World Health Organization

Department of Immunization, Vaccines and Biologicals (IVB)

SAGE

meeting

Strategic Advisory Group of Experts on Immunization
25-29 September 2023

Hybrid meeting, WHO
Geneva, Switzerland

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Version 19 September2023

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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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World Health Organization

Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization
25-29 September 2023
Hybrid Meeting (CET)
Draft Agenda

Day 1: Monday, 25 September 2023 (time is Central European Time)

Time CET	Session	Purpose of session, target outcomes and questions for SAGE	Duration
9h15	**Closed SAGE meeting**	Preparation of the sessions of the day.	**1h15**
10h30	**Break**	**Break**	**15 min**
10h45	**Opening and welcome – introduction of participants**		**15 min**
11h00	**<u>Global reports – Session 1</u>** Report from the Director of IVB. K. O'BRIEN. WHO. 30 min. Update from Gavi. GAVI. 20 min. Discussion. 25 min.	**FOR INFORMATION**	**1h15**
12h15	**Break**	**Break**	**1h00**
13:15	**<u>Dengue – Session 2</u>** Introduction to the agenda and objectives- P PITISUTTITHUM. SAGE member. 5 min. Global burden of dengue. G. VAZQUEZ PROKOPEC. SAGE WG member. 5 min. Immunology and clinical manifestations K. ANDERSON. SAGE WG member. 5 min. Phase 3 trial results, D WALLACE. Takeda. 30 min. Clarifying questions to the company. 15 min. E2R and GRADing of the Phase 3 trial results. T CHERIAN. WHO consultant. 15 min. Modelling results. N. FERGUSON. SAGE WG member. 30 min Discussion. 15 min.	**FOR RECOMMENDATION** To review the public health burden of dengue To review the efficacy and safety live attenuated tetravalent dengue vaccine, TAK-003 To formulate policy recommendations for the programmatic use of TAK-003, taking the imbalanced vaccine performance into consideration The goal is to update WHO's position paper on dengue vaccination (2018) that is currently limited to the first-generation dengue vaccine (Dengvaxia®)	**(3h in total)** **2h**
15:15	**Break**	**Break**	**15 min.**
15:30	**<u>Dengue – Session 2</u> (continued)** Rationale for the Recommendations and Discussions, A. WILDER-SMITH. WHO. 25 min. Presentation of the final wording of the Recommendations, P. PITISUTTITHUM. SAGE member. 20 min. Discussion. 20 min.	**FOR RECOMMENDATION**	**1h**
16h30	**<u>Anti-microbial resistance – Session 3</u>** Introduction. G. LEUNG. SAGE member. 5 min.	**FOR DISCUSSION**	**1h00**

	Context: Burden of AMR, and the role of vaccine, action framework, pipeline analysis. M.HASSO-AGOPSOWICZ. WHO. 10 min. Value of vaccines in reducing AMR and implications for vaccine development and policy. W. HAUSDORFF. 25 min. Discussion. 25 min.	SAGE is requested to comment on the technical feasibility of the conducted analyses and their suitability for the policy decision making. SAGE is requested to highlight that vaccines can play a role in reducing AMR and should be considered as part of the package of AMR related interventions as well as during vaccine development, policy decision, and country uptake. SAGE is requested to highlight the need for further research and data collection and analysis on the role of vaccines in reducing AMR, especially in low- and middle-income countries and in a context of clinical trials.	
17h30	**End of day**		

Day 2: Tuesday 26 September 2023

Time CET	Session	Purpose of session, target outcomes and questions for SAGE	Duration
9:15	**Closed SAGE meeting**	Development of recommendations of day 1. Preparation of the sessions of the day. Other important discussion items.	**1h 30**
10:45	**Break**	**Break**	**15 min.**
11:00	**<u>Meningitis – Session 4</u>** Session introduction. Z. MEMISH. SAGE Meningitis WG chair and SAGE member. Meningococcal epidemics and epidemiology in countries of the African meningitis belt. This will include an overview of the burden of meningitis and the risk of epidemics and an overview of meningococcal carriage, D. CAUGANT. Norwegian Institute of Public Health. 15 min. Clinical data on the recently WHO pre-qualified pentavalent meningococcal (A,C,Y,W,X) polysaccharide conjugate vaccine (MenFive®). This will include safety, immunogenicity and co-administration with other vaccines. P. KULKARNI. Serum Institute of India, S. SOW. Center for Vaccine Development Mali. W. CHEN. Center for Vaccine Development Baltimore. 15 min. Modelling of strategies for the introduction and routine use of MMCVs in the meningitis belt. This will cover different MMCV deployment scenarios in countries, including different target age groups for preventive campaigns, and routine introduction alone vs combined with preventive campaigns. C. TROTTER. University of Cambridge. 20 min. Q and A session to clarify evidence. 10 min. Draft recommendation – Z. MEMISH. SAGE Meningitis WG chair and SAGE member. 10 min. Discussion. 50 min.	**FOR RECOMMENDATION** The purpose of the session is to recommend strategies for the introduction of Multivalent Meningococcal Conjugate Vaccines (MMCVs) in countries of the African meningitis belt, to prevent meningitis disease and epidemics. SAGE will be asked to make recommendations on i) the strategy for the roll-out of MMCVs, including according to the level of disease burden (routine alone vs routine and mass preventive campaigns) ii) the preferred routine schedule(s) and target age group of mass preventive campaigns, to efficiently reduce bacterial carriage and transmission iii) the response strategy to meningococcal meningitis outbreaks in close connection with the prevention strategy	**2h00**
13:00	**Break**	**Break**	**1h**

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14:00	**<u>IA2030 and Regional updates – Session 5</u>** Introduction. F. OLAYINKA. SAGE member. 5 min. Overview of IA2030 Technical Progress Report analyses. E. LEMANGO. IACG co-chair. 15 min. Reports from the WHO Regions. (1h50 min) Presentations from AFRO, EMRO, EURO. 10 min each. Discussion. 20 min. Presentations from PAHO, WPRO, SEARO.10 min each. Discussion. 20 min. Overview of progress to implement IA2030, Oct. 2022-Sept 2023. A. LINDSTRAND. WHO. Q&A. 20 min. Discussion.	**FOR DISCUSSION** Brief update on IA2030 implementation progress, in line with the IA2030 Framework for Action. Present the IA2030 Technical Progress Report for 2023, including analyses of global and regional progress towards IA2030 impact goal targets and strategic priority objectives Present progress on the 2022 high-level recommendations developed collectively across the IA2030 partnership to further guide a coordinated collective response to address widening immunization gaps **Ask to SAGE:** Receive endorsement from SAGE on these proposed recommendations developed collectively across the IA2030 partnership	**2h20 (3h15 in total)**
16:15	**Break**	**Break**	**10 min**
16:30	**<u>IA2030 and Regional updates – Session 5</u> (continued)** Looking ahead: IA2030 Operational Model and Proposed 2023 IA2030 Recommendations for endorsement by SAGE. K. O'BRIEN. WHO. Discussion. 1h00	**FOR RECOMMENDATION**	**1h00**
17:30	**End of the day**		

Day 3: Wednesday 27 September 2023

Time CET	Session	Purpose of session, target outcomes and questions for SAGE	Duration
9:15	**Closed SAGE meeting**	Development of recommendations of day 2. Preparation of the sessions of the day. Other important discussion items.	**1h 30.**
10:45	**Break**	**Break**	**15 min.**
11:00	**<u>Polio – Session 6</u>** Session overview by S. MADHI. SAGE member and Working Group chair. 5 min. Update from the Global Polio Eradication Initiative. A. O'LEARY. WHO. 20 min. Questions and answers. 15 min. Options for outbreak response in areas with type 1 and 2 cocirculation. WHO. 20 min. Questions and answers. 5 min. Update on work and priorities of Global Certification Commission (GCC). D. SALISBURY. GCC chair. 15 min. Questions and answers. 5 min.	**FOR RECOMMENDATION** 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 be updated on the use and clinical development of novel OPVs. SAGE will be updated on GCC's work and priorities SAGE will be asked to review and consider for endorsement: • Recommendation on vaccine options for outbreak response in areas with type 1 and 2 cocirculation • Recommendation on interval of second IPV dose when first IPV dose is administered later in life	**2h**

	Report from SAGE Polio Working Group including update on novel OPVs. S. MADHI, SAGE member and Working Group chair. 20 min Discussion. 15 min.	• Statement on measures to mitigate cVDPV2 emergences linked to nOPV2	
13:00	**Break**	**Break**	**1h**
14:00	**<u>Malaria – Session 7</u>** **JOINT SAGE – Malaria Policy Advisory Group (MPAG) session** Opening remarks. K. O'BRIEN. WHO. , WHO. 5 min Opening of joint session and overview of session. H. NOHYNEK. SAGE chair , and D. WIRTH. MPAG chair. 10 min. Malaria disease burden, status of malaria control, and recommended interventions. D. NGAMIJE. WHO. 10 min. Lessons learned from pilot, current WHO recommendation and status of vaccine implementation. M. HAMEL. WHO. 10 min Review of evidence on R21/Matrix-M efficacy and impact. P. SMITH SAGE/MPAG WG chair. 20 min. Summary of cost-effectiveness and public health impact modelling. P. WINSKILL. Imperial College London. 10 min. Review of evidence on R21/Matrix-M safety and assessment by GACVS. K. NEUZIL. SAGE/MPAG WG member. 15 min. Comments & questions. 40 min.	**FOR RECOMMENDATION** This will be a joint session of SAGE and the Malaria Policy Advisory Group (MPAG) to present evidence on the R21/Matrix-M malaria vaccine and the recommendations of the SAGE/MPAG working group on malaria vaccines. SAGE and MPAG are requested to address the following question: Does the available evidence support a WHO recommendation for use of R21/Matrix-M in children to prevent P. falciparum burden and disease in endemic areas?	**2h**
16:00	**Break**	**Break**	**15 min**
16:15	**<u>Malaria– Session 7</u> (continued)** **JOINT SAGE – Malaria Policy Advisory Group (MPAG) session** Assessment and recommendations of the SAGE/MPAG Working Group on Malaria Vaccines. P. SMITH. & E. MACETE SAGE/MPAG WG chairs. 15 min. Discussion and formulation of recommendations. 45 min.	**FOR RECOMMENDATION**	**1h**
17h15	**End of the day**		

Day 4: Thursday 28 September 2023

Time CET	Session	Purpose of session, target outcomes and questions for SAGE	Duration
9:15	**Closed SAGE meeting**	Development of recommendations of day 3. Preparation of the sessions of the day. Other important discussion items.	**1h 30.**
10:45	**Break**	**Break**	**15 min.**
11:00	**<u>Smallpox – Session 8</u>**	**FOR RECOMMENDATION**	**2h**

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	Introduction of session. K. NEUZIL. SAGE member. 5 min. Scope and context for the smallpox recommendations. R. LEWIS. WHO. 15 min. Evidence on vaccine safety and immunogenicity – systematic review. N. MARTINEZ. Q&A. 30 min. Draft recommendations. K. NEUZIL. SAGE member. 20 min. Discussion and conclusions. 50 min.	Provide scope and context for the smallpox recommendations including composition of the WHO smallpox vaccine reserve and smallpox outbreak modelling Recommend updates needed to the WHO 2013 recommendations on smallpox vaccines based on a systematic review, with specific consideration of: • Preventive vaccination • Vaccines for the WHO smallpox reserve • Choice of vaccines for outbreak response • Choice of vaccines for special populations	
13:00	**Break**	**Break**	**1h**
14:00	**<u>COVID-19 – Session 9</u>** COVID-19 epidemiology in the era of XBB variants. WHO. 15 min. Vaccine effectiveness of current vaccines over time and against different clinical endpoints in the era of XBB variants. A. VARMA, WHO. 15 min Immunogenicity data for monovalent XBB vaccines. Jerry Weir, FDA. 15 min. Modelling data on the relative benefit of using monovalent XBB vaccines. D. CROMER, Kirby Institute, Australia. 15 min Questions and answers. 15 min Rationale for simplified vaccine schedules and rationale for not routinely recommending vaccination in children. S. OMER, SAGE member. 15 min. Updated Roadmap including Roadmap Table. S. KOCHHAR. SAGE WG Chair. 15 min. Discussions. 15 min.	**FOR RECOMMENDATION *** Revise WHO's Good Practice Statement on the use of variant-containing vaccines to account for novel monovalent XBB variant vaccines. Update WHO's Roadmap for prioritizing the use of COVID-19 vaccines with consideration of novel monovalent XBB vaccines in relation to timing and frequency of booster intervals, and primary immunization schedules. Review evidence in relation to priority use groups (in particular primary vaccination in children)	**2h**
16:00	**Break**	**Break**	**15 min**
16:15	**Closed SAGE meeting**	**Wrap up**	**1h30**
17:45	**End of closed meeting**		

Day 5: Friday 29 September 2023

Time CET	Session	Purpose of session, target outcomes and questions for SAGE	Duration
9:15	**Closed SAGE meeting**	Development of recommendations of day 3. Preparation of the sessions of the day. Other important discussion items.	**1h30**
10:45	**Break**	**Break**	**15 min.**
11:00	**<u>Mumps – Session 10</u>** Introduction of the session, objective and critical questions. P. MCINTYRE. SAGE member. 5 min Epidemiology, burden of disease and genotype distribution of mumps. T. EVANS-GILBERT, WHO PAHO. N MASTERS, CDC. 20 min.	**FOR RECOMMENDATION** To present SAGE with the latest evidence on changes in the epidemiological features of mumps virus infection in several countries, supply and use of mumps containing vaccines, and new evidence on their public health benefits and potential for	**2h**

	Current mumps vaccines available (market status, coverage). G. STATHOPOULOS, WHO. 10 min. Questions and answers on first 3 topics. 5 min. Outcomes of Cochrane systematic review. E. KROW-LUCAL, WHO. 15 min. GRADE and EtR. E. KROW-LUCAL. WHO. 10 min. Questions and answers outcomes of review, GRADE and EtR. 10 min. Recommendations. P. MCINTYRE. SAGE member. 15 min Discussion and wrap-up. 30 min.	long-term protection, in order to update the 2007 WHO recommendation on mumps vaccines. SAGE will be asked to revisit or confirm the 2007 recommendation	
13:00	**Break**	**Break**	**1h**
14:00	**<u>Cholera – Session 11</u>** Session overview by R.GRAIS. SAGE member. 5 minutes Update on Cholera- epidemiology and global roadmap. P. BARBOZA. WHO. 10 min. Update on Cholera supply and forecasting. P. BARBOZA. WHO. 10 min. New evidence on vaccination during pregnancy and update on ongoing work and priorities. P. BARBOZA. WHO. 10 min. Questions. 5 min. Discussion. 30 min.	**FOR DISCUSSION** Inform SAGE on the current Cholera epidemiology and the vaccine availability and forecasting. SAGE will be asked to advise on what could be done to enforce the 2017 recommendation on vaccination during pregnancy in the context of OCV campaigns which is still not implemented in many countries	**1h**
15:00	**End of plenary meeting**		

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SESSION 1: GLOBAL REPORTS

EXECUTIVE SUMMARY	
1.0	Executive summary: Global reports

BACKGROUND DOCUMENTS (essential)	
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BACKGROUND DOCUMENTS (additional)	
1.1	32nd Meeting Report of The Technical Advisory Group On Immunization And Vaccine-Preventable Diseases In The Western Pacific Region
1.2	Twenty-second Meeting Report of the European Technical Advisory Group of Experts on Immunization (ETAGE)
1.3	Report of the Meeting of the WHO Global Advisory Committee on Vaccine Safety, 15–16 May 2023
1.4	Meeting report: WHO Product Development for Vaccines Advisory Committee Meeting on Measles-Rubella Microarray patches (MR-MAPs)
1.5	WHO/IVB's Product Development for Vaccines Advisory Committee (PDVAC)-Report from Hybrid meeting
1.6	Meeting of the Advisory Committee on Immunization and Vaccines-related Implementation Research (IVIR-AC)-Draft Agenda

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SESSION 2: DENGUE

EXECUTIVE SUMMARY	
2.0	Executive Summary: Dengue

BACKGROUND DOCUMENTS (essential)	
2.1	Background Paper on Dengue Vaccines
2.2	GRADE and Evidence to recommendation tables

BACKGROUND DOCUMENTS (additional)	
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SESSION 3: ANTI-MICROBIAL RESISTANCE

EXECUTIVE SUMMARY	
3.0	Executive Summary: Anti-microbial resistance

BACKGROUND DOCUMENTS (essential)	
3.1	Leveraging Vaccines to Reduce Antibiotic Use and Prevent Antimicrobial Resistance: A World Health Organization Action Framework
3.2	Global and regional burden of attributable and associated bacterial antimicrobial resistance avertable by vaccination: modelling study

BACKGROUND DOCUMENTS (additional)	
3.3	The approach of World Health Organization to articulate the role and assure impact of vaccines against antimicrobial resistance
3.4	A presentation to show the approach and results to estimate the value of vaccines in reducing antibiotic use
3.5	A presentation to show the approach and results to estimate the value of vaccines in reducing AMR economic burden
3.6	Bacterial vaccines in clinical and preclinical development 2021

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SESSION 4: MENINGITIS

EXECUTIVE SUMMARY	
4.0	Executive Summary: Meningitis

BACKGROUND DOCUMENTS (essential)	
4.1	Overview of meningococcal disease epidemiology in countries of the African meningitis belt
4.2	Modelling of strategies for the introduction and routine use of MMCVs in the African meningitis belt. Executive summary prepared for the SAGE, September 2023
4.3	MenFive® – Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried) Clinical Overview, 2022
4.4	Current results from the Meningococcal Serogroup ACYWX Conjugate Vaccine randomized controlled trial in infants (a Phase 3 Trial to Evaluate the Safety, Immunogenicity, and Non-Interference with Concomitant Routine Vaccines, of a Meningococcal Serogroup ACYWX Conjugate Vaccine (NmCV-5) in Comparison with MenACWY-TT Conjugate Vaccine in Healthy Malian Infants). Executive summary prepared for the SAGE, September 2023
4.5	Grading of evidence - Evidence to recommendation tables

BACKGROUND DOCUMENTS (additional)	
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SESSION 5: IA2030 AND REGIONAL UPDATES

EXECUTIVE SUMMARY	
5.0	Executive Summary: IA2030 and Regional updates

BACKGROUND DOCUMENTS (essential)	
5.1	IA2030 Technical Progress Report 2023

BACKGROUND DOCUMENTS (additional)	
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6.0	Executive Summary: Polio

BACKGROUND DOCUMENTS (essential)	
6.1	Report from polio SAGE WG meeting
6.2	Report from the meeting of GACVS sub-committee on nOPV2 safety

BACKGROUND DOCUMENTS (additional)	
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EXECUTIVE SUMMARY	
7.0	Executive Summary: Malaria Vaccines

BACKGROUND DOCUMENTS (essential)	
7.1	Full evidence report on the R21/Matrix-M™ malaria vaccine
7.2	Grading of recommendations, assessment, development and evaluations (GRADE) review of malaria vaccine evidence
7.3	Evidence to Recommendation framework table for use of the R21/ Matrix-M malaria vaccine

BACKGROUND DOCUMENTS (additional)	
7.4	A Phase III randomized controlled multi-centre trial to evaluate the efficacy of the R21/Matrix-M vaccine in African children against clinical malaria
7.5	VAC078 Phase 3 trial of R21/Matrix-M Statistical Analysis Plan
7.6	R21/Matrix-M Supplementary tables and figures
7.7	The public health impact and cost-effectiveness of the R21/ Matrix-M malaria vaccine: a mathematical modelling study

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SESSION 8: SMALLPOX

EXECUTIVE SUMMARY	
8.0	Executive Summary: Smallpox

BACKGROUND DOCUMENTS (essential)	
8.1	Background document for the SAGE September 2023 session on smallpox vaccines
8.2	Strategic Advisory Group of Experts (SAGE) on Immunization Evidence to recommendations framework
8.3	Summary of Findings Tables for Report 1
8.4	Summary of Findings Tables for Report 2

BACKGROUND DOCUMENTS (additional)	
8.5	Rapid Systematic Reviews: Smallpox vaccines as pre-exposure or post-exposure vaccination against smallpox and mpox: safety and immunogenicity

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SESSION 9: COVID-19

EXECUTIVE SUMMARY	
9.0	Executive Summary: COVID-19

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

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SESSION 10: MUMPS

EXECUTIVE SUMMARY	
10.0	Executive Summary: Mumps

BACKGROUND DOCUMENTS (essential)	
10.1	Background Paper on Mumps Containing Vaccines
10.2	Summary of Cochrane review on MMRV results related to mumps vaccines (effectiveness and safety) from Di Pietrantonj C, et al Vaccines for measles, mumps, rubella, and varicella in children. Cochrane Database of Systematic Reviews 2021, Issue 11
10.3	GRADE tables and Evidence to Recommendations table

BACKGROUND DOCUMENTS (additional)	
10.4	Cochrane review 2021 Vaccines for measles, mumps, rubella, and varicella in children_abstract.pdf
10.5	Global Market Study Measles containing vaccines (MCV) Market study MMRV
10.6	WHO Mumps Virus Vaccines Position Paper 2007

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SESSION 11: CHOLERA

EXECUTIVE SUMMARY	
11.0	Executive Summary: Cholera

BACKGROUND DOCUMENTS (essential)	
11.1	Update on cholera vaccine

BACKGROUND DOCUMENTS (additional)	
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