



**Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization  
4-8 October 2021  
Virtual Meeting  
Draft Agenda**

**Day 1: SAGE meeting**

**Monday, 4 October 2021**

<b>10:00</b>	<b>Closed SAGE meeting</b>	Preparation of the sessions of the day.	1h
<b>11:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:15</b>	<b>Opening and welcome – introduction of participants</b> DG A. CRAVIOTO. Chair of SAGE	<b>Opening of the Plenary Meeting</b>	15 min.
<b>11:30</b>	<b>Global and Regional Reports - Session 1</b>	<b>FOR INFORMATION</b>	2h 45 min.
	<ul style="list-style-type: none"> <li>– Report from the Director of IVB. K. O'BRIEN. WHO. 20 min.</li> <li>– Reports from the Regions – including impact of the COVID-19 pandemic and COVID-19 vaccination on immunization services. WHO. 1h.</li> <li>– Update from Gavi. S. BERKLEY. GAVI. 10 min.</li> <li>– Update on COVID-19 Global Vaccine Strategy. T. CERNUSCHI. WHO. 15 min.</li> <li>– Discussion. 1h.</li> </ul>		
<b>14:15</b>	<b>Break</b>	<b>Break</b>	<b>30 min.</b>
<b>14:45</b>	<b>Monitoring IA2030/Zero dose children/Immunization during and post-COVID-19 pandemic- Session 2</b>	<b>FOR RECOMMENDATION</b>	1h 30 min.
	<ul style="list-style-type: none"> <li>– Global immunization - opportunities and challenges for the decade ahead; presentation of the IA2030 2019 baseline and 2020 data. A. LINDSTRAND. WHO. 15 min.</li> <li>– IA2030 implementation progress, including IA2030 M&amp;E Framework. A. LINDSTRAND. WHO/E. MAST. CDC. 10 min.</li> <li>– Expected role of SAGE within the IA2030 partnership model. A. LINDSTRAND. WHO. 10 min.</li> <li>– Discussion. 55 min.</li> </ul>	Purpose of the session: <ul style="list-style-type: none"> <li>– Present a summary of global immunization data, the IA2030 Monitoring and Evaluation baseline from 2019 and the impact of the pandemic in 2020 and to provide insights into opportunities and challenges for the decade ahead</li> <li>– Share IA2030 implementation progress; Regional IA2030 plans, M&amp;E, Ownership and accountability and the learning agenda</li> <li>– Propose the expected role of SAGE within the IA2030 partnership model</li> <li>– Receive feedback from SAGE on:               <ul style="list-style-type: none"> <li>○ Reported data and key assessment of global immunization progress from 2019 and 2020</li> <li>○ IA2030 implementation progress, including IA2030 structures, reporting and decision-making mechanisms, communications, regional and country</li> </ul> </li> </ul>	

	immunization programme implementation, and the IA2030 Learning Agenda
	– Role and associated processes for SAGE to provide Independent Technical Review of IA2030 progress and provide recommendations to the IAPC, IA2030 working groups, and to regions and countries
<b>16:15</b>	<b>End of the day</b>

**Day 2: SAGE meeting****Tuesday, 5 October 2021**

<b>10:00</b>	<b>Closed SAGE meeting</b>	Preparation of the sessions of the day. Recap of day 1. Other important discussion items.	1h
<b>11:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:15</b>	<b>Polio - Session 3</b>	<b>FOR RECOMMENDATION</b>	1h 30 min.
	<ul style="list-style-type: none"> <li>– Update from the Global Polio Eradication Initiative. A. O’LEARY. WHO. 10 min.</li> <li>– Questions: 10 min.</li> <li>– IPV only schedule options, including Hexavalent vaccine H. VERMA. WHO. 10 min.</li> <li>– Questions: 5 min.</li> <li>– Update on nOPV2 first use, clinical development, assessment of safety data and transition from initial to wider nOPV2 use. S. ZIPURSKY, G. MACKLIN and O. MACH. WHO; A. BANDYOPADHYAY. BMGF. 20 min.</li> <li>– Questions: 10 min.</li> <li>– Report from SAGE Polio Working Group including I. JANI. SAGE Member. 15 min.</li> <li>– Discussion: 10 min.</li> </ul>	<p>SAGE will be informed on the current status of the polio eradication program; and launch of the new polio eradication strategy</p> <p>SAGE will be asked to review and consider for endorsement:</p> <ul style="list-style-type: none"> <li>– WG’s recommendation on IPV only schedules including Hexavalent schedules in polio program.</li> <li>– WG’s recommendation on transition from initial to wider nOPV2 use based on GACVS safety data assessment.</li> </ul>	
<b>12:45</b>	<b>Break</b>	<b>Break</b>	<b>30 min.</b>
<b>13:15</b>	<b>COVID-19 vaccines – Session 4</b>	<b>FOR RECOMMENDATION</b>	1h 30 min.
	<p><b>PART 1- Bharat Biotech COVID-19 vaccine</b></p> <p>Introduction, session objective setting, update on regulatory decisions and overview of Working Group deliverables. H. NOHYNEK. SAGE member. 5 min.</p> <p>Vaccine safety and efficacy data emerging from Bharat Biotech COVID-19 vaccine clinical trials (phase 1-3 trial results and post marketing). Risk management plans and other implementation considerations. COMPANY PRESENTATION. 20 min.</p> <p>Safety monitoring. (presenter tbc) 10 min.</p> <p>Assessment of Evidence (SAGE working group). 15 min.</p>	<p>Objectives for this session:</p> <p>Presentation of clinical data on Covaxin™ from phase 1, 2, 3 and post marketing studies on safety, immunogenicity, efficacy and effectiveness.</p> <p>Outline of ongoing and planned studies on safety and effectiveness.</p> <p>Update on global, regional and country level plans for vaccine safety monitoring.</p> <p>Presentation of the assessment of the SAGE working group on the available evidences and the strength of evidences on the questions of the evidence to decision tables.</p>	

	<p>Presentation of draft recommendations. H. NOHYNEK. SAGE Member. 15 min.</p> <p>Discussion. 25 min.</p>	<p>Based on the presented evidences, presentation of draft recommendations on the use of Bharat Biotech vaccine in priority populations.</p>	
<b>14:50</b>	<p><b>COVID-19 vaccines – Session 4</b></p> <p><b>PART 2 – The need for additional COVID-19 vaccine doses</b></p> <p>Review of evidence on the need for an additional COVID-19 vaccine dose in immunocompromised individuals. TBD. 25 min.</p> <p>Questions. 5 min.</p> <p>Presentation of draft recommendations. TBD. 20 min.</p> <p>Review of evidence on the need for an additional homologous third dose of Sinovac and Sinopharm COVID-19 vaccine. TBD. 20 min.</p> <p>Questions. 5 min.</p> <p>Presentation of draft recommendations. TBD. 15 min.</p>	<p><b>FOR DISCUSSION AND RECOMMENDATION</b></p> <p>Objective of the session:</p> <p>This first session on the topic of additional doses of COVID-19 vaccines will focus on the need for additional COVID-19 vaccine doses in immunocompromised individuals.</p> <p>SAGE will further be presented with the available evidence to address the issue of providing an additional vaccine dose to those having received two doses of Sinovac and Sinopharm.</p> <p>In the context of a rapidly changing environment with important data gaps, SAGE will be asked whether the evidence to date are sufficient to provide policy updates on the beforementioned topics.</p> <p>Over the coming months, SAGE will closely follow the emerging evidence on the issue of additional/ booster doses of COVID-19 vaccines and may provide further policy updates at consecutive (extraordinary) SAGE meetings.</p>	1h 30 min.
<b>16:45</b>	<b>End of the day</b>		

### Day 3: Joint meeting of SAGE and the Malaria Policy Advisory Group (MPAG)

Wednesday, 6 October 2021

Time	Session	Purpose of session, target outcomes and questions for SAGE	Duration
<b>10:00</b>	<b>Closed SAGE meeting</b>	Preparation of the sessions of the day. Recap of day 2. Other important discussion items.	1h
<b>11:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:15</b>	<p><b>Opening and welcome of joint session</b>  P. ALONSO, K O'BRIEN, WHO. 5 min.  A. CRAVIOTO. Chair of SAGE and  D. WIRTH. Chair of MPAG. 5 min.</p>	<b>Opening of the Plenary Meeting</b>	10 min.
<b>11:25</b>	<p><b>Malaria vaccine - Session 5 (JOINT SESSION SAGE and MPAG)</b></p> <p>Introduction to the session, Framework for WHO recommendation on RTS,S/AS01 malaria vaccine and summary findings.  K. MULHOLLAND. SAGE Member. 5 min.</p> <p>Malaria disease burden, epidemiology, status of malaria control and surveillance, and the need for new interventions.  D. SCHELLENBERG. WHO. 5 min.</p>	<p><b>FOR RECOMMENDATION</b></p> <p>The purpose is to present SAGE and MPAG with updated evidence on feasibility, impact and safety of the RTS,S/AS01 malaria vaccine and the proposed recommendations of the Malaria Vaccine Implementation Programme Advisory Group (MVIP PAG).</p> <p>SAGE and MPAG are requested to address the following question:</p> <ul style="list-style-type: none"> <li>Does the additional evidence on the feasibility, safety and impact of the RTS,S/AS01 vaccine support a WHO</li> </ul>	1h 15 min.

Overview of evidence as of 2015 leading to WHO pilot recommendation, remaining key questions and the Malaria Vaccine Implementation Programme (MVIP)  
M. HAMEL. WHO. 10 min.

**Addressing outstanding question 1: Feasibility**

Malaria vaccine implementation experience.  
R. JALANG'O. National Vaccines and Immunization Programme, Kenya. 10 min.

Summary of feasibility evidence.  
P. NJUGUNA. WHO. 15 min.

**Addressing outstanding question 2: Impact**

Summary of impact evidence.  
P. MILLIGAN. LSHTM. 10 min.

Comments & questions: 20 min.

recommendation for use of the vaccine in children in sub-Saharan Africa beyond the current pilot implementation?

The SAGE/MPAG recommendations will then be used to update the WHO position paper on the use of a malaria vaccine.

<b>12:40</b>	<b>Break</b>	<b>Break</b>	<b>30 min.</b>
<b>13:10</b>	<b>Malaria vaccine, contd. - Session 5 (JOINT SESSION SAGE and MPAG)</b>	<b>FOR RECOMMENDATION</b>	<b>2h 5 min.</b>
	<p><i>Addressing outstanding question 3: Safety</i> Summary of safety evidence and assessment by the MVIP Data Safety and Monitoring Board (DSMB). C. WHITNEY. Chair of MVIP DSMB. 15 min.</p> <p>Comments &amp; questions: 25 min</p> <p>RTS,S SAGE/MPAG Working Group assessment and proposed recommendations. P. SMITH and E. MACETE, Chair and Co-Chair of RTS,S SAGE MPAG Working Group. 15 min.</p> <p>Discussion and formulation of recommendation: 60 min</p> <p>Closing remarks. D. WIRTH. Chair of MPAG, and A. CRAVIOTO, Chair of SAGE. 10 min.</p>	<p>The purpose is to present SAGE and MPAG with updated evidence on feasibility, impact and safety of the RTS,S/AS01 malaria vaccine and the proposed recommendations of the Malaria Vaccine Implementation Programme Advisory Group (MVIP PAG).</p> <p>SAGE and MPAG are requested to address the following question:</p> <ul style="list-style-type: none"> <li>Does the additional evidence on the feasibility, safety and impact of the RTS,S/AS01 vaccine support a WHO recommendation for use of the vaccine in children in sub-Saharan Africa beyond the current pilot implementation?</li> </ul> <p>The SAGE/MPAG recommendations will then be used to update the WHO position paper on the use of a malaria vaccine.</p>	
<b>15:15</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>15:30</b>	<b>Closed SAGE/MPAG meeting</b>		<b>30 min.</b>
<b>16:00</b>	<b>End of the day</b>		

**Day 4: SAGE meeting****Thursday, 7 October 2021**

<b>Time</b>	<b>Session</b>	<b>Purpose of session, target outcomes and questions for SAGE</b>	<b>Duration</b>
<b>10:00</b>	<b>Closed SAGE meeting</b>	Preparation of the sessions of the day. Recap of day 3. Other important discussion items.	1h
<b>11:00</b>	<b>Break</b>	<b>Break</b>	<b>15 min.</b>
<b>11:15</b>	<b>Influenza vaccine - Session 6</b>	<b>FOR RECOMMENDATION</b>	1h 30 min.
	<p>Introduction. A. POLLARD. SAGE member. 5 min.</p> <p>Review of the evidence on the effects of prior immunization on the effectiveness of seasonal influenza vaccines. S. SULLIVAN. WHO Collaborating Centre for Reference and Research on Influenza, Australia. 10 min. Questions: 5 min.</p> <p>Review of the evidence on the effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines. C. CHADWICK. 10 min. Questions: 5 min.</p> <p>Review of the evidence for target groups for seasonal influenza vaccination. B. WARSHAWSKY. Public Health Agency of Canada. 15 min. Questions: 5 min.</p> <p>Presentation of draft recommendations. A. POLLARD. SAGE member. 15 min.</p> <p>Discussion: 20 min.</p>	<p>The purpose of the influenza session is to seek SAGE advice on the revision of the global policy on the use of seasonal influenza vaccines and the subsequent update of the WHO position paper on influenza vaccines.</p> <p>SAGE will specifically be asked for its advice on the following issues that are tentatively proposed by the SAGE Working Group on Influenza as requiring specifics recommendations or statements:</p> <ul style="list-style-type: none"> <li>• Revision of the target groups previously identified in the 2012 WHO position paper on influenza;</li> <li>• Impact of repeat influenza vaccination;</li> <li>• Effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines; and</li> <li>• Research priorities.</li> </ul>	
<b>12:45</b>	<b>Break</b>	<b>Break</b>	<b>30 min.</b>
<b>13:15</b>	<b>Vaccine Acceptance and Uptake - Session 7</b>	<b>FOR RECOMMENDATION</b>	1h 30 min.
	<p>Introduction and framing. N. MACDONALD. SAGE member. 5 min.</p> <p>Overview of objectives and process to gather and translate evidence. J. LEASK. University of Sydney. 10 min.</p> <p>Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina. 10 min.</p> <p>Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford. 10 min.</p> <p>Operational considerations: guidance and support to Member States to gather and use data for evidence-based implementation. L. MENNING. WHO. 10 min.</p> <p>Draft recommendations for consideration by SAGE. N. MACDONALD. SAGE member. 5 min.</p> <p>Q&amp;A and discussion. 40 min.</p>	<p>Questions posed to SAGE:</p> <ul style="list-style-type: none"> <li>– Does SAGE have any feedback on the findings and considerations put forward?</li> <li>– Are there any added resources or methods which should be incorporated? <ul style="list-style-type: none"> <li>○ What recommendations can be put forward to Member States?</li> </ul> </li> </ul>	
<b>14.45</b>	<b>Hepatitis E vaccines- Session 8</b>	<b>FOR INFORMATION AND DISCUSSION</b>	1h

Introduction and recap of current policy. M. MARTI. WHO. 5 min.	Inform SAGE on new data and recent developments that have emerged since the issuance of the 2015 WHO vaccine position paper on Hepatitis E vaccine.
Past activities and recent developments. I. CIGLENECKI. MSF. 10 min.	Highlight existing data gaps and issues preventing use of the vaccine.
New evidence, ongoing trials, vaccine landscape and existing data gaps. Facilitating factors, remaining obstacles and proposed path forward. R. AGGARWAL. SAGE Member. 15 min.	SAGE will be asked to advise on critical data needed to update policy.
Discussion. 30 min.	SAGE will be consulted to identify enablers (e.g. operational guidance) for vaccine use.
<b>15:45 Closing</b>	<b>15 min.</b>
<b>16:00 End of the Plenary SAGE meeting</b>	

**Day 5: SAGE meeting****Friday, 8 October 2021**

<b>12:00 Closed SAGE meeting: wrap up</b>	Recap of day 4. Other important discussion items. Meeting wrap up.	2h 30 min.
<b>14:30 End of final closed meeting</b>		