

Terms of Reference for the Strategic Advisory Group of Experts (SAGE) on Immunization
Working group on Pertussis Vaccines
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The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 1999 to provide policy and strategy advice on vaccines and immunization to the Director-General of the World Health Organization (WHO). SAGE is the principal advisory group to WHO for vaccines and immunization. All vaccine-and immunization-related topics of public health relevance for which WHO requires strategic and policy advice need to be reviewed by SAGE.

From March 2013 to August 2015, a SAGE Working Group on Pertussis Vaccines¹ (from now referred as SAGE WG) was established in the light of the resurgence of pertussis and the related increase in infant mortality in some countries. This SAGE WG reviewed data and proposed draft recommendations, including on maternal vaccination, to SAGE. As a result of this work, WHO issued updated recommendations for the use of pertussis vaccines, published in the “Pertussis vaccines: WHO position paper – August 2015)² which included the following recommendations:

- Main aim of pertussis vaccination is protecting infants and young children and high coverage with 3 doses of either whole cell (wP) and acellular (aP) plus booster will reduce severe disease in children in the <5 year age.
- Timely vaccination at 6 weeks (8 weeks max) is paramount.
- Maternal vaccination should be considered.
- National programmes should not switch from wP to aP vaccine.
- National programmes already using aP vaccine may continue using this vaccine but should consider the need for additional booster doses and strategies to prevent early childhood mortality such as maternal immunization in case of resurgence of pertussis.
- A booster dose in adolescence has been shown to decrease disease in adolescents but is not recommended as a means of controlling pertussis in infants.

Ten years on, additional evidence on various pertussis and pertussis vaccine related topics have accrued. Further, in 2023 and 2024, multiple countries in all WHO regions have been/ are facing resurgence of pertussis, possibly linked to the lifting of public health measures and drop in routine vaccination coverage during the Covid-19 pandemic.

In addition, whole cell pertussis containing hexavalent vaccines have become prequalified and are being introduced into country immunization schedules. Additional new pertussis vaccines have been licensed or are in clinical development and would require consideration. This warrants a review of the current vaccine position paper and the WHO recommendation it contains, specifically regarding the impact of maternal immunization, the impact of wP and aP pertussis vaccines on resurgence in different settings and the impact of pertussis boosters during adolescence and adulthood.

The SAGE WG will act as an advisory body to WHO in this field.

I. Functions

¹ See [https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/working-groups/pertussis-vaccines-\(march-2013---august-2015\)](https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/working-groups/pertussis-vaccines-(march-2013---august-2015))

² See <https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers/pertussis>

The SAGE WG will be expected to formulate critical questions for which an in-depth review of evidence is needed to address current knowledge gaps and issue recommendations for updated programmatic recommendations on the use of pertussis vaccines, and optimisation of the current vaccination schedule, specifically the need for maternal vaccination as well as the impact and optimal use of booster vaccination. Updated recommendations will be submitted for consideration to SAGE to inform the revision of the global policy on pertussis vaccine use, and for subsequent updating the WHO position paper on pertussis vaccines.

In its capacity as an advisory body to WHO, the SAGE WG will review global, regional and country-level age-disaggregated *Bordetella pertussis* (*B. pertussis*) morbidity and mortality burden estimates, including the contribution of *B. pertussis* to overall, and age specific, child mortality, taking into consideration vaccination coverage, strategies and policies in place (e.g. maternal immunization) and products used.

SAGE will be asked to revisit the following strategic and policy areas:

Infant schedule

- What are the schedules/products used globally and what is the impact of wP and aP vaccines on pertussis infant mortality and disease.

Maternal immunization

- In which setting (epidemiology, coverage, product, schedules used) will maternal aP vaccination have the greatest impact.
- What is the safety and effectiveness of maternal immunization.

Booster doses

- What is the impact of pertussis vaccine booster doses (wP or aP) during childhood, adolescence and adults by setting on disease resurgence, epidemics and infant mortality.

Countries facing resurgence/ outbreaks

- What are the potential mitigation measures for countries facing current outbreaks/resurgence of pertussis.

The SAGE WG will be expected to present the results of the evidence review as requested by WHO and address additional issues as requested. The SAGE WG will be expected to highlight any knowledge gaps and research questions that might require further evidence review and/or the generation of new data through scientific research.

II. Composition

1. The SAGE WG shall have up to 15 members³, who shall serve in their personal capacities to represent the following disciplines relevant to: pertussis disease and vaccine; epidemiology/public health expertise and, particularly in low and middle income countries experiencing pertussis outbreaks; immunology; vaccinology and, specifically, in the domain of pertussis vaccines; immunisation programme planning/management, implementation and monitoring; modelling of immunization schedule optimization; vaccine safety. In the selection of the WG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the SAGE WG, including the Chairperson, shall be selected and appointed by WHO⁴ following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the SAGE WG;
 - to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson, consideration shall be given to gender and geographical representation.

3. Members of the SAGE WG shall be appointed to serve for a period of 2 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the SAGE WG, but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson is terminated when the SAGE WG is closed after completion of its mandate (see section *I. Functions*) and may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member's appointment is terminated, WHO may decide to appoint a replacement member.
4. SAGE WG members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.
5. Following a determination that a proposed member's participation in the WG would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the SAGE WG. Their appointment to the WG is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, SAGE WG members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.

³ Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.

6. As contemplated in paragraph II.4 above, WHO may, from time to time, request SAGE WG members to complete a new declaration of interest form. This may be before a SAGE WG meeting or any other SAGE WG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the SAGE WG member's participation in the SAGE WG activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.
7. Where a SAGE WG member is invited by WHO to travel to an in-person SAGE WG meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter'). WHO shall not authorize travel by a SAGE WG member, until it receives a countersigned Temporary Adviser Letter.
8. SAGE WG members do not receive any remuneration from the Organization for any work related to the SAGE WG. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

III. Operation

1. The SAGE WG accomplishes most of its work virtually via video or teleconferences. One or more SAGE WG meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

SAGE WG meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

- (a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).
 - (b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the WG and essential WHO Secretariat staff.
2. The quorum for SAGE WG meetings shall be two thirds of the members.
3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of a SAGE WG, or parts thereof, as "observers". Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-State actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the SAGE WG. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers

shall normally attend meetings of the SAGE WG at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting recommendations of the SAGE WG.

4. The SAGE WG may decide to establish smaller working groups (sub-groups of the SAGE WG) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the SAGE WG for review at one of its meetings.
5. SAGE WG members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the SAGE WG.
6. All conclusions and recommendations from the SAGE WG are submitted for consideration to WHO and are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the SAGE WG. WHO uses the analysis and recommendations to inform policy development by SAGE.
7. The SAGE WG shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.
8. Active participation is expected from all SAGE WG members, including in working groups, teleconferences, and interaction over email. SAGE WG members may, in advance of SAGE WG meetings, be requested to review meeting materials and to provide their views for consideration by the SAGE WG.
9. WHO shall determine the modes of communication by the SAGE WG, including between WHO and the SAGE WG members, and the SAGE WG members among themselves.
10. SAGE WG members shall not speak on behalf of, or represent, the SAGE WG or WHO to any third party.

IV. Time frame

The WG is expected to operate for a period of up to 3 years. WHO may decide to disestablish or extend the period of operations of this WG at any time.

V. Secretariat

WHO shall provide the secretariat for the SAGE WG, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion

papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat.

VI. Information and documentation

1. Information and documentation to which members may gain access in performing SAGE WG related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, SAGE WG members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their WG-related activities shall be exclusively vested in WHO.
2. SAGE WG members and Observers shall not quote from, circulate or use SAGE WG documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.
3. WHO retains full control over the publication of the reports of the SAGE WG, including deciding whether or not to publish them.