>17h30</b>	<b>End of day 1</b>
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<b>Day 2: Tuesday 12 March 2024</b>			
<b>Time CET</b>	<b>Session</b>	<b>Purpose of session, target outcomes and questions for SAGE</b>	<b>Duration</b>
<b>9:00</b>	<b>Closed SAGE meeting</b>	Development of recommendations of day 1. Preparation of the sessions of the day. Other important discussion items.	<b>1h 30</b>
<b>10:45</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:00</b>	<b>Polio – Session 3</b>	<b>FOR INFORMATION AND RECOMMENDATION</b>	<b>2h30</b>
	<p>Session overview by S. MADHI. SAGE Member . 5 min.</p> <p>Update from the Global Polio Eradication Initiative. A. O'LEARY. WHO. 15 min.</p> <p>Questions. 20 min.</p> <p>Lessons learned from switch of tOPV to bOPV in 2016 relevant to bOPV cessation. R. SUTTER. 15 min.</p> <p>Policy considerations for bOPV Cessation Planning. O. MACH. WHO. 10 min.</p> <p>Questions. 20 min.</p> <p>Consideration for use of fIPV intramuscular. O. MACH. WHO. 5 min.</p> <p>Questions. 20 min.</p> <p>Report from SAGE Polio Working Group including update on novel OPVs. S. MADHI. SAGE Member. 15 min.</p> <p>Discussion. 25 min.</p>	<p>SAGE will be informed on the current status of the polio eradication program and of the implementation of the new polio eradication strategy. SAGE will discuss the policy framework and triggers for bOPV cessation planning. SAGE will be updated on the use and clinical development of novel OPVs.</p> <p>SAGE will be asked to review and consider for endorsement:</p> <ul style="list-style-type: none"> <li>• Recommendation on use of fIPV administered i.m.</li> </ul>	
<b>13:30</b>	<b>Break</b>	<b>Break</b>	<b>1h</b>
<b>14:30</b>	<b>Hepatitis E – Session 4</b>	<b>FOR RECOMMENDATION</b>	<b>1h30</b>
	<p>Introduction, update on recent developments and HEV in pregnant women. R. GRAIS. SAGE member. 15 min.</p> <p>Review of recent safety data on HepE vaccine (Hecolin) in Pregnancy.K. MACARTNEY. Chair Hep E Safety WG 15 min.</p> <p>Questions. 10 min.</p> <p>Presentation of evidence on immunogenicity, efficacy and effectiveness of less than 3 doses. B. AZAM. 10 min.</p> <p>Questions. 10 min.</p> <p>Recommendations. R. GRAIS. SAGE member. 5 min.</p> <p>Discussion. 25 min.</p>	<p>Present SAGE with GACVS assessment of Hepatitis E vaccine use during pregnancy.</p> <p>SAGE will be asked to advise on the risk-benefit of vaccination of pregnant women in the contexts of outbreaks occurring in fragile and conflict-affected settings.</p> <p>Inform SAGE on vaccine immunogenicity, efficacy and effectiveness of less than the full schedule (3 doses) and ask for SAGE's guidance on using less than the full schedule in outbreak settings.</p>	
<b>16:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min</b>

<b>16:15</b>	<b>COVID-19 – Session 5</b>	<b>FOR INFORMATION</b>	<b>1h</b>
	<p>Introduction of the session, S. KOCHHAR. SAGE member. 5 min.</p> <p>Update on the epidemiology of COVID-19 with a focus on severe disease by priority use groups. M. VAN KERKHOVE. WHO. 15 min.</p> <p>Uptake of monovalent XBB vaccines. D. BROOKS. WHO. 5 min.</p> <p>Vaccine effectiveness of monovalent XBB vaccines. A. VARMA. WHO. 10 min.</p> <p>Q&amp;A, Discussion. 25 min.</p>	<ul style="list-style-type: none"> <li>• Update on the epidemiology of COVID-19 by priority use group</li> <li>• Update on circulating virus strains</li> <li>• Rationale for the TAG COVAC recommendations</li> <li>• Experiences with the monovalent XBB vaccines: VE, safety, uptake</li> </ul>	
<b>17:15</b>	<b>End of day 2</b>		

<b>Day 3: Wednesday 13 March 2024</b>			
<b>Time CET</b>	<b>Session</b>	<b>Purpose of session, target outcomes and questions for SAGE</b>	<b>Duration</b>
<b>9:00</b>	<b>Closed SAGE meeting</b>	Development of recommendations of day 2. Preparation of the sessions of the day. Other important discussion items.	<b>1h 30</b>
<b>10:45</b>	<b>Break</b>	<b>Break</b>	<b>15 min</b>
<b>11:00</b>	<b>Mpox – Session 6</b>	<b>FOR RECOMMENDATION</b>	<b>2h</b>
	<p>Introduction of the session. K. NEUZIL. SAGE member. 5 min.</p> <p>Update on disease epidemiology, including epidemiology from the African region and access and availability of vaccines. R. LEWIS. WHO. 15 min.</p> <p>Evidence on vaccine effectiveness, of mpox vaccines – systematic review; Q&amp;A. L. PISCHEL. Yale U. 15 min.</p> <p>Evidence on vaccine safety of mpox vaccines – systematic review; Q&amp;A. J. VAN HOLTEN. WHO. 15 min.</p> <p>Draft recommendations and research priorities. K. NEUZIL. SAGE member &amp; WG chair. 20 min.</p> <p>Discussion and conclusions. 50 min.</p>	<ol style="list-style-type: none"> <li>1. Provide a brief update on mpox epidemiology, including from the African Region</li> <li>2. Recommend any update needed to WHO's interim guidance on mpox vaccination based on systematic reviews and experience from vaccination, with specific consideration of: <ol style="list-style-type: none"> <li>a. Vaccination for outbreak response</li> <li>b. Vaccination for preventive use</li> <li>c. Choice of vaccines for outbreak response and preventive vaccination</li> <li>d. Choice of vaccines for special populations</li> <li>e. Access and availability of mpox vaccines</li> </ol> </li> </ol>	
<b>13:00</b>	<b>Break</b>	<b>Break</b>	<b>1h</b>
<b>14:00</b>	<b>Immune correlates – Session 7</b>	<b>FOR DISCUSSION</b>	<b>1h</b>
	<p>Introduction. S. MADHI. SAGE member. 2 min.</p> <p>The immune correlate pathway to licensure for Chikungunya vaccines. T. ENDY. CEPI. 10 min.</p> <p>Next steps for SAGE: A. WILDER-SMITH. WHO. 3 min.</p> <p>Critical issues with immune correlates for licensure and policy. Z. DANGOR. Wits U. (South Africa). 10 min.</p> <p>Considerations for Phase IV trials if a GBS vaccine is licensed based on an immunological endpoint. M. VOYSEY. Oxford U. (UK). 8 min.</p> <p>Report on meeting with regulatory bodies and pathway forward. K. LE DOARE. WHO. 7 min.</p> <p>Discussion. 20 min.</p>	<p>To review two vaccines for which traditional Phase 3 efficacy trials will not be feasible: Chikungunya vaccines and Group B Streptococci (GBS) vaccines.</p> <p>The question to SAGE will be whether SAGE concurs with the immune correlate approach.</p>	
<b>15:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min</b>
<b>15:15</b>	<b>RSV – Session 8</b>	<b>FOR INFORMATION</b>	<b>1h</b>
	<p>Overview of session. K. NEUZIL. SAGE member &amp; WG chair. 3 min.</p>	<p>This is an informational session to update SAGE on the latest data on RSV maternal immunization and WHO activities in</p>	

<p>Product status updates (Phase 3 results, NRA approvals, NITAG recommendations, real-world use):</p> <ul style="list-style-type: none"> <li>Nirsevimab long-acting infant mAb, E. SPARROW. WHO. 7 min.</li> <li>Abrysvo maternal vaccine, D. FEIKIN. WHO. 10 min.</li> </ul> <p>WHO activities: SAGE WG; Impact study update; GACVS; RSV Roadshow. D. FEIKIN. WHO. 10 min.</p> <p>What to expect in September: Full presentation of phase III data by Pfizer; Benefit-Risk analysis South Africa and Kenya; GRADE/PICO, etc. K. NEUZIL. SAGE member &amp; WG chair. 5 min.</p> <p>Discussion 25 min.</p>	<p>preparation for a SAGE policy recommendation in September 2024.</p>
<p><b>16:15 End of Plenary Meeting</b></p>	

<b>Day 4: Thursday 14 March 2024</b>			
<b>Time CET</b>	<b>Session</b>	<b>Purpose of session, target outcomes and questions for SAGE</b>	<b>Duration</b>
<b>9:00</b>	<b>Closed SAGE meeting</b>	Development of recommendations of day 3. Any outstanding closed session items not covered previously.	<b>2h15min.</b>
<b>11:15</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:30</b>	<b>Closed SAGE meeting (SAGE members only)</b>		<b>1h</b>
<b>12:30</b>	<b>Closing</b>		
<b>12:45</b>	<b>Lunch</b>		