World Health Organization

Department of Immunization, Vaccines and Biologicals (IVB)

SAGE

meeting

Strategic Advisory Group of Experts on Immunization
22-25 September 2025

Hybrid meeting, WHO
Geneva, Switzerland

See page 2 for instructions about how to open and use this interactive pdf document

Back to table of contents

All meeting material, including this document and list of participants can be found online at the following link:
https://www.who.int/news-room/events/detail/2025/09/22/default-calendar/strategic-advisory-group-of-experts-on-immunization-september-2025

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 contents page. Each session landing page contains links to the executive summary and all background documents (tagged as either essential or additional). All session documents are open as new tabs in Adobe Reader (pdf attachments).

Tip: Avoid opening more than 6–8 tabs at a time to preserve navigability.

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.

Back to table of contents

TABLE OF CONTENTS

AGENDA	
SAGE ADMINISTRATION AND GENERAL DOCUMENTS	
A	Terms of reference
B	SAGE members
C	Summary of declared interests of the SAGE members
D	Current SAGE working groups
E	"How to" guide for interactive SAGE yellow book
SESSIONS (with access to background materials)	
1.	Global and Regional reports
2.	IA2030
3.	Covid-19
4.	Tuberculosis
5.	Combination Vaccines
6.	Polio
7.	Malaria
8.	Influenza H5

Back to table of contents

World Health Organization

Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization

22-25 September 2025

Hybrid Meeting
WHO HQ (Geneva)

Draft Agenda

Day 1: Monday, 22 September 2025 (time is Central European Time (CET))			
Time CET	**Session**	**Purpose of session, target outcomes and questions for SAGE**	**Duration**
9:00	**Closed SAGE meeting**	Preparation of the sessions of the day.	**1h 45 min.**
10:45	**Break**	**Break**	**15 min.**
11:00	**Opening and welcome – introduction of participants** K. O'BRIEN. Director IVB, WHO. 5 min. H. NOHYNEK. SAGE Chair. 5 min. J. HOMBACH. SAGE Secretariat. WHO. 5 min.		**15 min.**
11:15	**Global and regional reports – Session 1** Report from the Director of IVB, K. O'BRIEN. WHO. 20 min. Update from Gavi, A. VERMEERSCH. Chief Vaccine Programmes and Markets Officer, Gavi, the Vaccine Alliance. 10 min. Discussion. 40 min.	**FOR INFORMATION**	**1h 10 min.**
12:25	**Lunch Break**	**Break**	**1h**
13:25	**Global and regional reports – Session 1 Continue: Regional reports** Presentations from AFRO, EMRO, EURO. 10 min. each. Discussion. 25 min. Presentations from PAHO, WPRO, SEARO. 10 min. each. Discussion. 25 min.	**FOR DISCUSSION** Each Regional report focuses on one theme of particular importance for the Region	**1h 50 min.** **(3h 15 min. in total)**
15:15	**Break**	**Break**	**15 min.**
15:30	**Global and regional reports - Session 1 continued** Update on changing landscape. 30 min.	**FOR DISCUSSION**	**30 min.**

Back to table of contents

16:00	**IA2030 Mid-term Review – Session 2** Opening. H. NOHYNEK. SAGE Chair. 10 min. IA2030 Mid-Term Review: Presentation of Findings and Recommendations. E. LEMANGO. UNICEF. 45 min. Discussion. 65 min.	**FOR DISCUSSION** SAGE to receive a briefing on the key findings of the IA2030 Mid-Term Review (MTR) report and to facilitate an in-depth discussion on the proposed recommendations and actions aimed at enhancing IA2030's effectiveness during the second half of the strategy. This session is a critical step in preparing for the formal presentation of the MTR at the World Health Assembly (WHA) in 2026.	**2h**
18:00	**End of day 1**		

Day 2: Tuesday, 23 September 2025			
Time CET	**Session**	**Purpose of session, target outcomes and questions for SAGE**	**Duration**
9:00	**Closed SAGE meeting**	Development of recommendations of day 1. Preparation of the sessions of the day. Other important discussion items.	**1h 45 min.**
10:45	**Break**	**Break**	**15 min.**
11:00	**Covid-19 – Session 3** Introduction. S. KOCHHAR, SAGE member. 5 min. Current burden of disease by risk group. A. ACMA, WHO. 15 min. Prequalified vaccines, vaccine uptake and access by WHO Region and risk group. E. PLUUT and G. STATHOPOULOS, WHO. 15 min. Vaccine effectiveness by risk group. D. FEIKIN, WHO. 20 min. Vaccine safety by risk group. E. KIM, WHO. 20 min. Way forward. A. WILDER-SMITH, WHO. 5 min. Discussion. 40 min.	**FOR INFORMATION AND DISCUSSION** The purpose of this session is to update on the current epidemiology of COVID-19 by priority-use groups, vaccine effectiveness and vaccine safety, and discuss next steps towards the development of a position paper.	**2h**
13:00	**Lunch Break**	**Break**	**1h**

14:00	**Tuberculosis – Session 4** Introduction. S. KOCHHAR, SAGE member. 5 min Overview of the activities under the TB Vaccine Accelerator Council. B. GIERSING, WHO. 10 min. Overview of the TB vaccine pipeline, timelines and key assumptions. W. HANEKOM, Africa Health Research Institute and special advisor to the TB Vaccine Accelerator. 10 min. Presentation from the Technical Advisory Group (TAG) on the key learnings from the technical consultations with developers. G. CHURCHYARD, co-chair of the TAG on Evidence for Clinical and Policy Considerations for New TB Vaccines. 20 min. Roadmap for including asymptomatic TB as an efficacy endpoint. S. DEN BOON, WHO. 10 min. SAGE discussion. 65 min.	**FOR DISCUSSION** The purpose of the session is to update SAGE on the activities taking place under the TB Vaccine Accelerator Council, to provide an overview of the TB vaccine pipeline, to discuss the potential risk of product development strategies and feasibility of a global policy recommendation for the most advanced candidates for global access, and to seek for advice on the proposed steps to evaluate asymptomatic TB as a potential efficacy endpoint.	**2h**
16:00	**Break**	**Break**	**15 min.**
16:15	**Combination Vaccines– Session 5** Introduction. M. HASSO-AGOPSOWICZ, WHO. 5 min The context and problem statement. W. HAUSDORFF, PATH. 10 min. Methodology, approach and early findings. A. HWANG, PATH. 15 min. Next phase. M. HASSO-AGOPSOWICZ, WHO. 10 min. Discussion. 50 min.	**FOR DISCUSSION** To obtain SAGE guidance on the analysis, prioritization and policy pathway for novel combination vaccines.	**1h 30 min.**
17:45	**End of day 2**		

Day 3: Wednesday, 24 September 2025			
Time CET	**Session**	**Purpose of session, target outcomes and questions for SAGE**	**Duration**
9:00	**Closed SAGE meeting**	Development of recommendations of day 2. Preparation of the sessions of the day. Other important discussion items.	**1h 45 min.**
10:45	**Break**	**Break**	**15 min.**
11:00	**Polio– Session 6** Session overview by S. MADHI, SAGE member. 5 min. Update from the Global Polio Eradication Initiative. J. AHMED, WHO. 15 min. Questions. 15 min. Update on bOPV Cessation Planning, O. MACH, WHO. 5 min. (I) Fractional Sabin IPV – new data and programmatic importance; (II) guidance for countries introducing wP-	**FOR RECOMMENDATION** SAGE will be informed on the current status of the polio eradication program and on the development of the new polio action plan. SAGE will be informed about current status of bOPV Cessation planning; and about development of novel OPV1 and 3 SAGE will be presented with a consolidated table of IPV related recommendations	**2h**

	Hexa in routine immunization programmes regarding bOPV. O. MACH, WHO. 10 min. Options for nOPV2 use outside of strict outbreak response. A. BANDYOPADHYAY, Gates Foundation. 15 min. Questions. 15 min. Report from the SAGE Polio Working Group including update on nOPV development and proposed recommendations. S. MADHI, SAGE Member. 10 min. Discussion. 30 min.	SAGE will be asked to review and consider for recommendation: • Recommendation on use of fractional Sabin IPV (fIPV) • Guidance for countries introducing wP-Hexa in RIs regarding bOPV • Recommendation on use of nOPV2 outside of strict outbreak response campaigns	
13:00	**Lunch Break**	**Break**	**1h**
14:00	**Malaria-Session 7 (joint session of SAGE and MPAG)** Opening of joint session and overview of session. H. NOHYNEK. SAGE chair, and D. WIRTH. MPAG chair. 5 min. Introduction and rationale. M. HAMEL. WHO. 10 min. MVIP case control study evidence on 3 vs 4 doses: effectiveness against severe malaria and safety. A. FOGELSON, LSHTM. 20 min. Discussion. 15 min. Modelled public health impact and cost-effectiveness of a three-dose versus four-dose RTS,S/AS01 malaria vaccine schedule. L. OKELL, Imperial College London, and A. SHATTOCK, The Kids Research Institute Australia. 15 min. Discussion. 15 min. Programmatic considerations of three-dose versus four-dose schedules. R. JALANG'O, Kenya Ministry of Health. 10 min. Discussion. 10 min.	**FOR RECOMMENDATION** The purpose of this joint session is to present SAGE and MPAG with the latest evidence on effectiveness, safety, impact and programmatic considerations of a 3-dose compared to the currently recommended 4-dose malaria vaccination schedule in perennial (year-round) malaria transmission settings. The SAGE and MPAG are asked to review the Working Group recommendations and address the following questions: 1. Is a 3-dose schedule of malaria vaccine safe and effective? 2. Should a 3-dose malaria vaccine schedule be considered as an alternative option to a 4-dose schedule in some context?	**1h 40 min.** **(2h 40 min in total)**
15:40	**Break**	**Break**	**15 min.**
15:55	**Malaria-Session 7 continued** SAGE/MPAG Working Group on Malaria Vaccines assessment and proposed recommendations. P. SMITH and E. MACETE. Chair and Co-Chair of SAGE/MPAG Working Group on Malaria Vaccines. 15 min. Discussion and finalization of recommendations. 45 min. Closing remarks. D. WIRTH. Chair of MPAG, and H. NOHYNEK, Chair of SAGE. 5 min.	**FOR RECOMMENDATION**	**1h 5 min.**
17:00	**End of the plenary meeting Day 3**		
17:00	**Break**	**Break**	**15 min.**
17:15	**Closed SAGE/MPAG meeting**		**45 min.**
18:00	**End of day 3**		

Back to table of contents

Day 4: Thursday, 25 September 2025			
Time CET	**Session**	**Purpose of session, target outcomes and questions for SAGE**	**Duration**
9:00	**Closed SAGE meeting**	Development of recommendations of day 3. Preparation of the sessions of the day. Other important discussion items.	**1h 45 min.**
10:45	**Break**	**Break**	**15 min.**
11:00	**Influenza H5- Session 8** Epidemiological update, risk assessment, and characteristics of A(H5) human cases, M. VAN KERKHOVE, WHO. 15 min. Overview of landscape of human A(H5) vaccines. Licensed A(H5) vaccines S. GOLDIN, WHO. 10 min. Overview of landscape of human A(H5) vaccines, pipeline, new technologies and mRNA candidates. P. GSELL, WHO. 10 min. Summary of policy recommendations and use to date of A(H5) vaccines. A. VILAJELIU, WHO. 15 min. Conclusions and discussion. KOCHHAR. S. SAGE member. 70 min.	**FOR RECOMMENDATION** SAGE will be asked to advise on the use of human influenza A(H5) vaccines during the interpandemic and emergence periods. The session will include an epidemiological update, including key characteristics of reported human cases; an overview of the current landscape of human A(H5) vaccines; and a summary of existing national policy recommendations and lessons from use to date.	**2h**
13:00	**Closing**		
13:10	**End of the plenary meeting Day 4**		

SESSION 1: GLOBAL AND REGIONAL REPORTS

EXECUTIVE SUMMARY	
1.0	Executive summary: Global and regional reports

BACKGROUND DOCUMENTS (essential)	
-	None

BACKGROUND DOCUMENTS (additional)	
1.1	Report of the meeting of Regional Immunization Technical Advisory Group (RITAG), African Region, 24–26 June 2025, Brazzaville, Congo
1.2	Report of the meeting of the Regional Immunization Technical Advisory Group (RITAG), Eastern Mediterranean Region Cairo, Egypt, 4 – 5 February 2025
1.3	Report of the 48th meeting of the WHO Global Advisory Committee on Vaccine Safety,15–16 May 2025
1.4	Report from the World Health Organization's immunization and vaccines-related implementation research advisory committee (IVIR-AC) meeting, virtual gathering, 17–21 February 2025
1.5	Report of the meeting of the Strategic Advisory Group of Experts on Immunization, March 2025: conclusions and recommendations
1.6	WHO Expert Committee on Biological Standardization, Eightieth report

Back to table of contents

SESSION 2: IA2030

EXECUTIVE SUMMARY	
2.0	Executive Summary: IA2030

BACKGROUND DOCUMENTS (essential)	
2.1	IA2030 Draft Mid-Term Review document
2.2	IA2030 Global Progress Report – the detailed M&E data

BACKGROUND DOCUMENTS (additional)	
-	None

SESSION 3: COVID-19

EXECUTIVE SUMMARY	
3.0	Executive Summary: COVID-19

BACKGROUND DOCUMENTS (essential)	
3.1	2023 WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines
3.2	COVID-19 Overview- August 2025

BACKGROUND DOCUMENTS (additional)	
-	None

SESSION 4: TUBERCULOSIS

EXECUTIVE SUMMARY	
4.0	Executive Summary: Tuberculosis

BACKGROUND DOCUMENTS (essential)	
4.1	WHO TAG asymptomatic TB subgroup report on characteristics of asymptomatic TB endpoint for TB vaccine licensure trials.
4.2	WHO TAG outline for a roadmap for including asymptomatic TB as an efficacy endpoint.
4.3	Primer on the TB Vaccine Accelerator and its four Technical and Strategic Working Groups

BACKGROUND DOCUMENTS (additional)	
4.4	Evidence required to evaluate the use of bacteriologically confirmed asymptomatic tuberculosis disease as a primary endpoint in prevention of tuberculosis disease vaccine licensure trials
4.5	TAG Pipeline Report 2024: Tuberculosis Vaccines
4.6	MTBVAC, a live TB vaccine poised to initiate efficacy trials 100 years after BCG
4.7	Final analysis of a trial of M72/AS01E vaccine to prevent tuberculosis

Back to table of contents

SESSION 5: COMBINATION VACCINES

EXECUTIVE SUMMARY	
5.0	Executive Summary: Combination Vaccines

BACKGROUND DOCUMENTS (essential)	
5.1	Facilitating the development of urgently required combination vaccines
5.2	Supplementary appendix-Facilitating the development of urgently required combination vaccines.

BACKGROUND DOCUMENTS (additional)	
5.3	Report from the World Health Organization's immunization and vaccines-related implementation research advisory committee (IVIR-AC) meeting, virtual gathering, 17-21 February 2025. Vaccine
5.4	WHO SAGE Background Note - Regional Feedback on Combination Vaccines

Back to table of contents

SESSION 6: POLIO

EXECUTIVE SUMMARY	
6.0	Executive Summary: Polio

BACKGROUND DOCUMENTS (essential)	
6.1	Report from polio SAGE WG meeting
6.2	Report from the latest meeting on bOPV Cessation Planning
6.3	Summary table of IPV-related recommendations

BACKGROUND DOCUMENTS (additional)	
-	None

SESSION 7: MALARIA

EXECUTIVE SUMMARY	
7.0	Executive Summary: Malaria

BACKGROUND DOCUMENTS (essential)	
7.1	Background paper: Malaria vaccines evidence report: considerations for a three-dose versus four-dose vaccination schedule in areas of perennial malaria transmission

BACKGROUND DOCUMENTS (additional)	
7.2	Annex 1: Evidence to Recommendation framework table for 3-dose versus 4-dose malaria vaccination schedule
7.3	Annex 2: Grading of recommendations, assessment, development and evaluations (GRADE) review of malaria vaccine evidence
7.4	Annex 3: Case-control studies of the effectiveness of the RTS,S/AS01 malaria vaccine against hospital admission with severe malaria, and associations with safety signals
7.5	Annex 4. Public health impact the cost-effectiveness modelling of a 3-dose vs. a 4-dose schedule of RTS,S/AS01

SESSION 8: INFLUENZA H5

EXECUTIVE SUMMARY	
8.0	Executive Summary: Influenza H5

BACKGROUND DOCUMENTS (essential)	
8.1	Background document for a SAGE session on updated recommendations for the use of human vaccines against zoonotic influenza, A(H5) vaccines, during the interpandemic and emergence periods

BACKGROUND DOCUMENTS (additional)	
8.2	Considerations for use of avian influenza A(H5) vaccines during the interpandemic and emergence periods: Report of a WHO virtual scientific consultation, September 2024
8.3	Strategic Advisory Group of Experts: recommendations on the use of licensed human H5N1 influenza vaccines in the interpandemic period, June 2009
8.4	Meeting of the Strategic Advisory Group of Experts on immunization, November 2013 – conclusions and recommendations