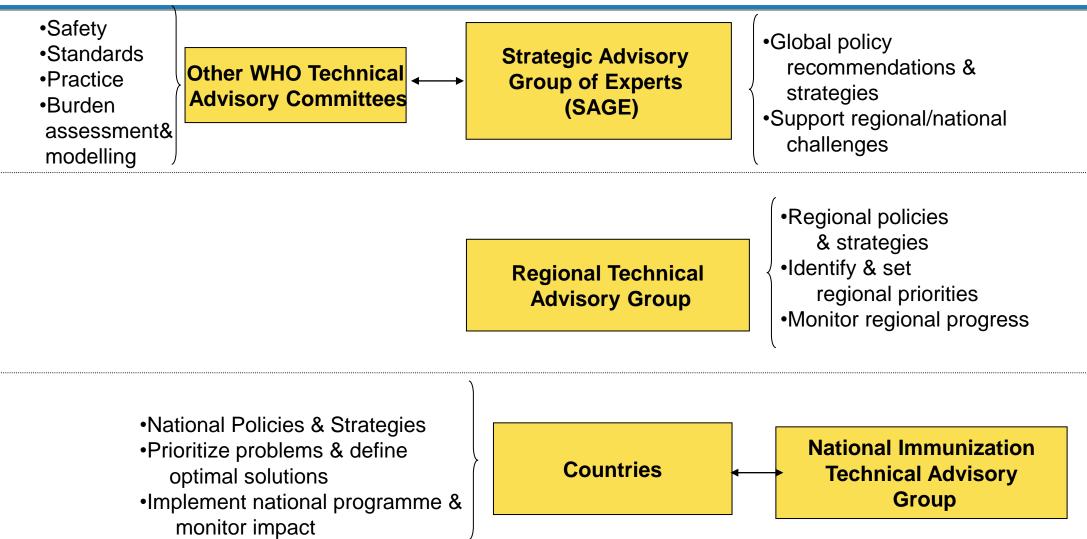
Creating global guidance for vaccination and immunization

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

Philippe Duclos, WHO

## Immunization Policy Advisory Framework





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# Strategic Advisory Group of Experts (SAGE) on Immunization

#### Principal advisory group to WHO for vaccines and immunization

 $\rightarrow$  reports directly to DG and involves all relevant WHO departments

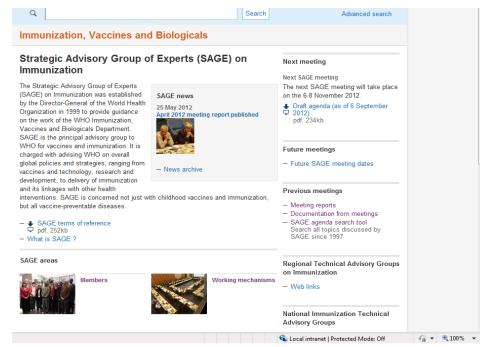
#### Membership - 15 members

- 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

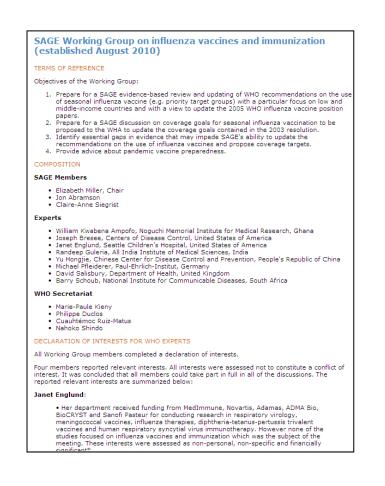




# **SAGE working groups**

#### 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)





### **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

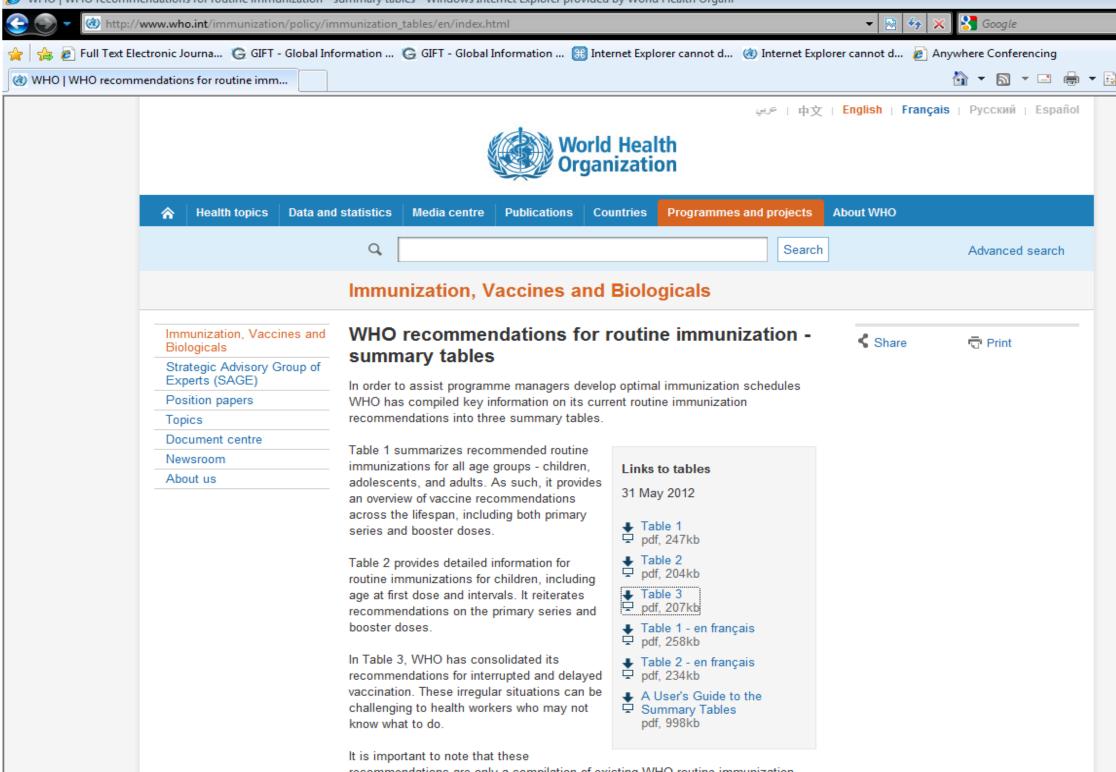
- Available in all 6 official languages
- Convergence of other WHO documents (International Travel and Health, Essential Drugs List, …)
- Developmental and review process (SAGE, extensive peer review including by industry, evidence-base, periodic updating)

#### 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)

	ч	Search	Advanced search
	Immunization, Vaccines an	d Biologicals	
Immunization, Vaccines and Biologicals	WHO vaccine position papers		Highlights
Strategic Advisory Group of Experts (SAGE)	In accordance with its mandate to provide guidance to Member States on health policy matters, WHO publishes vaccine position papers providing global vaccine position papers providing global vaccine and immunization recommendations for diseases that have an international public health impact. The papers summarize essential background information on respective diseases and vaccines, and conclude with the current WHO position concerning their use in the global context.	29 May 2012	
Position papers		Keleve epidemiologique nebdomadare	The Measles & Rubella Initiative Teams Up With Celebrated Illustrator Sophie
Topics		Blackall	
Document centre		28 May 2012	
Newsroom		Bernardsen (	List of WHO contracted laboratories for vaccine prequalification now online
About us			
			25 May 2012
			World Health Assembly Endorses New Plan to Increase Global Access to Vaccines
	The papers are designed for use by national public health officials and immunization programme managers. They may also be of interest to international funding agencies, the vaccine manufacturing industry, the medical community, and the scientific media.		25 May 2012
			<ul> <li>SAGE report of the April 2012</li> <li>meeting published pdf, 1,11Mb</li> </ul>
		WHO vaccine position papers — List of all position papers by disease	<ul> <li>Highlights archive</li> <li>Global Immunization News (GIN) archive</li> </ul>
	process both internally and externally prior to publication. Processes to manage potential conflicts of interest and to ensure careful and critical appraisal of the best scientific evidence have become more rigorous in recent years. A register of interests of SAGE members is maintained by WHO with summaries of interests declared relevant to SAGE topics published on the SAGE web site.		
			- Contact Us
	The position papers are published in the We French and translated into the other WHO o and Spanish. Each position paper is now ac slide formats, a list of key references, and t	fficial languages: Arabic, Chinese, Russian, companied by a summary in both text and	





recommendations are only a compilation of existing WHO routine immunization recommendations in a new format. All the recommendations come from WHO

# Interaction with manufacturers

- Sollicited 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 impactWithin limits
- A communication challenge
- A need to work towards reconciliation of public health recommendations and license



# Impact of SAGE recommendations and vaccine position papers

- Countries
- Partners

Industry

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

The WHO Vaccine ACs play an increasingly central role in determining
 Prequalification

•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 decisionmaking 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



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### Thank you



