# Global Immunisation Vision and Strategy (GIVS) and the role of SAGE.

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## Vision: A world in 2015 in which:

- Immunisation is highly valued;
- Every child, adolescent and adult has equal access to immunisation as provided for in their national schedule;
- More people are protected against more diseases;
- Immunisation and related interventions are sustained in conditions of diverse social values, changing demographics and economies, and evolving diseases;
- Immunisation is seen as crucial for the wider strengthening of health systems and a major element of efforts to attain the Millennium Development Goals;
- Vaccines are put to best use in improving health and security globally; and solidarity among the global community guarantees equitable access for all people to the vaccines they need.



# GIVS has four main aims

- To immunize more people against more diseases;
- to introduce a range of newly available vaccines and technologies;
- to integrate other critical health interventions with immunization; and
- to manage vaccination programmes within the context of global interdependence.


# The GIVS Challenges.

- Focus on sustaining gains and reaching the unreached to achieve existing goals.
- Continue to pursue linkages with child survival interventions through pro-poor outreach and facility-based strategies.
- Use introduction of new vaccines as a major opportunity to revitalize programming for pneumonia and diarrhoea.
- Utilize RED approach and EPI planning, supply chain. management and monitoring tools for broader systems strengthening goals.
- Integrate with national planning and budget cycles as part of revitalization of PHC.

# Global Interdependence …

"If we lose sight of our long-term priority to expand opportunity for the world's poor and abandon our commitments and partnerships to reduce inequity, we run the risk of emerging from the current economic downturn in a world with even greater disparities in health and education and fewer opportunities for people to improve their lives."

*Bill Gates, Davos, 2009*

# SAGE and GIVS

- GIVS sets out the strategic vision whereby immunisation programmes will develop over a ten-year period.
- SAGE provides the technical coordinating framework within which the GIVS objectives are examined for feasibility and progress is evaluated.
- SAGE acts as the technical advisory group on immunisation for WHO, UNICEF and GAVI.
- SAGE overarches all WHO's immunisation committees.

# SAGE – the history.


- The Global Advisory Group provided advice on the EPI programme – DTP, polio, measles, BCG, hepatitis B vaccines.
- SAGE 1 was the Scientific Advisory Group of Experts and was essentially a research advisory group.
- SAGE 2 (1999) was the Strategic Advisory Group of Experts and brought together the responsibilities of GAG and SAGE 1.
- The SAGE function was reviewed in 2004.
- SAGE 3 was then created, reviewed again in 2006/7 and its impacts have recently been reviewed again.
- The outcome of the 2006/7 review was that SAGE was fully delivering the requirements.

# SAGE – Terms of Reference


The Strategic Advisory Group of Experts (SAGE) on Immunization was established by the Director-General of the World Health Organization in 1999 to provide guidance on the work of the WHO Immunization Department. The Terms of reference of the Group were revised during 2007 in view of the development of the Global Immunization Vision and Strategy (GIVS). SAGE is the principal advisory group to WHO for vaccines and immunization. It is charged with advising WHO on overall global policies and strategies, ranging from vaccine and technology, research and development, to delivery of immunization and its linkages with other health interventions. SAGE is concerned not just with childhood vaccines and immunization, but all vaccine-preventable diseases.

# SAGE and its working groups

**SAGE** has members drawn from every WHO Region after open competition. Chairs of Regional TCGs support SAGE. UNICEF and GAVI are SAGE 'partners'.

- **Working groups – current, 'suspended' and new:**
- H5N1 vaccines;
- Inactivated polio vaccine;
- Hepatitis B vaccine;
- Measles vaccination;
- Pneumococcal conjugate vaccine;
- Pneumococcal polysaccharide vaccine;
- Optimising the use of conjugate vaccines.
- Rubella vaccination;
- Hepatitis A vaccine;
- Meningococcal vaccine.

# Groups advisory to SAGE.

- Global Advisory Committee on Vaccine Safety (GACVS).
- Expert Committee on Biological Standardisation (ECBS).
- Quantitative Immunization and Vaccines Related Research Advisory Committee (QUIVER)
- Advisory Committee of the Initiative for Vaccine Research (IVAC)
- Technologies and Logistics Advisory Committee (TLAC).
- Advisory Committee on Polio Eradication (ACPE).

# Technologies and Logistics Advisory Committee

- Advice on issues related to field operations, logistics, cold chain systems, and technological innovations.
- Most recommendations at level of programme operations but some of broader strategic nature to be first endorsed by SAGE
- First meeting - September 2008
  - Potential to move vaccines out of the cold chain,
  - Revision of multi-dose vial policy.
- Now becoming focused on implementation logistics.

# SAGE 2009 meetings: Topics covered.


## RUNNING ITEMS

- Progress on recommendations
- Regional reports (3 per meeting)
- Reports from other Immunization Advisory Committees
  - Advisory Committee on Polio Eradication
  - Global Advisory Committee on Vaccines Safety
  - Expert Committee on Biological Standardization
  - Advisory Committee of the Initiative for Vaccine Research
  - Technologies and Logistics Advisory Committee
  - Quantitative Immunization and Vaccines Related Research Advisory Committee
- Reports from the GAVI Alliance

## SPECIFIC TOPICS

- Polio eradication
- Immunization schedules and causes for under-immunisation
- H5N1 and H1N1 vaccine
- Measles eradication feasibility
- Cholera vaccine
- Rotavirus vaccines
- Hepatitis B vaccine
- Pertussis vaccination
- Malaria.
- Japanese encephalitis vaccine
- HPV vaccine

# SAGE - HPV vaccines .

Recognizing the importance of cervical cancer and other HPV-related diseases as global health problems, routine HPV vaccination should be included in national immunization programmes provided that:

- prevention of cervical cancer and other HPV-related diseases is a public health priority,
- vaccine introduction is programmatically feasible, and
- sustainable financing can be secured
- the cost-effectiveness of possible introduction and vaccination strategies in their country or region be considered.

Primary target population is likely to be girls within the age range of 9 or 10 through 13 years.

# SAGE - HPV vaccines

- HPV vaccines should be introduced as part of a coordinated strategy to prevent cervical cancer and other HPV-related diseases that includes:
  - education about reducing behaviours that increase disease risk
  - cervical cancer screening
  - diagnosis and treatment of precancerous lesions and cancer
  - However, HPV vaccination should not be deferred in countries because one or more of these interventions cannot be implemented at the time when vaccination could be introduced
- HPV vaccine introduction should not undermine or divert funding from screening programmes intended to reduce HPV-related disease at a population level.
- Vaccinated females should be screened later in life to prevent cancers caused by HPV types other than 16 and 18 that may cause up to 30% of cervical cancer cases.
- Opportunities to link HPV vaccines introduction to other programmes targeting young people should be sought (e.g. adolescent health, comprehensive adolescent health package).

# SAGE : IPV working group

- Very little prospect for IPV to be affordable outside of industrialised and middle income countries
- WG presented a framework to assess four potential options in the post-eradication era in low and middle income countries:
  - early childhood protection (3-4 IPV doses by 6 months of age);
  - protection by 1 year of age (2 doses, 4-6 months apart);
  - priming by 1 year of age (1 dose);
  - no vaccination.

- The WG also outlined an approach for updating the WHO position paper on polio vaccination, using a combination of poliovirus transmission potential and risk of infection to guide national policy.

# SAGE : Polio Eradication

- SAGE was extremely concerned with the continued poor quality of the polio campaigns in Nigeria's northern states.
- Five countries had been newly infected by the spread of polio from Nigeria in the past 6 months alone, SAGE asked that ACPE assess the role of OPV immunization of travelers to and from such areas.
- While appreciating the new Presidential Initiative on polio eradication and immunization in Kano, SAGE reiterated its concern that existing plans and commitments needed to be urgently followed by activities to rapidly improve polio campaign quality.

# SAGE : Polio Eradication.

- SAGE to assess the quality of strategy implementation in polio-infected countries at each meeting, to enhance advocacy with lagging areas and assist the work of the ACPE.
- At the next SAGE meeting, Pakistan and Nigeria should to report on progress in overcoming the barriers to achieving high coverage during their OPV campaigns.
- SAGE strongly endorses the ACPE recommendation that routine use of OPV be stopped in a coordinated manner as soon as possible after certification of global polio eradication, recognizing that major elements of the strategy for stopping OPV continue to evolve.
- SAGE endorses the IPV WG's recommendation that the supply base and economics of IPV containing combination vaccines be evaluated to better understand the implications of policy decisions on such products.
- SAGE recommends that the mathematical model(s) of post-eradication risks be evaluated by QUIVER.

# SAGE : Rotavirus vaccines

- Update on ongoing immunogenicity and efficacy studies in various mortality settings in Africa and Asia.
- No interference with the immune response to OPV vaccines.
- Preliminary analysis of the Rotarix study in South Africa and Malawi show significant impact.
- Complete analysis of the Rotarix trials in Africa tentatively planned for the April 2009 SAGE meeting.
- Other results from Asia and Africa expected later in 2009.

# SAGE : Measles


- SAGE reviewed the report from the WG on measles
  - Reaching all children with 2 doses of measles vaccine should be the standard for all national immunization programmes
  - Delivery of the 2nd dose through routine services or through campaigns
  - WHO measles vaccine position paper to be updated
  - SAGE agreed with the approach proposed to determine when countries should introduce a 2nd routine dose and WG will report at April 2009 meeting.

- SAGE agreed with the programme of work for assessing the feasibility of global elimination of measles
  - Will include a thorough analysis of the biologic, programmatic, economic, health systems impact, vaccine market analysis, and political aspects.

# SAGE : Beyond hepatitis B vaccine introduction – establishing disease control goals.

- Control goal, rather than an elimination or eradication goal.
- SAGE strongly recommended that all regions and associated countries should develop goals for hepatitis B control appropriate to their epidemiologic situations.
- Control goals are essential for regions and countries with intermediate or high endemicity of hepatitis B infection or subpopulations with these levels of infection.
- Indicators
  - Process indicators based on coverage with third dose of hepatitis B vaccine and with birth dose (with improved definition and monitoring)
  - Impact measures critical (serosurveys of HBsAg).

# SAGE - November 2008
# First meeting of the H5N1 influenza working group.

- **Background**: H5N1 vaccine stockpile - 150 million doses
- **Charge**: Prepare for SAGE deliberation on the policy and guidance on the potential use of H5N1 influenza vaccine in the inter-pandemic period
- **Four questions**:

1. Evidence to offer or recommend use of licensed human H5N1 vaccines in the inter-pandemic period in the following populations to protect them against H5N1 **avian influenza**?
   - Groups at high risk of infection
   - "Essential personnel"
   - General public
2. Evidence to offer or recommend use of licensed human H5N1 influenza vaccines in the inter-pandemic period in the following populations to prime or fully immunize them against infection with a **potential pandemic** H5N1 virus?
   - "Essential personnel"
   - Larger general population groups.

# SAGE - November 2008 meeting
# First meeting of the H5N1 influenza working group.

- 3. What should be done with the stockpiled H5N1 influenza vaccines as they approach expiry date, during the inter-pandemic period?
- 4. Should SAGE recommend a change in the size of the WHO international stockpile of H5N1 influenza vaccine?
- Determine need for additional evidence to be gathered or researched to facilitate the formulation by SAGE of policy recommendations at its next meeting in April 2009.

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# Influenza-like illness in the United States and Mexico

24 April 2009 -- The United States Government has reported seven confirmed human cases of Swine Influenza A/H1N1 in the USA (five in California and two in Texas) and nine suspect cases. All seven confirmed cases had mild Influenza-Like Illness (ILI), with only one requiring brief hospitalization. No deaths have been reported.

The Government of Mexico has reported three separate events. In the Federal District of Mexico, surveillance began picking up cases of ILI starting 18 March. The number of cases has risen steadily through April and as of 23 April there are now more than 854 cases of pneumonia from the capital. Of those, 59 have died. In San Luis Potosi, in central Mexico, 24 cases of ILI, with three deaths, have been reported. And from Mexicali, near the border with the United States, four cases of ILI, with no deaths, have been reported.

Of the Mexican cases, 18 have been laboratory confirmed in Canada as Swine Influenza A/H1N1, while 12 of those are genetically identical to the Swine Influenza A/H1N1 viruses from California.

The majority of these cases have occurred in otherwise healthy young adults. Influenza normally affects the very young and the very old, but these age groups have not been heavily affected in Mexico.

Because there are human cases associated with an animal influenza virus, and because of the geographical spread of multiple community outbreaks, plus the somewhat unusual age groups affected, these events are of high concern.

# The role of SAGE and A(H1N1) – June 2009.

- May 2009: SAGE offers to form an ad hoc expert group to act as external advisor to the WHO A(H1N1) vaccine task force (internal group).
- Ad hoc expert group composed of SAGE Chair, SAGE H5N1 working group chair and one wg member; one SAGE member; ECBS Chair, one ECBS member; GACVS Chair and one GACVS member; two independent expert members.
- The ad hoc group has held teleconferences every two weeks.
- The early June teleconference was shared with 45 participants and was followed by a SAGE/ad hoc group briefing with the WHO Director General.
- Critically important was the status of seasonal influenza vaccine production and the projections for completion of Northern Hemisphere manufacturing.

# The role of SAGE and A(H1N1) – June 2009.

- Any switch to H1N1 (Swine) vaccine manufacture should not compromise seasonal trivalent production.
- Manufacturers should start intensive preparatory work in readiness for a recommendation to switch production.
- Southern hemisphere trivalent seasonal vaccine production would be compromised by a switch to H1N1.
- In WHO's view, announcement of Pandemic Phase 6 did not imply an automatic switch from trivalent seasonal vaccine production to H1N1 production – but industrialised country contracts, drafted on an assumption of a severe pandemic with H5N1, specified that at Pandemic Phase 6, there would be a switch.

# The role of SAGE and A(H1N1). July 7th 2009 meeting

Update on epidemiology and disease burden.

- Current situation;
- Severity in industrialised and developing countries;
- Risk factors for severe disease;
- Forecasting drift and antiviral resistance;
- strain circulation and replacement of seasonal viruses;
- Effects of circulation on population susceptibility.

Update on vaccine availability.

- Production status for Northern Hemisphere 2009/10 season;
- Expected demand for seasonal vaccine;
- A(H1N1) and seasonal vaccine production plans for 2010;
- Impact of APAs on vaccine availability;
- UN procurement for LMICs.

# The role of SAGE and A(H1N1). July 7th 2009 meeting

Update on vaccine safety and regulatory issues.

- Regulatory pathways;
- Timelines for licensure;
- Timelines for immunogenicity and safety data;
- Levels of protection (one – two doses by age);
- immune responses to unadjuvanted plain vaccine by dose;
- Safety of adjuvanted vaccines.

Update on programmatic issues:

- Vaccine deployment strategies;
- Country capacities;
- Storage;
- Country plans and co-administration;
- Availability of syringes and injection equipment – including disposal.

# The role of SAGE and A(H1N1). July 7th 2009 meeting

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World Health Organization

Organisation mondiale de la Santé

## Weekly epidemiological record
## Relevé épidémiologique hebdomadaire

24 JULY 2009, 84th YEAR / 24 JUILLET 2009, 84e ANNÉE
**No. 30**, **2009**, **84**, 301–308
**http://www.who.int/wer**

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The Strategic Advisory Group of Experts on Immunization (SAGE) held an extraor-

### Groupe consultatif stratégique d'experts de la vaccination – rapport de la réunion extraordinaire sur la pandémie 2009 de grippe A (H1N1), 7 juillet 2009

Le Groupe consultatif stratégique d'experts de la vaccination (SAGE) a tenu une réunion

# The role of SAGE and A(H1N1). July 7th 2009 meeting

## SAGE recommendations

1. All countries should immunize their **health-care workers** (1–2% of the world's population) as a first priority to protect the essential health infrastructure. Significant pandemic-related morbidity in such workers will compromise the capacity of health services to care for patients sick with influenza and other life-threatening conditions. Health workers need to be able to protect their own lives while putting themselves at risk of infection through caring for influenza patients. Furthermore, infected health-care workers may spread the virus to vulnerable patients and initiate nosocomial outbreaks. There is a need to maintain general health services as the pandemic unfolds.

# The role of SAGE and A(H1N1). July 7th 2009 meeting

As insufficient vaccine will be available initially, a stepwise approach to vaccinate particular groups may be considered. SAGE suggests the following groups for consideration, noting that countries need to determine their order of priority based on country-specific conditions:

- **Pregnant women** (2% of the world's population). This group appears to be at increased risk for severe disease, potentially resulting in spontaneous abortion and/or death, especially during the second and third trimesters of pregnancy. Inactivated non-adjuvanted vaccines similar to most seasonal influenza vaccines are considered the preferred option given the extensive safety data on their use in pregnant women. However, if such a product is not available, pregnant women should be vaccinated with another pandemic influenza vaccine available at that time, for example, an adjuvanted inactivated influenza vaccine or a live attenuated influenza vaccine.
- **Individuals aged >6 months with one of several chronic medical conditions** in order to reduce morbidity and mortality. This group includes people with asthma and other chronic conditions such as morbid obesity.
- **Healthy young adults (aged >15 years and <49 years)** to reduce morbidity and mortality.
- **Healthy children.** This group was considered a potential target group, mainly to attempt to reduce transmission. However, there was uncertainty regarding the potential effectiveness of this approach.
- **Healthy adults aged >49 years and <65 years** to reduce morbidity and mortality.
- **Healthy adults aged >65 years** to reduce morbidity and mortality.

# GIVS and SAGE: strengths and challenges.

- Inclusiveness.
- Expertise.
- Timeliness – in line with global, regional and national priorities.
- Relevance – global, regional and national, industry, academia.
- Authority.
- Influence - Access to WHO Director-General, the World Health Assembly., GAVI Policy & Planning, UNICEF, Industry, Regions and countries

- Timeliness – not in line with global, regional or national priorities.
- Over-burden on WHO, UNICEF, Regions, countries against other competing priorities.
- Current and future economic climates.
- Relevance – global, regional and national, industry, academia.

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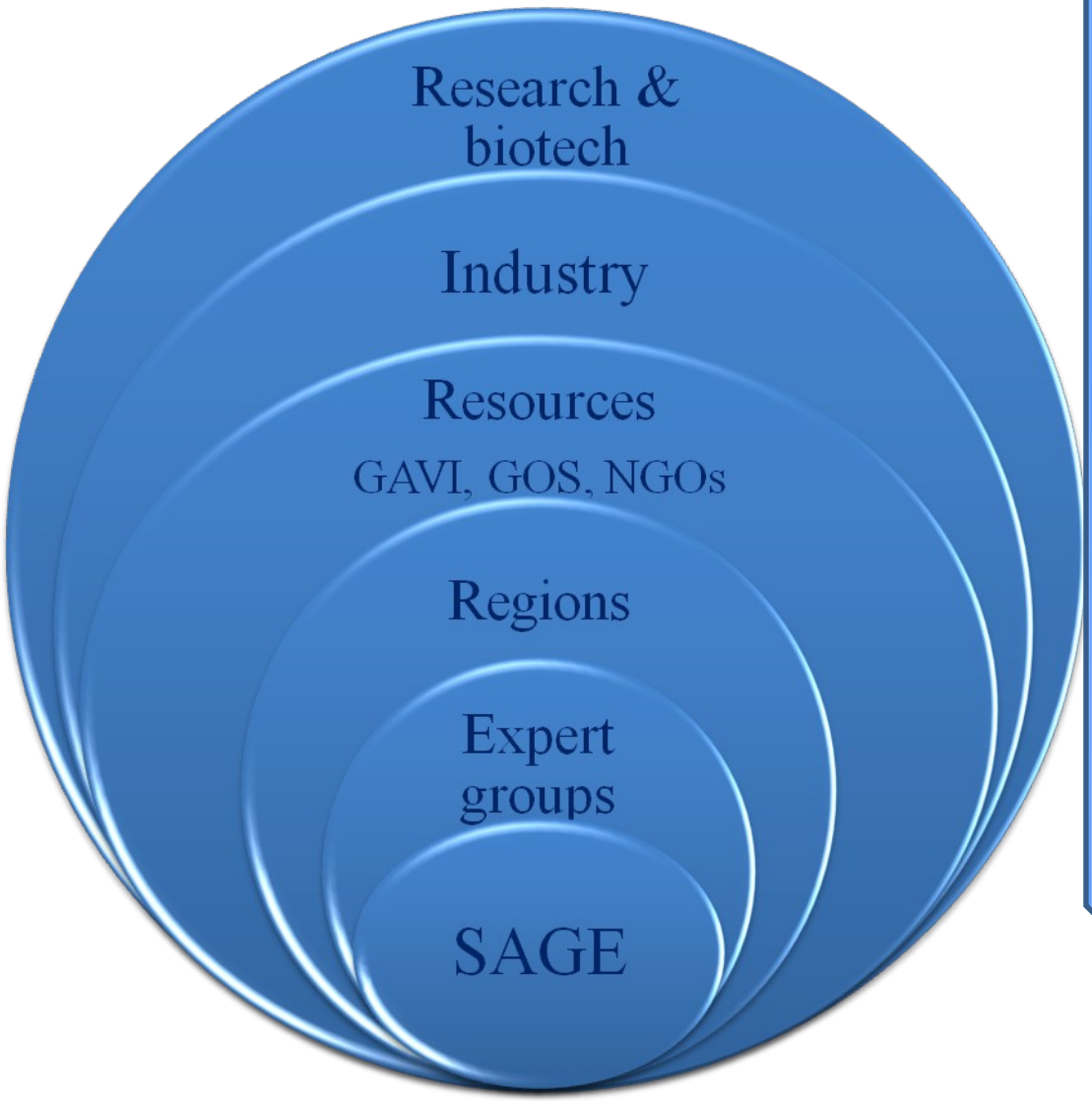


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# Key questions for SAGE.

- What groups should be immunised with A(H1N1) vaccine?
- How much vaccine will be needed?
- Which groups should be immunised first and in what order should other priority groups follow?
- What triggers could countries use to decide on vaccination of each or all groups?
- Should WHO make recommendations on adjuvanted, whole or plain vaccines? What doses will be effective – and impacts on capacity?

# Key questions for SAGE.

- What might be the consequences of regulatory decisions by industrialised countries on access to vaccines by developing countries?
- Will there be consequences from switching from trivalent seasonal to monovalent A(H1N1) vaccine?
- What will the impact be of A(H1N1) vaccine production on 2010 trivalent seasonal vaccine?
- For how long will monovalent A(H1N1) vaccine continue to be manufactured?
- Will 2010 seasonal vaccine be bivalent, trivalent or tetravalent?

World Health Organization

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# Strategic Advisory Group of Experts: Recommendations on the use of licensed human H5N1 influenza vaccines in the interpandemic period

Weekly epidemiological record
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12 June 2009, 84th year / 12 Juin 2009, 84e année
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