



**World Health
Organization**

**Department of Immunization,
Vaccines and Biologicals (IVB)**

SAGE

meeting

**Strategic Advisory Group of Experts
on Immunization
4-8 October 2021**

**Virtual meeting, WHO
Geneva, Switzerland**

This document can be found online after the meeting at the following link:

https://www.who.int/news-room/events/detail/2021/10/04/default-calendar/sage_meeting_october_2021

This interactive pdf contains all background documents for the corresponding meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization.

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Navigation is done via the interactive table of content page. Each session landing page contains links to the executive summary and all background documents (tagged as either essential or additional). All session documents open as new tabs in the Adobe reader (pdf attachments).

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Notes:

- (1) This document functions only in a limited mode on hand-held devices. See “How to Guide”.
- (2) Presentations from the meeting will be made available once the meeting has concluded at the above link and through an additional interactive PDF.

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**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

10:00	Closed SAGE meeting	Preparation of the sessions of the day.	1h
11:00	Break	Break	15 min.
11:15	Opening and welcome – introduction of participants DG A. CRAVIOTO. Chair of SAGE	Opening of the Plenary Meeting	15 min.
11:30	<u>Global and Regional Reports - Session 1</u> – Report from the Director of IVB. K. O'BRIEN. WHO. 20 min. – Reports from the Regions – including impact of the COVID-19 pandemic and COVID-19 vaccination on immunization services. WHO. 1h. – Update from Gavi. S. BERKLEY. GAVI. 10 min. – Update on COVID-19 Global Vaccine Strategy. T. CERNUSCHI. WHO. 15 min. – Discussion. 1h.	FOR INFORMATION	2h 45 min.
14:15	Break	Break	30 min.
14:45	<u>Monitoring IA2030/Zero dose children/Immunization during and post-COVID-19 pandemic- Session 2</u> – Global immunization - opportunities and challenges for the decade ahead; presentation of the IA2030 2019 baseline and 2020 data. A. LINDSTRAND. WHO. 15 min. – IA2030 implementation progress, including IA2030 M&E Framework. A. LINDSTRAND. WHO/E. MAST. CDC. 10 min. – Expected role of SAGE within the IA2030 partnership model. A. LINDSTRAND. WHO. 10 min. – Discussion. 55 min.	FOR RECOMMENDATION Purpose of the session: – 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 – Share IA2030 implementation progress; Regional IA2030 plans, M&E, Ownership and accountability and the learning agenda – Propose the expected role of SAGE within the IA2030 partnership model – Receive feedback from SAGE on: o Reported data and key assessment of global immunization progress from 2019 and 2020 o IA2030 implementation progress, including IA2030 structures, reporting and decision-making mechanisms,	1h 30 min.

communications, regional and country 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

16:15 End of the day

Day 2: SAGE meeting

Tuesday, 5 October 2021

10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 1. Other important discussion items.	1h
11:00	Break	Break	15 min.
11:15	Polio - Session 3	FOR RECOMMENDATION	1h 30 min.
	<ul style="list-style-type: none"> – Update from the Global Polio Eradication Initiative. A. O'LEARY. WHO. 10 min. – Questions: 10 min. – IPV only schedule options, including Hexavalent vaccine H. VERMA. WHO. 10 min. – Questions: 5 min. – 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. – Questions: 10 min. – Report from SAGE Polio Working Group including I. JANI. SAGE Member. 15 min. – Discussion: 10 min. 	<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"> – WG's recommendation on IPV only schedules including Hexavalent schedules in polio program. – WG's recommendation on transition from initial to wider nOPV2 use based on GACVS safety data assessment. 	
12:45	Break	Break	30 min.
13:15	COVID-19 vaccines – Session 4	FOR RECOMMENDATION	1h 30 min.
	<p>PART 1- Bharat Biotech COVID-19 vaccine</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>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>Safety monitoring. (presenter tbc) 10 min.</p> <p>Assessment of Evidence (SAGE working group). 15 min.</p> <p>Presentation of draft recommendations. H. NOHYNEK. SAGE Member. 15 min.</p> <p>Discussion. 25 min.</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>Based on the presented evidences, presentation of draft recommendations on the use of Bharat Biotech vaccine in priority populations.</p>	
14:50	<p>COVID-19 vaccines – Session 4</p> <p>PART 2 – The need for additional COVID-19 vaccine doses</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>TENTATIVE:</p> <p>Review of evidence on the need for an additional homologous third dose for inactivated COVID-19 vaccines. TBC. 40 min.</p>	<p>FOR DISCUSSION AND RECOMMENDATION</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>TENTATIVE</p> <p>SAGE will further be presented with the available evidence to address the issue of providing an additional inactivated vaccine dose</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>	1h 30 min.
16:45	End of the day		

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
10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 2. Other important discussion items.	1h
11:00	Break	Break	15 min.
11:15	<p>Opening and welcome of joint session</p> <p>P. ALONSO, K O'BRIEN, WHO. 5 min.</p> <p>A. CRAVIOTO. Chair of SAGE and</p> <p>D. WIRTH. Chair of MPAG. 5 min.</p>	Opening of the Plenary Meeting	10 min.
11:25	<p>Malaria vaccine - Session 5 (JOINT SESSION SAGE and MPAG)</p> <p>Introduction to the session, Framework for WHO recommendation on RTS,S/AS01 malaria vaccine and summary findings.</p> <p>K. MULHOLLAND. SAGE Member. 5 min.</p>	<p>FOR RECOMMENDATION</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>	1h 15 min.

Malaria disease burden, epidemiology, status of malaria control and surveillance, and the need for new interventions.

D. SCHELLENBERG. WHO. 5 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.

SAGE and MPAG are requested to address the following question:

- 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?

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

12:40	Break	Break	30 min.
13:10	Malaria vaccine, contd. - Session 5 (JOINT SESSION SAGE and MPAG)	FOR RECOMMENDATION	2h 5 min.
	<p><i>Addressing outstanding question 3: Safety</i></p> <p>Summary of safety evidence and assessment by the MVIP Data Safety and Monitoring Board (DSMB).</p> <p>C. WHITNEY. Chair of MVIP DSMB. 15 min.</p> <p>Comments & questions: 25 min</p> <p>RTS,S SAGE/MPAG Working Group assessment and proposed recommendations.</p> <p>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.</p> <p>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"> • 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? <p>The SAGE/MPAG recommendations will then be used to update the WHO position paper on the use of a malaria vaccine.</p>	
15:15	Break	Break	15 min.
15:30	Closed SAGE/MPAG meeting		30 min.
16:00	End of the day		

Day 4: SAGE meeting

Thursday, 7 October 2021

Time	Session	Purpose of session, target outcomes and questions for SAGE	Duration
10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 3. Other important discussion items.	1h
11:00	Break	Break	15 min.
11:15	<u>Influenza vaccine - Session 6</u>	FOR RECOMMENDATION	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.</p> <p>Questions: 5 min.</p> <p>Review of the evidence on the effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines. C. CHADWICK. 10 min.</p> <p>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.</p> <p>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"> • Revision of the target groups previously identified in the 2012 WHO position paper on influenza; • Impact of repeat influenza vaccination; • Effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines; and • Research priorities. 	
12:45	Break	Break	30 min.
13:15	<u>Behavioural and social drivers of vaccine uptake- Session 7</u>	FOR RECOMMENDATION	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. Univ. of Sydney, Australia. 10 min.</p> <p>Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 10 min.</p> <p>Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford, UK. 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>Questions posed to SAGE:</p> <ul style="list-style-type: none"> – Does SAGE have any feedback on the findings and considerations put forward? – Are there any added resources or methods which should be incorporated? – What recommendations can be put forward to Member States? 	

Draft recommendations for consideration by SAGE. N. MACDONALD. SAGE member. 5 min.			
Q&A and discussion. 40 min.			
14.45	Hepatitis E vaccines- Session 8	FOR INFORMATION AND DISCUSSION	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.	
15:45	Closing		15 min.
16:00	End of the Plenary SAGE meeting		

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Day 5: SAGE meeting

Friday, 8 October 2021

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

SESSION 1: GLOBAL AND REGIONAL REPORTS

EXECUTIVE SUMMARY	
1.0	Executive summary: Global and regional reports

BACKGROUND DOCUMENTS	
1.1	XXVI Meeting of PAHO's Technical Advisory Group (TAG) on Vaccine-Preventable Diseases. 14–16 July 2021
1.2	South-East Asia Region Immunization Technical Advisory Group Meeting. 9-11 August 2021
1.3	Ad-hoc meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE). 28 April 2021
1.4	European Technical Advisory Group of Experts on Immunization (ETAGE) interim recommendations. Inclusion of adolescents aged 12–15 years in national COVID-19 vaccination programmes. June 2021
1.5	Report of the Meeting of the WHO Global Advisory Committee on Vaccine Safety (GACVS), 8–9 June 2021
1.6	Meeting of the Immunization and Vaccine-related Implementation Research Advisory Committee (IVIR-AC), March 2021
1.7	Global COVID-19 Vaccination – Strategic Vision for 2022. V 14 September 2021
1.8	AFRO Regional Immunization Technical Advisory Group (RITAG) Virtual Meeting: 30 June – 1 July 2021

SESSION 2: IA2030

EXECUTIVE SUMMARY	
2.0	Executive Summary: IA2030

BACKGROUND DOCUMENTS (essential)	
2.1	Report: Immunization in 2020 and implementation of the Immunization Agenda 2030
2.2	IA2030 Framework for action
2.3	Annex 1 to IA2030 Framework for Action: Monitoring and Evaluation Framework
2.4	Annex 2 to IA2030 Framework for Action: Global-level Partnership Model

BACKGROUND DOCUMENTS (additional)	
2.5	National Immunization Strategy guidelines

SESSION 3: POLIO

EXECUTIVE SUMMARY	
3.0	Executive Summary: Polio

BACKGROUND DOCUMENTS (essential)	
3.1	Report from polio SAGE WG meeting 31st August – 2nd September 2021
3.2	Report from the GACVS meeting on assessment of nOPV2 safety data

BACKGROUND DOCUMENTS (additional)	
-	None

SESSION 4: COVID-19 VACCINES

EXECUTIVE SUMMARY	
4.0	-

BACKGROUND DOCUMENTS (essential)	
4.1	-

BACKGROUND DOCUMENTS (additional)	
4.3	-

Please note that due to the rapidly evolving situation, the material for the Covid-19 vaccine session will be shared separately at short notice.

SESSION 5: MALARIA

EXECUTIVE SUMMARY	
5.0	Executive Summary: Malaria - RTS,S vaccine

BACKGROUND DOCUMENTS (essential)	
5.1	Full Evidence Report on the RTS,S/AS01 Malaria Vaccine, background paper prepared by the RTS,S SAGE MPAG Working Group, summarizing all relevant evidence and the proposed recommendations

BACKGROUND DOCUMENTS (additional)	
5.2	Annex 1: Framework for WHO Recommendation on RTS,S/AS01 Malaria Vaccine
5.3	Annex 2: Malaria vaccine targets and pipeline
5.4	Annex 3: Statistical report on the results of the RTS,S/AS01 Malaria Vaccine Pilot Evaluation 24 months after the vaccine was introduced (July 2021, v1.2)
5.5	Annex 4: Publication Chandramohan et al. Seasonal Malaria Vaccination with or without Seasonal Malaria Chemoprevention. NEJM. 2021;
5.6	Annex 5: Health Utilisation Study (HUS) Round 2 - cross-country report on findings from the Primary Child Caregiver cohort sample
5.7	Annex 6: MVIP Data Safety and Monitoring Board meeting recommendations following review of malaria vaccine pilot evaluation results (July 2021)
5.8	Annex 7: Reports of the extraordinary meetings by the African Advisory Committee on Vaccine Safety (AACVS) and the Global Advisory Committee on Vaccine Safety (GACVS) Recommendations by the AACVS and GACVS
5.9	Annex 8: Modelled public health impact and cost effectiveness of RTS,S/AS01 in seasonal and perennial settings (August 2021)
5.10	Annex 9: GRADE and Evidence to Recommendation table on the use of malaria vaccine

SESSION 6: INFLUENZA

EXECUTIVE SUMMARY	
6.0	Executive Summary: Influenza

BACKGROUND DOCUMENTS (essential)	
6.1	Background document on influenza and influenza vaccines
6.2	Draft recommendations and evidence to recommendations tables for children (aged 6-59 months), health workers, indigenous populations, individuals with specific chronic medical conditions, older adults and pregnant women
6.3	Systematic review and meta-analysis on the effects of prior immunization on the effectiveness of seasonal influenza vaccines.

BACKGROUND DOCUMENTS (additional)	
6.4	Vaccines against influenza: WHO position paper – November 2012

SESSION 7: BEHAVIOURAL AND SOCIAL DRIVERS OF VACCINE UPTAKE

EXECUTIVE SUMMARY	
7.0	Executive Summary: Behavioural and Social Drivers of Vaccine Uptake

BACKGROUND DOCUMENTS (essential)	
7.1	Background Paper on Behavioural and Social Drivers of Vaccine Uptake. 15 Sept 2021.

BACKGROUND DOCUMENTS (additional)	
7.2	Data for action: achieving high uptake of vaccines. 15 Sept 2021

SESSION 8: HEPATITIS E

EXECUTIVE SUMMARY	
8.0	Executive Summary: Hepatitis E

BACKGROUND DOCUMENTS (essential)	
8.1	Background document on Hepatitis E
8.2	2015 WHO Hepatitis E vaccine position paper

BACKGROUND DOCUMENTS (additional)	
-	None