Global guidance for immunization

WHO's Strategic Advisory Group of Experts (SAGE) on immunization and perspective on National Immunization Technical Advisory Groups

Philippe Duclos, WHO

Unravelling and understanding the roles of different bodies in the vaccines decision making, Les Pensières, Veyrier du Lac, November 26-28, 2012
Immunization Policy Advisory Framework

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 Technical Advisory Group on Immunization

- National policies & strategies
- Prioritize problems & define optimal solutions
- Implement national programme & monitor impact
Strategic Advisory Group of Experts (SAGE) on Immunization

Principal advisory group to WHO for vaccines and immunization → reports directly to D-G and involves all relevant WHO departments

Membership - 15 members
- Individual capacity
- Broad range of expertise, balance of professional affiliation & geographic representation
- Declarations of interest
- Selection panel - Public call for nominations

Meetings & processes
- Two meetings a year (April and Nov)
- Only plenary sessions – transparent process
- Extensive representation from key partner organizations including industry
- Experts invited as needed
- Evidence-based – GRADing of evidence
- Working groups

Report and communications
Pathways for WHO Recommendations on Vaccine Use

SAGE

Background Paper

Relevant existing technical advisory committee

WHO DG

WHO Position Paper

Regional TAGS

Regional consultations

Industry and other partners

Global Advisory Committee on Vaccine Safety

Expert committee on Biological Standardization

Immunization Practices Advisory Committee

Immunization and Vaccines Related Implementation Research Advisory Committee

Input

Request for review of evidence

Other relevant non immunization related WHO policy recommendation making body

Country Decision making
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 discussions at SAGE when issue is complex
- Not allowed to make decisions or speak on behalf of SAGE
- Time limited
Issues taken into consideration by SAGE

- Disease epidemiology
- Clinical characteristics
- Vaccines and immunization characteristics
- Economic considerations
Issues taken into consideration by SAGE

- Health system opportunities and existence of, and interaction with, other existing intervention and control strategies
- Social impacts
- Legal considerations
- Ethical considerations
2012-2014 SAGE Meetings: Some Key Topics

Cross-cutting
- DOV – GVAP: Monitoring & accountability
- Vaccination in humanitarian emergencies (Framework)
- Non specific effects of vaccines
- Dealing with vaccine hesitancy
- Financial challenges for lower middle income countries
- Maternal immunization
- Involvement of private sector

Vaccine specific
- Polio eradication
- Measles & rubella status report
- Impact/implementation monitoring (hepatitis B, meningitis)
- Pertussis
- Yellow Fever
- Varicella & herpes zoster
- Malaria
- Dengue
WHO Vaccine Position Papers

- Position papers = Key reference documents
- Developmental and review process (SAGE, extensive peer review including by industry, evidence-base, periodic updating)
- Published in the Weekly Epidemiological Record
- Additional posting of information on the web: Grading of recommendations Assessment, Development and Evaluation (GRADE) tables, references, summaries (one pager and PowerPoint presentation),…

World Health Organization
Updating of recommendations

- Need to adapt to evolving epidemiologic situation
- Need to reflect the best data available and update recommendations particularly after experience is gained on vaccine use and its impact
- Need to optimize programs and reduce their cost
- Position papers are reviewed periodically to determine critical need for full or brief update
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
# Impact of SAGE recommendations and vaccine position papers

<table>
<thead>
<tr>
<th>Countries</th>
<th>A STAKEHOLDERS' PANEL TO EVALUATE THE IMPACT OF &quot;STRENGTHENING WHO'S NORMATIVE AND POLICY SETTING FUNCTIONS FOR IMMUNIZATION, 2006-2010&quot;, March 2009</th>
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<tbody>
<tr>
<td>Partners</td>
<td>- The WHO Vaccine ACs play an increasingly central role in determining global vaccine policy.</td>
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<tr>
<td>Prequalification</td>
<td>- 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.</td>
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<tr>
<td>Industry</td>
<td>Timely guidance needed to avoid copy-paste from industrialized countries</td>
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First strategic objective: All countries commit to immunization as a priority

"National legislation, policies and resource allocation decisions should be informed by credible and current evidence regarding the direct and indirect impact of immunization. Much of the evidence base exists but does not reach policy-makers, as those who generate the evidence are not always those who interact with these decision-makers. ...."
First strategic objective: All countries commit to immunization as a priority

"Independent bodies such as regional or national immunization technical advisory groups (NITAGs) that can guide country policies and strategies based on local epidemiology and cost effectiveness should be established or strengthened, thus reducing dependency on external bodies for policy guidance. …It is important that NITAGs or their regional equivalents, engage with academia, professional societies, and other national agencies and committees..to ensure a cohesive and coordinated approach to achieving national health priorities….."
Purpose of National Immunization Technical Advisory Groups (NITAGs)

Technical resource and deliberative body to:

Guide/enable policy makers and program managers to make evidence-based immunization (all ages, all vaccines) related policy decisions

Empowers government:
- comprehensive and integrated approach
- neutral forum
- credibility of process
- help resist pressure from interest groups
National Immunization Technical Advisory Groups (NITAGs) in 2011* by WHO regions

- 59 Countries meeting the 6 NITAG criteria**
- 99 Countries having a NITAG with administrative or legislative basis
- 103 Countries Reporting the Existence of a NITAG with ToRs
- 114 Countries Reporting the Existence of a NITAG
- Not available
- Not applicable

*Based on the 2012 JRF

**Formal ToRs, legislative or administrative basis, at least 5 areas of expertise, at least one meeting a year, agenda distributed >= 1 week ahead of meetings, mandatory declaration of interests
NITAGs established in 35 countries, but the status, stage of development and extent of activity varies considerably. ETAGE is encouraged by progress made in the development of NITAGs within the Region, and acknowledges the high level of commitment shown by Member States, WHO and its partners, particularly SIVAC, in establishing and strengthening these groups.

ETAGE noted the broader focus of NITAGs in non GAVI eligible countries (all immunization including routine and SIAs) and was concerned by exclusive focus on new vaccines in GAVI eligible countries and was concerned with sustainability of rotavirus vaccine introduction in GAVI eligible countries with very low mortality.

ETAGE recognizes that NITAGs have specific requirements for information and support and encourages sharing of data and expertise both between NITAGs and with ETAGE and WHO.
Off-license indications

- Need for off-license indications
- Different perspective between National Regulatory Authorities (NRAs) and public health
- Need for understanding and communications
- Need incentives to reconcile when possible
- Need for guidance for NRAs and NITAGs
Thank you