Overview of WHO's Strategic Advisory Group of Experts (SAGE) on Immunization

Jon S. Abramson MD, Chair of SAGE
Pathways for WHO Recommendations on Vaccine Use

- **Industry and other partners**
  - Global Advisory Committee on Vaccine Safety
  - Expert committee on Biological Standardization
  - Product Development for Vaccines Advisory Committee

- **Background Paper**
  - Relevant existing technical advisory committee
  - SAGE working group

- **SAGE**
  - Recommendations

- **WHO DG**
  - WHO Position Paper

- **Regional TAGS**
  - Regional consultations

- **Other relevant non immunization related WHO policy recommendation making body**

- **Input**
  - Request for review of evidence
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
  - 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 for how recommendations to the DG are made
  - Extensive representation from key partner organizations and industry
  - Experts invited as needed
  - Evidence-based – GRADing of quality of evidence (Grading of Recommendations Assessment, Development and Evaluation)
  - Working groups- ToR decided by WHO and SAGE. ≥2 SAGE members and ~ 8 outside experts make recommendations to SAGE to consider.
SAGE Recommendations
Issues Taken into Consideration

- Disease epidemiology and burden
- Clinical characteristics
- Vaccine and immunization characteristics
- Economic considerations
- Health system opportunities and existence of, and interaction with, other existing intervention and control strategies
- Social impact
- Legal and ethical considerations
- Off-label recommendations are considered acceptable
April 2015 SAGE Meeting

RUNNING ITEMS
- Global and Gavi Reports
- Report from other Advisory Committees on Immunization
  - Global Advisory Committee on Vaccine safety (GACVS)
  - Product Development for Vaccines Advisory Committee (PDVAC)
    - Role of PDVAC and interaction with SAGE clarified
      - No direct role in vaccine development
      - Access vaccine pipeline
      - Pre-licensure trial design
      - R&D roadmaps

SPECIFIC TOPICS
- Polio eradication
- Multiple injectable vaccines
- Pain mitigation at the time of vaccination
- Sustained access to vaccines in middle income countries
- Ebola vaccines and vaccination
- Maternal vaccination
- Pertussis vaccination schedules
October 2015 SAGE Meeting

RUNNING ITEMS
- Global and Gavi reports
- Report from other Advisory Committees on Immunization
  - Global Advisory Committee on Vaccine safety (GACVS)
  - Product Development for Vaccines Advisory Committee (PDVAC)
  - Report of the Immunization Practices Advisory Committee (IPAC)
  - Report of the Immunization and vaccines related implementation research advisory committee (IVIR-AC)
  - Report of the Expert Committee on Biological Standardization (ECBS)

SPECIFIC TOPICS
- Polio eradication
- Measles and Rubella vaccine
- Ebola vaccines
- Malaria vaccines - joint with Malaria Policy Advisory Committee
- Global Vaccine Action Plan
- Report on activities from international immunization partners
Examples of SAGE Vaccine Recommendations 2010 - 2015 (1)

- Hepatitis A- decreased recommended doses from 2 to 1.
- HPV- decreased recommended doses from 3 to 2 for those immunized between 9 – 14 yrs of age.
- Influenza- pregnant women given highest priority for getting the vaccine.
- Measles and Rubella elimination- all countries should give the combined measles and rubella vaccine rather than continuing separate immunization programs with each one.
- Meningococcal A- recommended a large scale immunization campaign using a conjugated meningococcal A vaccine ($0.50/ dose) for all 23 countries in the African meningitis belt.
  - In countries where this has been completed the disease incidence has decreased >95%.
  - Some of these countries have also begun routine infants immunization with this vaccine.
Examples of SAGE Vaccine Recommendations
2010 - 2015 (2)

- Pertussis WG- the global switch to acellular pertussis vaccine has been put on hold due to apparent lower efficacy of acellular vs whole cell pertussis vaccines. Use of vaccine in pregnant women recommended if increased infant deaths are occurring in a country.

- Rotavirus- removal of age restriction allows additional lives to be saved.

- Tick-borne encephalitis- consider use based on geographical disease incidence.

- Vaccine Non-specific Effects WG- evidence reviewed for BCG, DWP'T and measles vaccines. Studies considered to be inconclusive and no change in schedule recommended at this time.

- Yellow fever- only one dose needed and use in pregnant and lactating women should be considered in an outbreak setting based on risk-benefit assessment.
Anticipated New Topics for Discussion at SAGE in 2016

- Cholera vaccine- expanding the use of vaccines to control high incidence endemic disease and outbreaks
- Dengue virus vaccine- the potential use of the Sanofi Pasteur CYD-TDV dengue vaccine in high risk countries.
- Hepatitis B vaccine- increasing vaccination in infants and in others at high risk for the disease
- Maternal neonatal tetanus vaccination- how to improve vaccination rates and eliminate this disease
- Vaccine Shortages