

**Creating global guidance for vaccination and
immunization**

**WHO's Strategic Advisory Group
of Experts (SAGE) on
immunization – Impact on global
immunization**

Philippe Duclos, WHO

Immunization Policy Advisory Framework

- Safety
- Standards
- Practice
- Burden assessment & modelling

Other WHO Technical Advisory Committees



Strategic Advisory Group of Experts (SAGE)

- Global policy recommendations & strategies
- Support regional/national challenges

Regional Technical Advisory Group

- Regional policies & strategies
- Identify & set regional priorities
- Monitor regional progress

- National Policies & Strategies
- Prioritize problems & define optimal solutions
- Implement national programme & monitor impact

Countries



National Immunization Technical Advisory Group

Strategic Advisory Group of Experts (SAGE) on Immunization

- Principal advisory group to WHO for vaccines and immunization

→ reports directly to DG and involves all relevant WHO departments

- **Membership - 15 members**

- Individual capacity and broad range of expertise
- Balance of professional affiliation, geographic representation
- **Declarations of interest – strict avoidance of conflicts**
- Appointed by WHO DG upon recommendation of external selection panel - Public call for nominations

- **Meetings and operational procedures**

- Two meetings a year (April and Oct)
- Only plenary sessions – transparent process
- Extensive representation from key partner organizations **including industry**
- Experts invited as needed on ad hoc basis
- Evidence-based – GRADing of evidence
- Working groups

- **Report and communications**



The screenshot shows the official website of the Strategic Advisory Group of Experts (SAGE) on Immunization. The page is titled "Immunization, Vaccines and Biologicals" and features a search bar at the top. The main content area includes a description of SAGE, a "SAGE news" section with a link to the "April 2012 meeting report published", and a "Next meeting" section stating the next meeting will take place on 6-8 November 2012. There are also links to "Future meetings", "Previous meetings", and "SAGE areas". The footer of the page indicates it is a "Local intranet" in "Protected Mode: Off".

SAGE working groups

- Establishment and ToRs decided by WHO and SAGE members
- Composition
 - Public call for nominations
 - At least two SAGE members & additional experts
 - Declaration of interests
- To review evidence and address specific issues in great depth and prepare for fruitful discussions at plenary SAGE meetings
- Not allowed to make decisions or speak on behalf of SAGE
- No observers
- Time limited though some set to run over a number of years (e.g. GVAP)

SAGE Working Group on influenza vaccines and immunization (established August 2010)

TERMS OF REFERENCE

Objectives of the Working Group:

1. Prepare for a SAGE evidence-based review and updating of WHO recommendations on the use of seasonal influenza vaccine (e.g. priority target groups) with a particular focus on low and middle-income countries and with a view to update the 2005 WHO influenza vaccine position papers.
2. Prepare for a SAGE discussion on coverage goals for seasonal influenza vaccination to be proposed to the WHA to update the coverage goals contained in the 2003 resolution.
3. Identify essential gaps in evidence that may impede SAGE's ability to update the recommendations on the use of influenza vaccines and propose coverage targets.
4. Provide advice about pandemic vaccine preparedness.

COMPOSITION

SAGE Members

- Elizabeth Miller, Chair
- Jon Abramson
- Claire-Anne Siegrist

Experts

- William Kwabena Ampofo, Noguchi Memorial Institute for Medical Research, Ghana
- Joseph Bresee, Centers of Disease Control, United States of America
- Janet Englund, Seattle Children's Hospital, United States of America
- Randeep Guleria, All India Institute of Medical Sciences, India
- Yu Hongjie, Chinese Center for Disease Control and Prevention, People's Republic of China
- Michael Pfeleiderer, Paul-Ehrlich-Institut, Germany
- David Salisbury, Department of Health, United Kingdom
- Barry Schoub, National Institute for Communicable Diseases, South Africa

WHO Secretariat

- Marie-Paule Kieny
- Philippe Duclos
- Cuauhtémoc Ruiz-Matus
- Nahoko Shindo

DECLARATION OF INTERESTS FOR WHO EXPERTS

All Working Group members completed a declaration of interests.

Four members reported relevant interests. All interests were assessed not to constitute a conflict of interest. It was concluded that all members could take part in full in all of the discussions. The reported relevant interests are summarized below:

Janet Englund:

- Her department received funding from MedImmune, Novartis, Adamas, ADMA Bio, BioCRYS and Sanofi Pasteur for conducting research in respiratory virology, meningococcal vaccines, influenza therapies, diphtheria-tetanus-pertussis trivalent vaccines and human respiratory syncytial virus immunotherapy. However none of the studies focused on influenza vaccines and immunization which was the subject of the meeting. These interests were assessed as non-personal, non-specific and financially significant.

Issues taken into consideration by SAGE

■ Disease epidemiology

- disease burden including age specific mortality, morbidity, and societal impact; projections for future disease burden; specific risk groups; epidemic potential; disease occurrence over time; serogroup or serotype distribution; and changes in epidemiology over time

■ Clinical characteristics

- clinical management of disease, disease severity, primary/secondary/tertiary care implications, long term complications of disease and medical requirements

Issues taken into consideration by SAGE

■ Vaccine and immunization characteristics

- efficacy, effectiveness and population impact of vaccine; indirect effects; vaccine safety; cold chain and logistics concerns; vaccine availability; vaccine schedules; schedules acceptability and ability to deliver

■ Economic considerations

- disease, vaccine and vaccine delivery costs, perspective for vaccine price reduction, vaccine cost and cost-effectiveness of immunization programmes and affordability of immunization

Issues taken into consideration by SAGE in developing recommendations

- Health system opportunities and other existing intervention and control strategies
- Social impacts
- Legal considerations
- Ethical considerations

Aspects for which there is a lack of data to support decision making

- Effectiveness in developing countries and herd immunity
- Adjust schedules: reduce number of doses, dose spacing and duration of protection
- Vaccines co-administration
- Risk groups: immunodeficient, pregnant women, very young and very old
- Impact of vaccination strategies
- Cost-effectiveness studies

→ **Need good and coordinated surveillance**

WHO Vaccine Position Papers

- **Position papers = Key reference documents**
 - Available in all 6 official languages
 - Convergence of other WHO documents (International Travel and Health, Essential Drugs List, ...)
- **Developmental and review process (SAGE, extensive peer review including by industry, evidence-base, periodic updating)**
- **Format**
 - **Weekly Epidemiological Record**
 - **Current structure (Intro, background (Disease epidemiology, the pathogen, disease...), info on vaccines (composition, safety, immune response, efficacy and effectiveness, cost effectiveness and any other relevant issue), WHO position)**
- **Additional posting of information on the web: Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables, references, summaries (one pager and PowerPoint presentation)**

The screenshot displays the WHO website's 'Immunization, Vaccines and Biologicals' section. The main heading is 'WHO vaccine position papers'. Below this, a paragraph explains that WHO publishes these papers to provide guidance on health policy matters. A sidebar on the left lists navigation options: 'Immunization, Vaccines and Biologicals', 'Strategic Advisory Group of Experts (SAGE)', 'Position papers', 'Topics', 'Document centre', 'Newsroom', and 'About us'. The main content area includes a 'Highlights' section with dates and titles of recent papers, such as 'The Measles & Rubella Initiative Teams Up With Celebrated Illustrator Sophie Blackall' and 'World Health Assembly Endorses New Plan to Increase Global Access to Vaccines'. There is also a section for 'WHO position papers' with a link to 'List of all position papers by disease'. The bottom of the page mentions that the papers are published in the Weekly Epidemiological Record and are available in multiple languages.



Immunization, Vaccines and Biologicals

Immunization, Vaccines and Biologicals

[Strategic Advisory Group of Experts \(SAGE\)](#)

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WHO recommendations for routine immunization - summary tables

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In order to assist programme managers develop optimal immunization schedules WHO has compiled key information on its current routine immunization recommendations into three summary tables.

Table 1 summarizes recommended routine immunizations for all age groups - children, adolescents, and adults. As such, it provides an overview of vaccine recommendations across the lifespan, including both primary series and booster doses.

Table 2 provides detailed information for routine immunizations for children, including age at first dose and intervals. It reiterates recommendations on the primary series and booster doses.

In Table 3, WHO has consolidated its recommendations for interrupted and delayed vaccination. These irregular situations can be challenging to health workers who may not know what to do.

It is important to note that these recommendations are only a compilation of existing WHO routine immunization recommendations in a new format. All the recommendations come from WHO

Links to tables

31 May 2012

[Table 1](#)
pdf, 247kb

[Table 2](#)
pdf, 204kb

[Table 3](#)
pdf, 207kb

[Table 1 - en français](#)
pdf, 258kb

[Table 2 - en français](#)
pdf, 234kb

[A User's Guide to the Summary Tables](#)
pdf, 998kb

Interaction with manufacturers

- **Solicited at all stages**
- **Input to SAGE processes**
 - Contribution with unpublished information
 - Need access to information submitted for licensure and prequalification
 - Production and distribution forecasts
- **Participate in peer review of vaccine position papers**
- **Appropriate processes – watch for conflicts of interest and equity – cannot have direct membership on SAGE or its working groups**

Off license indications

- **A must to optimize public health impact**
- **Within limits**
- **A communication challenge**
- **A need to work towards reconciliation of public health recommendations and license**

Impact of SAGE recommendations and vaccine position papers

**A STAKEHOLDERS' PANEL TO
EVALUATE THE IMPACT OF
"STRENGTHENING WHO'S NORMATIVE
AND POLICY SETTING FUNCTIONS FOR
IMMUNIZATION, 2006-2010", March 2009**

■ **Countries**

■ **Partners**

■ **Prequalification**

■ **Industry**

● **The WHO Vaccine ACs play an increasingly central role in determining global vaccine policy.**

● **WHO Vaccine AC recommendations have become a necessary step in the pathway to the introduction and use of vaccines, especially in developing countries and, as a consequence, have clear and significant impact.**

SAGE – November 2012 meeting

Vaccination in Humanitarian Emergencies

- SAGE endorsed the framework on the use of vaccinations during humanitarian emergencies
- SAGE noted that framework fills an existing gap to guide decision-making processes, yet acknowledged the focus on vaccination which is only one priority consideration in humanitarian emergencies
- Three iterative steps:
 - an **assessment of the epidemiological risk** posed by each VPD
 - **consideration of the vaccine properties** and a context-specific analysis of logistics for a mass campaign
 - **prioritization in relation to other urgent public health actions and in light of contextual factors** such as political realities, security issues, as well as available human and financial resources

SAGE – April 2013 meeting

Haemophilus influenzae b

- **SAGE concerned that despite a 2006 WHO recommendation calling for the universal introduction of Hib vaccines **9% of member states have not yet introduced the vaccine****
→ SAGE urged policy makers in these countries to support the introduction of Hib vaccines
- **SAGE recommended any one of the following schedules:**
 - three primary doses without a booster (3p+0)
 - two primary doses plus a booster (2p+1)
 - three primary doses with a booster (3 p+1)
- **Age at first dose should be determined based on the local epidemiology, vaccine presentation (Hib monovalent vaccine versus combination) and, how this fits into the overall immunization schedule.**

SAGE – April 2013 meeting

SAGE recommendations on Yellow Fever Vaccination

- A single dose of YF vaccine is sufficient to confer sustained immunity and life-long protection against yellow fever disease → a booster dose of YF vaccine is not needed.
- Surveillance in endemic countries and clinical studies may possibly identify specific risk groups (such as infants or HIV-infected patients) that could benefit from a second primary or booster dose.
- Need to revisit the International Health Regulations provisions relating to the period of validity for international certificates for vaccination against YF.
- All countries with areas at risk from YF disease to set time defined objectives for the introduction of YF vaccine into their immunization programme and establish regional plans for controlling YF.

Draft ToRs for SAGE Working Group on Japanese Encephalitis Vaccines

- Review the evidence, identify information gaps, and formulate proposed recommendations on the use of JE vaccines for a SAGE review. This will lead to an update of the 2006 JE vaccine position paper targeted for early 2015.
- More specifically review the:
 - global prevalence and burden of disease
 - role of inactivated mouse-brain based JE vaccines
 - safety, effectiveness, and immunogenicity profile of inactivated, live attenuated, and chimeric JE vaccines*
 - schedule and age of administration for the first dose of inactivated, live attenuated, and chimeric JE vaccines*
 - duration of protection following immunization with inactivated, live attenuated, and chimeric JE vaccines*
 - co-administration of JE vaccines* with other vaccines
 - use of JE vaccines* in special populations (e.g. immunosuppressed, pregnancy)
 - disease impact and cost-effectiveness of JE immunization programs

*Due to the large number of available JE vaccines with limited global use, the Working Group will focus its in-depth evidence review on products with current or likely international distribution.



SAGE: November 2013 meeting

Tentative specific topics

- Vaccination of pregnant and lactating women
- Polio eradication
- DoV GVAP Monitoring of progress
- Stockpile for pandemic influenza vaccines
- Measles & rubella status report
- Smallpox vaccines
- Immunization supply chain & logistics
- Sentinel sites surveillance

SAGE 2014-2015 meetings

Topics on the horizons- cross-cutting and strategic issues

- **DOV GVAP monitoring of implementation**
- **Surveillance**
- **Dealing with vaccine hesitancy**
- **Non specific effects of vaccines**
- **Use of vaccines in immunocompromised populations**
- **Immunization supply chain and logistics**
- **Strengthening routine vaccination and integration in primary health care**
- **Involvement of the private sector**
- **Strengthening of NITAGs**
- **Accessibility to affordable vaccines and WHO's role**



SAGE 2014-2015 meetings

Topics on the horizons- vaccine specific recommendations and updates

- Polio eradication
- Measles elimination
- Optimizing immunization schedules
- Vaccine specific impact monitoring
- **Pertussis**
- Vaccine specific Preferred Product Characteristics
- Varicella & herpes zoster
- Japanese encephalitis
- HPV
- Hepatitis E
- Malaria

Thank you

