World Health Organization

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

# SAGE

## meeting

## Strategic Advisory Group of Experts on Immunization
## 11-14 March 2024

## Hybrid meeting, WHO
## Geneva, Switzerland

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

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This document can be found online at the following link:
https://www.who.int/news-room/events/detail/2024/03/11/default-calendar/sage_meeting_march_2024

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

**To function correctly, this document needs to be downloaded and opened with Acrobat Reader (please download software if necessary). DO NOT OPEN IT in a web browser as it will not allow to access embedded documents**.

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).

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.

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World Health Organization

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

| **Day 1: Monday, 11 March 2024 (time is Central European Time)** | | | |
|---|---|---|---|
| **Time CET** | **Session** | **Purpose of session, target outcomes and questions for SAGE** | **Duration** |
| **9h00** | **Closed SAGE meeting** | Preparation of the sessions of the day. | **1h15** |
| **10h45** | **Break** | **Break** | **15 min** |
| **11h00** | **Opening and welcome – introduction of participants**<br>R. B. AYLWARD. ADG/UHL. WHO. 10 min<br>K. O'BRIEN. Dir. IVB. WHO. 5 min<br>J. HOMBACH. SAGE Secretariat. WHO. 5 min. | | **20 min** |
| **11h15** | **Global and regional reports – Session 1**<br>Report from the Director of IVB. K. O'BRIEN. WHO. 30 min.<br>Update from Gavi. A. NGUYEN. GAVI. 20 min.<br>Discussion. 30 min. | **FOR INFORMATION** | **1h30** |
| **12h45** | **Break** | **Break** | **1h00** |
| **13:45** | **Global and regional reports – Session 1 Continue**<br>Regional reports focused on the "Big catch up" theme | **FOR DISCUSSION** | **2h** |
| **15:45** | **Break** | **Break** | **15 min.** |
| **16:00** | **IA2030 deep dive – Session 2**<br>The Big Catch-Up: Overview, Progress, and Plans for 2024 Potential: A. LINDSTRAND. WHO or S. SHENDALE. WHO. 5-10 min.<br>Monitoring and Learning for the Big Catch-Up: Approaches and Considerations<br>Potential: C. DANOVARO. WHO and/or I. DADARI. UNICEF. 10 min.<br>Country Presentation #1: BCU implementation strategy and monitoring approach<br>Country to be determined. 10-15 min.<br>Country Presentation #2: BCU implementation strategy and monitoring approach. Country to be determined. 10-15 min.<br>Discussion. 40-50 min. | **FOR DISCUSSION**<br>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.<br>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. | **1h30** |
| **17h30** | **End of day 1** | | |

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| Day 2: Tuesday 12 March 2024 | | | |
|---|---|---|---|
| **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 30** |
| **10:45** | **Break** | **Break** | **15 min.** |
| **11:00** | **Polio – Session 3**<br><br>Session overview by S. MADHI. SAGE Member . 5 min.<br><br>Update from the Global Polio Eradication Initiative. A. O'LEARY. WHO. 15 min.<br><br>Questions. 20 min.<br><br>Lessons learned from switch of tOPV to bOPV in 2016 relevant to bOPV cessation. R. SUTTER. 15 min.<br><br>Policy considerations for bOPV Cessation Planning. O. MACH. WHO. 10 min.<br><br>Questions. 20 min.<br><br>Consideration for use of fIPV intramuscular. O. MACH. WHO. 5 min.<br><br>Questions. 20 min.<br><br>Report from SAGE Polio Working Group including update on novel OPVs. S. MADHI. SAGE Member. 15 min.<br><br>Discussion. 25 min. | **FOR INFORMATION AND RECOMMENDATION**<br><br>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.<br><br>SAGE will be asked to review and consider for endorsement:<br><br>• Recommendation on use of fIPV administered i.m. | **2h30** |
| **13:30** | **Break** | **Break** | **1h** |
| **14:30** | **Hepatitis E – Session 4**<br><br>Introduction, update on recent developments and HEV in pregnant women. R. GRAIS. SAGE member. 15 min.<br>GACVS assessment of Hepatitis E vaccination during pregnancy. GACVS (TBD). 15 min.<br>Questions. 10 min.<br>Presentation of evidence on immunogenicity, efficacy and effectiveness of less than 3 doses. B. AZAM. 10 min.<br><br>Questions. 10 min.<br><br>Recommendations. R. GRAIS. SAGE member. 5 min.<br><br>Discussion. 25 min. | **FOR RECOMMENDATION**<br><br>Present SAGE with GACVS assessment of Hepatitis E vaccine use during pregnancy.<br><br>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.<br><br>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. | **1h30** |
| **16:00** | **Break** | **Break** | **15 min** |

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| **16:15** | **COVID-19 – Session 5**<br><br>Introduction of the session, S.KOCHHAR. SAGE member. 5 min.<br>Update on the epidemiology of COVID-19 with a focus on severe disease by priority use groups. M. VAN KERKHOVE. WHO. 15 min.<br>Uptake of monovalent XBB vaccines. D. BROOKS. WHO. 5 min.<br>Vaccine effectiveness of monovalent XBB vaccines. A. VARMA. WHO. 10 min.<br>Q&A, Discussion. 25 min. | **FOR INFORMATION**<br><br>• Update on the epidemiology of COVID-19 by priority use group<br>• Update on circulating virus strains<br>• Rationale for the TAG COVAC recommendations<br>• Experiences with the monovalent XBB vaccines: VE, safety, uptake | **1h** |
| **17:15** | **End of day 2** | | |

| **Day 3: Wednesday 13 March 2024** | | | |
|---|---|---|---|
| **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 30** |
| **10:45** | **Break** | **Break** | **15 min** |
| **11:00** | **Mpox – Session 6**<br><br>Introduction of the session. K. NEUZIL. SAGE member. 5 min.<br>Update on disease epidemiology, including epidemiology from the African region and access and availability of vaccines. R. LEWIS. WHO. 15 min.<br>Evidence on vaccine effectiveness, of mpox vaccines – systematic review; Q&A. L. PISCHEL. Yale U. 15 min.<br>Evidence on vaccine safety of mpox vaccines – systematic review; Q&A. J. VAN HOLTEN. WHO. 15 min.<br>Draft recommendations and research priorities. K. NEUZIL, SAGE member & WG chair. 20 min.<br>Discussion and conclusions. 50 min. | **FOR RECOMMENDATION**<br><br>1. Provide a brief update on mpox epidemiology, including from the African Region<br>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:<br>a. Vaccination for outbreak response<br>b. Vaccination for preventive use<br>c. Choice of vaccines for outbreak response and preventive vaccination<br>d. Choice of vaccines for special populations<br>e. Access and availability of mpox vaccines | **2h** |
| **13:00** | **Break** | **Break** | **1h** |
| **14:00** | **Immune correlates – Session 7**<br><br>Introduction. S. MADHI. SAGE member. 2 min.<br>The immune correlate pathway to licensure for Chikungunya vaccines. T. ENDY. CEPI. 10 min.<br>Next steps for SAGE: A. WILDER-SMITH. WHO. 3 min.<br>Critical issues with immune correlates for licensure and policy . Z. DANGOR. Wits U. (South Africa). 10 min. | **FOR DISCUSSION**<br><br>To review two vaccines for which traditional Phase 3 efficacy trials will not be feasible: Chikungunya vaccines and Group B Streptococci (GBS) vaccines.<br><br>The question to SAGE will be whether SAGE concurs with the immune correlate approach. | **1h** |

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| | Considerations for Phase IV trials if a GBS vaccine is licensed based on an immunological endpoint. M. VOYSEY. Oxford U. (UK). 8 min.<br>Report on meeting with regulatory bodies and pathway forward. K. LE DOARE. WHO. 7 min.<br>Discussion. 20 min. | | |
| **15:00** | **Break** | **Break** | **15 min** |
| **15:15** | **RSV – Session 8**<br>Overview of session. K. NEUZIL. SAGE member & WG chair. 3 min.<br>Product status updates (Phase 3 results, NRA approvals, NITAG recommendations, real-world use):<br>• Nirsevimab long-acting infant mAb, E. SPARROW. WHO. 7 min<br>• Abrysvo maternal vaccine, D. FEIKIN. WHO. 10 min<br>.<br>WHO activities: SAGE WG; Impact study update; GACVS; RSV Roadshow. D. FEIKIN. WHO. 10 min.<br>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 & WG chair. 5 min.<br>Discussion 25 min. | **FOR INFORMATION**<br>This is an informational session to update SAGE on the latest data on RSV maternal immunization and WHO activities in preparation for a SAGE policy recommendation in September 2024. | **1h** |
| **14:15** | **End of Plenary Meeting** | | |

## Day 4: Thursday 14 March 2024

| Time CET | Session | Purpose of session, target outcomes and questions for SAGE | Duration |
|---|---|---|---|
| **9:00** | **Closed SAGE meeting** | Development of recommendations of day 3.<br>Any outstanding closed session items not covered previously. | **1h.** |
| **10:45** | **Break** | **Break** | **15 min.** |
| **11:00** | **Closed SAGE meeting (SAGE members only)** | | **1h 30** |
| **12:00** | **Closing** | | |

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# SESSION 1: GLOBAL REPORTS

| EXECUTIVE SUMMARY | |
|---|---|
| 1.0 | Executive summary: Global and regional reports |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 1.1 | Meeting of the Strategic Advisory Group of Experts on Immunization, September 2023: conclusions and recommendations |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
| 1.2 | Report of the Meeting of the Regional Immunization Technical Advisory Group (RITAG), Eastern Mediterranean Region Egypt, September 2023 |
| 1.3 | X Ad Hoc Meeting of the PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases, PAHO, May 2023 |
| 1.4 | Fourteenth Meeting of the WHO South-East Asia Regional Immunization Technical Advisory Group, September 2023, India |
| 1.5 | 32nd Meeting of the Technical Advisory Group on Immunizatin and Vaccine-Preventable Diseases in the Western Pacific Region, June 2023, Philippines |
| 1.6 | Meeting of the Immunization and Vaccine related Implementation Research Advisory Committee (IVIR-AC), September 2023 |
| 1.7 | WHO Product Development for Vaccines Advisory Committee, December 2023: DRAFT Executive summary & recommendations |

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# SESSION 2: IA2030 DEEP DIVE

| EXECUTIVE SUMMARY | |
|---|---|
| 2.0 | Executive Summary: IA2030 Deep Dive |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 2.1 | The Big Catch-Up: An essential immunization recovery plan for 2023 and beyond |
| 2.2 | Monitoring and reporting of essential immunization catch-up in the context of the Big Catch-up: Interim guidance |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
| 2.3 | Meeting of the Strategic Advisory Group of Experts on Immunization, April 2022: conclusions and recommendations -Session on catch-up vaccination |
| 2.4 | Leave no one behind: guidance for planning and implementing catch-up vaccination. April 2021 |
| 2.5 | WHO recommendations for interrupted and delayed vaccination |

# SESSION 3: POLIO

| EXECUTIVE SUMMARY | |
|---|---|
| 3.0 | Executive Summary: Polio |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 3.1 | Report from polio SAGE WG meeting |
| 3.2 | Report from the meeting on bOPV Cessation Planning |
| 3.3 | Report from the meeting of GACVS sub-committee on nOPV2 safety |
| 3.4 | Immunogenicity of Intramuscular Fractional Dose of Inactivated Poliovirus Vaccine |
| 3.5 | Immunogenicity of fIPV administered intradermally (ID) vs intramuscularly (IM) |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
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# SESSION 4: HEPATITIS E

| EXECUTIVE SUMMARY | |
|---|---|
| 4.0 | Executive Summary: Hepatitis E |

| BACKGROUND DOCUMENTS (essential) | |
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| BACKGROUND DOCUMENTS (additional) | |
|---|---|
| 4.1 | Hepatitis E vaccine: WHO position paper, May 2015 |

*Please note that the additional materials for the hepatitis E session will be shared separately early March 2024.*

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# SESSION 5: COVID-19

| EXECUTIVE SUMMARY | |
|---|---|
| 5.0 | Executive Summary: COVID-19 |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 5.1 | Recommendations from TAG-CO-VAC from December 2023 |
| 5.2 | Summary Status of COVID-19 Vaccines within WHO EUL-PQ evaluation process |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
| 5.3 | WHO roadmap on uses of COVID-19 vaccines in the context of Omicron and high population immunity |

# SESSION 6: MPOX

| EXECUTIVE SUMMARY | |
|---|---|
| 6.0 | Executive Summary: Mpox |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 6.1 | Background document for the SAGE March 2024 session on mpox vaccines and immunization |
| 6.2 | Mpox vaccines draft recommendations |
| 6.3 | Update on the safety component of the rapid systematic review-first generation smallpox vaccines ACAM2000, MVA-BN and LC16m8 as prevention or post-exposure prophylaxis for mpox. |
| 6.4 | Vaccine effectiveness of 3rd generation Orthopoxvirus vaccines against mpox: A living systematic review and meta-analysis |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
| 6.5 | Mpox GRADE and Evidence to Decision Tables |
| 6.6 | Multi-country outbreak of mpox. External Situation Report 31, December 2023, with special focus on mission to DRC |
| 6.7 | Monkeypox in the Democratic Republic of Congo Assessment of the situation. WHO and Ministry of Health joint mpox evaluation mission. November-December 2023 |
| 6.8 | Mpox (monkeypox) - Democratic Republic of the Congo: Disease outbreak news 23 November 2023 |

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# SESSION 7: IMMUNE CORRELATES

| EXECUTIVE SUMMARY | |
|---|---|
| 7.0 | Executive Summary: Immune correlates |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 7.1 | WHO Product Development for Vaccines Advisory Committee, December 2023: DRAFT Executive summary & recommendations |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
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# SESSION 8: RSV

| EXECUTIVE SUMMARY | |
|---|---|
| 8.0 | Executive Summary: RSV |

| BACKGROUND DOCUMENTS (essential) | |
|---|---|
| 8.1 | Kampmann et al., Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants |
| 8.2 | Terms of Reference for the Strategic Advisory Group of Experts (SAGE) on Immunization Working group on respiratory syncytial virus (RSV) immunization Version: January 2023 |
| 8.3 | Recently licensed RSV products and pipeline overview |

| BACKGROUND DOCUMENTS (additional) | |
|---|---|
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