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LIST OF ACRONYMS

ECBS  Expert Committee on Biological Standardization
GACVS  Global Advisory Committee on Vaccine Safety
GIVS  Global Immunization Vision and Strategy
IFFim  International Finance Facility for immunisation
ITAG  Immunization Technical Advisory Group
IVB  Department of Immunization, Vaccines and Biologicals
SAGE  Strategic Advisory Group of Experts
1. Background

Over the past decade, the global immunization landscape has changed substantially. There are many more stakeholders in the vaccine and immunization arena. The scope of immunization efforts has broadened, including a need to target wider age groups, an increased number of new vaccines and technologies becoming available, and emphasis on provision of other critical health interventions (e.g. malaria control and nutrition) at immunization contacts.

During 2004, recognizing the new challenges related to global immunization and the need to meet the Millennium Development Goals, WHO and UNICEF began rethinking the framework for their activities in this area. This strategic planning progress resulted in the Global Immunization and Vaccine Strategy (GIVS). Using GIVS as the foundation, and taking into account the WHO Director-General's intention to decentralize activities from WHO headquarters to regional and country offices, the Department of Immunization, Vaccines and Biologicals (IVB) developed its Strategic Plan for 2006-2009.

The GIVS includes areas identified as core functions for WHO headquarters, specifically immunization policy development; research and development of vaccines and immunization technologies; quality and safety; and access to immunization services. Immunization policy development provides the backbone of all other activities, both at WHO headquarters and in regions and countries. WHO relies on committees of scientific and public health experts from across the world to contribute to the development of these policies.

It had become increasingly apparent that the structure and operating mechanisms of the WHO advisory committees for vaccines and immunization were no longer appropriate to meet the challenges arising from the new environment.

Over the years many specialized advisory committees had been established. These committees had become independent from each other, leading to a loss of synergy and coherence in the formulation and dissemination of policies and recommendations, and an inability to be proactive.

It was clear that efforts were required to address these issues, and ultimately increase the acceptance of WHO policy and recommendations on vaccines and immunization. There was
consensus that this could be carried out through: 1) a more transparent and consultative framework for policy development than was in place; and 2) improved procedures for communication of policies to target audiences: national decision-makers — including responsible officers for national immunization programmes, national regulatory authorities, and safety monitoring groups; WHO staff at regional and country levels; immunization committees internal and external to WHO; the pharmaceutical industry; research organizations; other partner organizations such as UNICEF and the GAVI Alliance; and international professional organizations.

As a result, WHO/IVB with support from the Bill & Melinda Gates Foundation and WHO core resources decided to implement a project aimed at "Strengthening WHO's normative and policy-setting functions for immunization". The key objective of the project aimed for a five year period running till end of 2010 was to increase the acceptance of WHO policy recommendations on vaccines and immunization through a more transparent and consultative framework for policy development and improved procedures for communication of these policies to target audiences. In this context, WHO/IVB resolved to undertake a series of reforms aimed at improving the formulation of evidence-based policy recommendations and the functioning of the "Strategic Advisory Group of Experts" (SAGE) and other main advisory bodies with respect to policy formulation and norms and standards development such as the Expert Committee on Biological Standardization (ECBS) and the Global Advisory Committee on Vaccine Safety (GACVS).

An initial attempt at restructuring and improving the modus operandi of the SAGE to support the goals laid out in the GIVS has resulted in enhanced credibility. This was witnessed through the completion of another important element of this project i.e. a thorough external, independent high level review of the scope and roles of existing advisory committees for vaccines and immunization. The review acknowledged the centrality of SAGE and supported the recent reforms relating to transparency of the membership selection process and of deliberations and processes of working groups. As a result of this review a new comprehensive structure of advisory committees was adopted together with a definition of Advisory Committees and criteria for sound and effective committees. An enhancement of communications has taken place, including prompt publication and translation of the committee's conclusions. Vaccine position papers have been placed under
the umbrella of SAGE. The ability of the ECBS and the GACVS to deal with new vaccines through newly established working groups and processes has also sustained significant enhancements.

A mid-term independent evaluation was planned to assess progress with reaching the objective of the above mentioned project to allow the potential obstacles to the achievement of the Project's objective to be addressed. It was agreed that this evaluation would best be conducted by an independent panel representing key stakeholders of the global immunization community. The panel would also be asked to conduct a second and final review 5 years after the project onset.
2. Objectives of the Evaluation

Overall objective

To determine the impact of policy recommendations and norms and standards set by WHO and formulated by its key advisory committees

Specific objectives

1. To review whether the key objective of "increasing the acceptance of WHO policy recommendations" has been / is being met and to identify key recommendations to improve impact
2. To review the robustness and comprehensiveness of the current policy development framework
3. To review the "PERTINENCE" and "VALUE" of policies and recommendations in relation to the global immunization agenda
4. To assess the efficiency and effectiveness of the strategies outlined in the communications plan for reaching target audiences
5. To identify any additional benefits
3. Membership of the panel

In mid 2008, work began to constitute a panel with representation from across the global immunization community to undertake the above-mentioned evaluation.

The panel was composed of:

- Dr David Fleming, Chair of the Panel and Director and Health Officer for public health, Seattle and King County
- Dr Saeedeh Fakhrzadeh, Expert on Pharmaceutical and Biological Products, Ministry of Health and Medical Education, Islamic Republic of Iran
- Dr François Gasse, Senior Project Officer for Immunization, UNICEF
- Dr Alan Hinman, Senior Public Health Scientist, Task Force for Child Survival and Development, Decatur
- Dr Pierluigi Lopalco, European Center for Disease Prevention and Control, Solna
- Prof Peter Ndumbe, Dean, Faculty of Health Sciences, University of Buea – Cameroon and Chair of the African Region Task Force on Immunization
- Dr Pieter Neels, Federal Agency for Medicinal and Health Products, Brussels - Belgium
- Dr Nina Schwalbe, Director of Policy, GAVI Alliance
- Dr Pierre Ongolo-Zogo, Centre for Development of Best Practices in Health, Yaoundé Central Hospital, Faculty of Medicine and Biomedical Sciences, University of Yaoundé - Cameroon and Chair of the Steering Group, EVIPNet Africa
4. Methodology

The panel held one teleconference and two face-to-face meetings in November 2008 and February 2009.

The panel discussed extensively the framework and scope of work as well as the appropriate methodology. Acknowledging that the ideal was to measure the absolute impact (i.e. ability to lead to significant changes), the panel recognized the difficulties to tease out the impact of WHO's recommendations from many other factors. Taking into account the short timelines, it was agreed to organize the work around qualitative assessment by key actors such as national immunization programme managers, partner agencies, and members of advisory committees. A critical appraisal of internal monitoring and evaluation reports and communication strategies including dedicated web sites was conducted. Tools were agreed upon to assess the usefulness of the reports and recommendations, and any perceived recent changes; to solicit suggestions for ways to improve impact including identification of gaps in the WHO policy recommendations framework; to assess access and credibility of the recommendations; and to determine what is working or not.

The following summarizes information provided to the panel:

1. Background information (via a series of presentations and written documents) relating to the project "increasing the acceptance of WHO policies and recommendations on vaccines and immunization 2006-2010"; the report of an independent review previously undertaken to examine the functioning of the advisory committees and policy making processes; and a description of the structure and functioning of WHO immunization advisory committees with particular focus on SAGE, ECBS, and the GACVS, highlighting changes implemented as part of the project. This included advisory committees' terms of reference, agendas, and meeting reports.

2. Information on processes relating to the development of WHO policy recommendations on immunization and on the development of vaccine position papers including examples of vaccine position papers in both the initial (hepatitis B) and new format (23-valent polysaccharide pneumococcal vaccine), and the communications plan established in the context of the project.
3. Mapping of WHO's work and resources in relation to SAGE, GACVS, the ECBS and the position papers.

4. A list of potential indicators (including availability and limitations) for measuring access to and dissemination of WHO documents; reports of user surveys on the availability and format of documents; and general web statistics collected for 2006, 2007 and 2008 to assess the extent of use of the IVB web site and estimate evolution over time.

5. The volume of downloads for selected reports of SAGE and GACVS meetings and position papers on vaccines both prior and subsequent to implementation of a dissemination strategy (which began in May 2006 and was implemented in full from early 2007). The evolution of downloads over a period of three months for the three types of document was considered, again both prior and subsequent to implementation of the dissemination strategy. Lastly, the volume of downloads for the Arabic, Chinese, Russian and Spanish versions of one document over a three-month period were considered (Annex 1).

6. A series of WHO recommendations and/or committee statements or products provided as potential case studies for impact assessment. This included recommendations on the use of pneumococcal, rotavirus and *Haemophilus influenzae* type b vaccines, the development of a pneumococcal vaccine Target Product Profile, the GACVS statements on hepatitis B and multiple sclerosis, and an example of ECBS written standards.

7. Mapping of country compliance with WHO policy recommendations (Annex 2)

8. Several WHO recommendations from vaccine position papers or other WHO documents containing policy recommendations. Where possible, practice both prior and subsequent to the year of recommendation were considered. In instances when this was not possible, current practice or the period 2000-2007 as a whole were considered. The data source used was the WHO/UNICEF Joint Reporting Form submitted by Member States. Recommendations for the use of BCG (Bacille Calmette-Guérin), DTP (diphtheria-tetanus-pertussis), hepatitis B, and *Haemophilus influenzae* type b vaccines, the comprehensive multi-year plan and immunization safety were considered as examples.

9. The results of a global survey on national immunization technical advisory groups and national decision-making processes. This survey was conducted in collaboration with
the University of Ottawa, the Public Health Agency of Canada, and the University of Michigan (the latter for the European region).

10. Findings from a project completed by Oliver Wyman, in collaboration with WHO, relating to the development of post-eradication inactivated polio vaccine (IPV) supply strategies and focusing on conclusions from the project on the relative importance of WHO policy recommendations.

11. A report from McKinsey and Company on mapping of influencers in the vaccine introduction decision-making process in developing countries. This was part of the report “A better way to speed the adoption of vaccines”, published in the McKinsey Quarterly in August 2008.

12. The results from a survey of randomly selected countries conducted by McKinsey and Company upon the request of the stakeholders’ panel. The survey targeted national immunization managers (and other decision-makers on immunization at country level) and covered awareness and use of WHO recommendations and standards (Annex 3).

13. Reports from interviews held by panel members with the Chairs of ECBS, GACVS and SAGE (Annex 4) and with the Chair of the European Technical Advisory Group of Experts (ETAGE).

The panel was also updated on ongoing efforts to improve WHO guidelines and on relevant WHO activities aimed at strengthening WHO’s normative and policy-setting functions beyond the IVB department. This included information on EVIPNET - an evidence-informed policy network, which aims to: promote systematic use of evidence in policy-making in low and middle-income countries; and promote partnerships at country level between policymakers, researchers and civil society to facilitate policy development and implementation through use of the best scientific evidence available. Key background documents provided are listed in Annex 5 and a list of key informants included in Annex 6. All presentations delivered to the panel can be accessed at http://www.who.int/immunization/stakeholders_presentations/en/index.html.
5. Conclusions and Recommendations

SUMMARY CONCLUSION:

The WHO Vaccine Advisory Committees play an increasingly central role in determining global vaccine policy. WHO Vaccine Advisory Committee 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.

Brief discussion: Over the past several years, WHO has implemented a noteworthy programme of reform in the structure and operations of its Vaccine Advisory Committees. Details and documentation of the specific steps taken are outlined at http://www.who.int/immunization/stakeholders_presentations/en/index.html. Because policy recommendations are only part of an integrated process leading to successful immunization of a child, it is not possible to point to and count specific children who have been successfully immunized because of the resulting improved Vaccine Advisory Committee procedures and policy. Nonetheless, the evidence of impact is clear. The major global Alliance working to improve immunization in the developing world – GAVI -- now predicates its actions on WHO Vaccine Advisory Committee recommendations and Vaccine Position Papers. Countries, particularly developing countries, report that WHO recommendations are central to their policy making process. Evidence of SAGE recommendations driving vaccine introduction and immunization practice includes the rapidly expanding use of Hib and pneumococcal vaccines. Committee meetings are highly visible and well attended, and reviews by these committees are viewed as critical to the policy pathway for adoption of new vaccines, as evidenced by the large number of requests to have issues on the committee agendas. WHO should be proud of its accomplishments to date to increase the qualifications and credibility of members, transparency of process, effective use of evidence, and quality of resulting reports and recommendations.

Moving forward, the recommendations of this mid-grant evaluation report will need to be incorporated into the overall work plan for the remaining years of the Bill & Melinda Gates Foundation grant. Further, increasing thought needs to be given to how this project – its successes and lessons learned – should be incorporated more broadly into WHO’s Advisory Committee structure and policy setting functions in areas outside of immunization.

SUMMARY RECOMMENDATIONS:

1) WHO should be commended for the increasing prominence and impact of WHO Vaccine Advisory Committees in setting global immunization policy.

2) WHO should take immediate steps to consolidate and build on the successes of its Vaccine Advisory Committee reformation in five key areas, as outlined below:
I. The mission and objectives of the Advisory Committees;

II. The structure of Committees and their relation to WHO;

III. Staffing resources and agenda prioritization;

IV. Ongoing monitoring and evaluation;

V. Communication of Advisory Committee recommendations.

3) WHO should develop an action plan with timelines and deliverables integrated across these five work areas.

4) WHO should use the Vaccine Advisory Committee reformation process as a model for considering similar reform of its other normative policy setting Committees.

I. EVOLVING MISSION AND OBJECTIVES OF ADVISORY COMMITTEES:

CONCLUSION: The WHO Vaccine Advisory Committees should evolve to a more strategic approach that comprehensively considers the immunization challenges at both the global and national levels. This shift should include: 1) greater attention to cost effectiveness; 2) broader consideration of the role of immunization vis-à-vis other interventions; 3) barriers to adoption of new/underused vaccines at country level; and 4) barriers to use of/adoption of evidence-based national immunization policies and practice, including resistance to vaccination by some civil society groups.

Brief discussion: The review undertaken by this Panel (see Section 4 - Methodology) provided ample evidence that the global immunization landscape is rapidly evolving and new challenges are emerging for those providing strategic thinking and advice for WHO. One set of challenges centers on the increasing importance of transnational issues and regional and global strategies for the introduction of new vaccines, vaccine technology, and immunization practices. A second set of challenges revolves around the increasing need for attention to barriers to delivery of immunization at the front line and the need to foster the development of robust National Regulatory Authorities and National Technical Advisory Groups. These challenges must be met by increased evidence-based decision making, improved governance, inclusiveness, transparency, and equity in order to achieve the health related Millennium Development Goals. As one example, while recognising recent improvements in economic analyses in Advisory Committee Recommendations and Vaccine Position Papers, the Panel believes that need still goes beyond current Committee practice. Financial constraints are identified by many as the main barrier in adopting new vaccines, highlighting the need for stronger and contextualized economic analysis/cost effectiveness analysis, including the assessment of opportunity costs and the potential to create synergies between EPI and other interventions at country level. The Panel understands that the Quantitative
Immunization and Vaccines Related Research Advisory Committee (QUIVER) has initiated work in this domain.

**Specific recommendations for WHO:**

1) Vaccine Advisory Committees should assume a broader and increasingly strategic perspective in their review of evidence and in the nature of their recommendations. This could include, for example:

   a. More robust economic analyses including both cost effectiveness and opportunity costs for developing countries with limited health budgets;

   b. Further enhancing analysis of immunization interventions in relation to other non-immunization interventions;

   c. Consideration of health systems and other barriers to adoption of new and underused vaccines at country level, barriers to implementation of evidence-based national immunization policies, and resistance to vaccination by some civil society groups.

2) Vaccine Advisory Committees should conduct an ongoing “horizon scan” of emerging global and transnational issues and explicitly dedicate a portion of their agenda to these issues. Examples of recommendations flowing from this work might include, for example:

   a. Value and methods of harmonization of national immunization policies across borders;

   b. Development of Target Product Profiles of desirable new vaccines, even in the absence of dedicated funding, for example, an Advance Market Commitment.

3) WHO and Vaccine Advisory Committees should consider options for playing more active role in encouraging and assisting in the development of robust national immunization Technical Advisory Groups and National Regulatory Agencies in developing countries, including the development and active promulgation of recommendations for the formation and operation of such groups.

4) Membership in Advisory Committees should include consideration of the skills and background necessary for these evolving roles. Special active and ongoing attention should be given to identifying appropriate expertise from regions that have experienced historical difficulties in membership recruitment.
II. THE STRUCTURES OF COMMITTEES AND THEIR RELATION TO WHO

CONCLUSION: WHO has made remarkable progress in increasing the transparency, quality, and engagement of outside stakeholders and experts in its Vaccine Advisory Committee process. However, the Panel recommends continued work to further evolve and clarify the roles of the Committees relative to WHO and to continue to refine, streamline, and delineate Committee organizational structure.

Brief discussion: There is continuing uncertainty regarding the respective role and responsibilities of Advisory Committees relative to WHO, including agreement on when recommendations become sufficiently certain to guide stakeholder policy action. In other words, what is the process and timing by which an advisory recommendation becomes official WHO policy? This uncertainty is accentuated by concerns regarding the timeliness of Advisory Committees’ recommendations, especially the delay between finalization of Advisory Committee recommendations and official release of recommendations by WHO. As a remedy, the Panel recommends better delineation of roles and responsibilities of the Advisory Committees. This delineation should be carried out in the context of the clear added value of the reformed Vaccine Advisory Committee model in comparison to other WHO advisory committees. The panel also recommends collaboration with other groups within WHO working on delivery of interventions and health systems, and with national regulatory authorities. As a separate issue, the internal organizational and reporting structure of the Committees and relationships and linkages with other regional/national bodies remains ill-defined. Procedures of Advisory Committees are often not well known amongst interested parties such as relevant civil society groups, medical associations and media.

Specific recommendations for WHO:

1) Develop a model timeline of the optimum vaccine recommendation process, including mapping the process/relationship between advisory committee recommendations and official WHO policy.

2) Include stages at which recommendations can be adopted by stakeholders.

3) Examine and implement options to further minimize the time lag between Advisory Committee recommendations and incorporation into WHO policy.

4) Create a clear, usable, and short explanatory document outlining Vaccine Advisory Committee organizational structure, including roles and relationships. Opportunities for further streamlining of function should be considered as this document is developed.

5) Actively explore opportunities and develop mechanisms to ensure support of outside entities, including international civil society organizations and other credible professional
organizations that develop recommendations on issues that may overlap with WHO Vaccine Advisory Committee work. This would enhance country buy-in.

III. STAFFING RESOURCES AND AGENDA PRIORITIZATION

CONCLUSION: The process of developing WHO vaccine and immunization recommendations has been substantially improved as a result of the Vaccine Advisory Committee process reform undertaken over the past several years. The Panel is very concerned, however, about a current and intensifying mismatch between Secretariat staffing needs and existing resources resulting from the new processes and intensifying demand. Urgent action is needed to: 1) assure maximum staffing efficiency; 2) increase staffing resources to align with current demands; 3) identify and assure long-term resources for continuing the reformed and improved Advisory Committee processes; and 4) develop deliberate and transparent mechanisms to prioritize issues brought to Committees for consideration.

Brief discussion: A primary concern of this Panel is that the resources required to continue and maintain the Vaccine Advisory Committee reform have not been assured, and that the process will eventually fail as a result. While the Panel did not have the time or expertise to make detailed, specific recommendations regarding staffing needs, it appears that the current system is insufficiently staffed and potentially not maximally efficient. This mismatch between capacity and expectations is likely to worsen with increasing workload as the agendas of the Committees become more crowded over time. Moreover, much of the current system is financed through a time-limited grant from the Bill & Melinda Gates Foundation. The Panel believes that WHO must address financial and human resource needs with a sense of urgency, given the time limitation of the Bill & Melinda Gates Foundation's grant. In addition, none of the Committees appear to have an explicitly stated mechanism for setting priorities for which issues are brought for consideration and there is the potential for unbalanced agendas driven mostly by products rather than delivery and programme issues. Robust mechanisms to assure prioritization of issues of importance to front-line programmes and practitioners do not seem to be in place.

Specific recommendations for WHO:

1) Conduct a cross-committee assessment to identify opportunities for staffing and process efficiency.

2) Assess and align assigned Secretariat workload with available human resources, increasing these resources as needed to meet required duties.
3) Assure adequate support of Committees by WHO technical staff (including non-Secretariat staff) and by WHO centralized resources, including language translation of recommendations and position papers.

4) Develop explicit and transparent criteria and processes for prioritization of Committee agendas. Consider the role that Regional advisory committees can play in sharing the expanded workload.

5) Further strengthen specific processes for soliciting agenda items from key stakeholders, especially developing countries, and for identifying programmatic and delivery barriers that could benefit from Committee consideration and recommendations.

IV. ONGOING MONITORING AND EVALUATION

CONCLUSION: The Panel was able to identify sufficient information regarding evaluation of Advisory Committee processes and outcomes to comfortably develop this set of findings regarding Advisory Committee impact and opportunities for improved function. However, critical gaps exist in how this information is being used. A systematic and ongoing monitoring and evaluation process is needed and should be rapidly developed and implemented.

Brief discussion:

Identification and ongoing monitoring of measures of Committee performance is critical. Currently, only minimal information is collected and this information is not routinely analysed. The informational interviews of Committee Chairs and the one time survey conducted by McKinsey and Company for this project (Section 6) are examples of the insights that can be gained by feedback from stakeholders. To monitor implementation of committee recommendations, review using existing routine data sources (i.e. WHO/UNICEF Joint Reporting Form) should be undertaken and appropriate follow up actions identified by WHO.

Specific recommendations for WHO:

1) Refine and implement a simple set of management indicators to monitor key recommendation attributes such as timeliness, accessibility, distribution and uptake of recommendations.

2) Clearly identify the range of intended end-users of recommendations and strengthen systems to periodically and routinely solicit their feedback.
3) Systematically track uptake by countries of key recommendations. Routinely identify countries that have not adopted recommendations and investigate reasons for non-adoption, particularly as they relate to the recommending process itself.

4) Periodically solicit evaluation feedback from committee chairs and members.

V. COMMUNICATION OF ADVISORY COMMITTEE RECOMMENDATIONS:

CONCLUSION: On balance, recommendations and position papers are available to and accessed by many of the important stakeholders for whom they are intended. However, the penetration and timely use of the recommendations could be improved by a more aggressive communication plan that actively pushes documents to key users, makes better use of dissemination through alternate channels including the media, and employs summaries specifically designed for policy makers and others not interested in the full technical detail.

Brief discussion:

One goal of the Vaccine Advisory Committee reform has been to increase the dissemination of timely and clear information regarding recommendations. Recommendations that are not translated into practice have no value, making effective communication of recommendations an essential part of the overall process. Over the past several years, progress has been made in this regard – Advisory Committee recommendations are available to and recognized by many key users as important quality documents. That said, considerable room for improvement remains. Numbers regarding web site access and downloads of key documents are disappointingly small. A comprehensive definition of key end-users has not been developed nor has an active list been maintained. To date, individuals beyond technical immunization staff, including, for example, policy makers, universities, ministries, civil society groups, media, and medical associations have not been prioritized in communication strategies. And strategies for more effective dissemination to a broader audience, including the routine development of alternative shorter documents summarizing recommendations and more effective use of the media and WHO Country representative have not been routinely employed.

Specific recommendations for WHO:

1) Take active steps to increase the access and use of Advisory Committee Recommendations and Vaccine Position Papers, including for example:

a. Proactively “pushing” documents by e-mail to an established and current list of key in-country users;
b. Improving WHO web site search functions and linkage to search engines, particularly for Advisory Committee recommendations;

c. Better using WHO Country representatives in disseminating recommendations and policies at the national level;

d. Creating synergies with existing regional and national initiatives to promote evidence–to-policy such as EVIPNet.

2) Create a user-friendly summary for each key recommendation for use by policy makers and stakeholders with less interest in specific technical details.

3) Employ the media more effectively through the routine use of press releases, particularly those accompanying key recommendations. Press releases should emphasize the role of external experts in the formulation of WHO policies.

4) Continue to translate recommendations into all the UN languages pending actions to increase the overall accessibility and use of the recommendations and Vaccine Position Papers. Re-evaluate once a more robust system is in place.

5) Evaluate the feasibility of making Advisory Committee members more available to countries and National Technical Advisory Groups at the time they are considering adoption and implementation of Advisory Committee recommendations.
6. Annexes

Annex 1: Web statistics for WHO policy documents on immunization. What do they tell us?
(Prepared by WHO Department of Immunization, Vaccines and Biologicals)
Web statistics for WHO policy documents on immunization

What do they tell us?

2nd Meeting of the Stakeholders' Panel to review progress in
"Strengthening WHO's normative and policy-setting functions for
immunization 2006-2010"

4-5 February 2009

Methodology (1)

- Web statistics downloaded for date of publication of Weekly Epidemiological Record for:
- 4 reports of SAGE meetings
  - 2 prior to implementation of dissemination plan (Jan 04 and Jan 06)
  - 2 post implementation of dissemination plan (Jan 08 and Jan 09)
- 4 position papers on vaccines
  - 2 prior to implementation of dissemination plan (yellow fever: Oct 03; influenza: Aug 05)
  - 2 post implementation of dissemination plan (rotavirus: Aug 07; PPV23: Oct 08)
- 4 reports of GACVS meetings
  - 2 prior to implementation of dissemination plan (Jan 04 and Jan 05)
  - 2 post implementation of dissemination plan (Jan 07 and Aug 08)
Downloads for SAGE reports

Other topics copied in same issue
Jan 04: avian influenza outbreak news, International Health Regulations
Jan 06: avian influenza outbreak news, International Health Regulations, web sites on infectious diseases
Jan 08: corrigendum
Jan 09: No other story

Downloads for position papers on vaccines

Other topics covered in same issue
Oct 03: Meningitis funds appeal, web sites on infectious diseases, International Health Regulations
Aug 05: Outbreak news, H5N1 avian influenza – vaccine development, polio: mandatory immunization for travellers arriving in Saudi Arabia, International Health Regulations
Aug 07: WHO web sites on infectious diseases
Oct 08: No other story
Downloads for GACVS reports

Other topics covered in same issue
Jan 04: Avian influenza, SARS, reducing global measles deaths, influenza, corrigendum, International Health Regulations
Jan 05: Outbreak news, polio outbreak, influenza, International Health Regulations
Jan 07: Outbreak news, International Health Regulations
Aug 08: WHO/CDC meeting on lab quality systems

Comparison of level of downloads for different types of report over 5 year period

Cholera (Aug 07) – week preceding rotavirus position paper
Report of Advisory Committee on Polio Eradication – week following SAGE report
Observations

- For all reports, decrease rather than increase over the period
- Quite possible that other topics in same issues of WER impact level of download (e.g. outbreak info)
- No consistent increase from publication date (Friday) to Monday of number of downloads
- No clear difference in volume over 5-year period for different types of report (SAGE/GACVS/position papers)

Methodology (2)

- Web statistics downloaded for WER for specific reports over a 3-month period
- 2 reports of SAGE meetings
  - 1 prior to implementation of dissemination plan (Jan 06)
  - 1 post implementation of dissemination plan (Jan 08)
- 2 position papers on vaccines
  - 1 prior to implementation of dissemination plan (influenza: Aug 05)
  - 1 post implementation of dissemination plan (PPV23: Oct 08)
- 2 reports of GACVS meetings
  - 1 prior to implementation of dissemination plan (Jan 04)
  - 1 post implementation of dissemination plan (Aug 08)
Downloads of WER reports over a 3-month period
Report of SAGE meeting published Jan 06

Access to WER reports over a 3-month period
Report of SAGE meeting published Jan 08
Access to WER reports over a 3-month period
WHO position paper on influenza vaccines – published Aug 05

Access to WER reports over a 3-month period
WHO position paper on PPV23 vaccines – published Oct 08
Access to WER reports over a 3-month period

Report on GACVS published Jan 04

[Graph image]

Access to WER reports over a 3-month period

Report on GACVS published Aug 08

[Graph image]
Observation

- For all reports, highest number of downloads is at time of publication, followed by rapid decrease

Methodology (3)

- Web statistics downloaded for Arabic, Chinese, Russian and Spanish versions of position paper on rotavirus vaccines over a 3-month period
Access to non-English WER reports over a 3-month period

Position paper on rotavirus vaccine - Arabic

Access to non-English WER reports over a 3-month period

Position paper on rotavirus vaccine - Chinese
Access to non-English WER reports over a 3-month period

Position paper on rotavirus vaccine - Russian

Access to non-English WER reports over a 3-month period

Position paper on rotavirus vaccine - Spanish
Observations

- Number of downloads very low for Arabic, Chinese, Spanish and Russian
  - Arabic (3 per day); Chinese (4 per day); Russian (12 per day); Spanish (8 per day)

Conclusions

- Statistics give us an idea of volume of downloads per report and evolution over time
- Do not provide evidence of increased access following more robust processes and systematic dissemination
- For non-English versions, either:
  - Poor investment of time, or
  - Need to be much more proactive in informing target audiences of availability
Annex 2: Mapping of country compliance with WHO policy recommendations
(prepared by WHO Department of Immunization, Vaccines and Biologicals)

Method:
Several WHO recommendations were selected from vaccine position papers or other WHO documents containing policy recommendations. If it was possible we defined the year of recommendation and looked at practice prior and after the recommendation. In some instances it was not possible to determine the baseline year, in this case we looked at current practice or the trend between 2000-2007.

Data source:
WHO collects data on immunization coverage, and selected vaccine preventable diseases. Beginning in 1998 WHO and UNICEF started a joint data collection and they collected data on national immunization systems through the WHO/UNICEF Joint Reporting Form on Immunization (JRF). The Joint Reporting Form annually collects national level data on:

- the incidence of selected vaccine preventable diseases,
- immunization coverage,
- recommended immunization schedules,
- vaccine supply, and
- other information on the structure, policies and performance of national immunization systems.

The data-collection form is reviewed periodically by WHO and UNICEF and, if necessary, modifications are made and translated into French, Russian and Spanish.

National authorities complete the form using one of the data-collection tools and submit the data to WHO and UNICEF during the second quarter of each year. Final country reports are available by early September and disseminated through a variety of mechanisms, including the World Wide Web, the annual joint WHO/UNICEF Immunization Summary http://www.unicef.org/publications/index_38256.html and the WHO Vaccine-Preventable Diseases: Monitoring System, Global Summary http://www.who.int/immunization/documents/WHO_IVB_2007/en/index.html.

Further information and copies of the print documents are available at the following websites:


UNICEF: http://www.childinfo.org/areas/immunization/

Unless otherwise specified this is the source of the data used for the analysis below.

Immunization policy:

BCG
The regularly-reviewed EPI policy recommendation for BCG is to continue the use of the vaccine as it prevents severe TB in some, but not all children who have been immunized. There should be no BCG booster doses. Should countries, based on cost-effectiveness considerations, decide to discontinue the use of BCG, WHO recommends applying the criteria defined by the International Union against Tuberculosis and Lung Disease (IUATLD). The criteria essentially refer to the requirement for an efficient case-notification system against a background of very low national prevalence figures for all forms of TB.
In 2003 there were 27 member states offering booster dose

In 2007 there were still 12 member states offering BCG booster dose. 11 in European region and 1 in African region

In countries with a high burden of TB, a single dose of BCG vaccine should be given to all infants as soon as possible after birth.  

In 2003 6 member states offering 1st dose of BCG for children older than 12 months. (3 EUR, 1 EMR, 1 AMR, 1 WPR)

In 2007 there were still 5 member states offering 1st dose of BCG for children older than 12 months. (3 EUR, 1 EMR, 1 AMR)

**DTP**

The recommended schedule for vaccination against diphtheria varies considerably between countries. According to the WHO/EPI schedule, the primary series of DTwP- or DTaP-containing vaccines should be administered in 3 doses, starting as early as 6 weeks of age and given with a minimum interval of 4 weeks. Where resources permit, additional doses can be given after the completion of the primary series. Many national immunization programmes offer 1-2 booster doses, for example one at 2 years of age and a second at age 4-7 years.  

The main aim of pertussis vaccination is to reduce the risk of severe pertussis in infancy. The vaccine is usually administered in the national childhood immunization programme as combined DTwP or DTaP vaccine, although the combination often includes additional vaccines (Haemophilus influenzae type b (Hib), hepatitis B (HepB), poliovirus vaccine (IPV)). The optimal schedule and number of immunizations are not well defined but, in most countries, 3 primary doses are administered with at least a 1-month interval to infants aged 2–6 months. A booster dose is commonly offered 1–6 years later. WHO recommends the primary series to be administered at the age of 6, 10 and 14 weeks. National recommendations vary considerably, however.  

In 1994/95 1 Member state starting DTP3 before 6 weeks (schedule is 4,8,12 weeks)  
- Papua New Guinea (1,2,3 months)

In 2007 2 Member state starting DTP3 before 6 weeks (schedule is 4,8,12 weeks)  
- United republic of Tanzania (Zanzibar offers 6,10,14 weeks)
- Papua New Guinea

In 1994/95 and in 2007 no member states give DTP doses in shorter than 4 weeks interval.

In 1994/95 104 (or 54%) member states giving booster dose of DTP.
In 2007 126 (or 65%) member states giving booster dose of DTP.

| Number and % of member states providing DTP booster dose by WHO regions, 1994/95 and 2007 |
|---------------------------------|-----------------|-----------------|
| WHO region | 1994/95 | 2007 |
| AFR | 10 (22%) | 9 (20%) |
| AMR | 25 (71%) | 32 (91%) |
| EMR | 13 (62%) | 16 (76%) |
| EUR* | 40 (75%) | 52 (98%) |
| SEAR | 5 (45%) | 3 (27%) |
| WPR | 11 (41%) | 14 (52%) |
| Total | 104 (54%) | 126 (65%) |

* in 1995 for 5 countries and in 2007 for 1 country information is not available

Number and % of member states providing DTP booster dose by World Bank regions by income status, 1994/95 and 2007

| Number and % of member states providing DTP booster dose by World Bank regions by income status, 1994/95 and 2007 |
|-------------------------------------------------|-----------------|-----------------|
| Income status | 1994/95 | 2007 |
| High Income * | 35 (73%) | 46 (96%) |
| Middle income* | 60 (65%) | 72 (78%) |
| Low income | 9 (18%) | 6 (12%) |
| not classified by WB | 0 | 2 |
| Total | 104 (54%) | 126 (65%) |

* in 1995 for 5 countries (3 high income and 2 middle income) and in 2007 for 1 high income country information is not available

Note: 11 countries offered booster dose in 1994/95 and discontinued.


**HepB**

It is **recommended that all infants receive three doses of hepatitis B vaccine during the first year of life.** More recently, some countries have been using a combination vaccine that includes vaccines for diphtheria, tetanus, pertussis, hepatitis B (hepB), and sometimes *Haemophilus influenzae* type b (Hib). Programmatically, it is usually easiest if the three doses of hepatitis B vaccine are given at the same time as the three doses of DTP. In countries where hepatitis B is highly endemic, where feasible, a birth dose of hepB is included in the schedule to prevent perinatal hepatitis B infection. Some countries also recommend immunizing adolescents, health workers and other risk groups.

Routine vaccination of all infants against HBV infection should become an integral part of national immunization schedules worldwide. High coverage with the primary vaccine series among infants has the greatest overall impact on the prevalence of chronic HBV infection in children and should be the highest HBV-related priority.
In 2003 137 member states introduced HepB in national immunization schedule.

By 2007 171 member states introduced HepB in national immunization schedule (of which 2 countries India and Sudan in part of the country)

In countries of high disease endemicity (HBsAg prevalence >8%), HBV is mainly spread from mother to infant at birth or from child to child during early childhood (<5 years). **In this epidemiological setting, schedules providing the first vaccine dose at birth are recommended.**


In 2003 Birth dose is in national immunization schedule for 76 member states (39%)
37 (43%) in high prevalence countries
29 (47%) in Intermediate prevalence countries
10 (23%) in low prevalence countries

In 2007 Birth dose is in national immunization schedule for 81 member states (42%)
38 (44%) in high prevalence countries
33 (53%) in Intermediate prevalence countries
10 (23%) in low prevalence countries

Note: 2 countries offered birth dose in 2003 and changed the schedule between 2003-2006
**Hib**

Routine Hib vaccination, bearing in mind issues such as vaccine supply and cost, and carefully exploring financing options. Cost-benefit studies would also be needed. Whether all countries need to undertake all of these activities has not been resolved. Limitations in laboratory capacity were identified as major impediments that needed to be properly addressed. New financing opportunities for the poorest countries, particularly through the Global Alliance for Vaccines and Immunization and the IFFIm, will need to be encouraged. SAGE strongly recommended that this new framework (GAVI Hib initiative) for Hib introduction should be expanded to the fullest extent possible to increase demand for the vaccine and accelerate the lowering of its price.

SAGE also recommended **global implementation of Hib vaccination** – unless robust epidemiological evidence exists of low disease burden, lack of benefit or overwhelming impediments to implementation.

*Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005*

In 2005 100 member states introduced Hib in national infant immunization schedule. Global coverage in 2005 21%

By 2007 115 member states introduced Hib in national infant immunization schedule. (of which 3 in part of the country)

**Number of countries introduced Hib vaccine** and global infant Hib3 coverage, 1989-2007

![Graph showing number of countries and global coverage](image)

**cMYP**

The decision to develop a cMYP should be made by each country, taking into account the timing of existing national planning instruments (e.g. health sector plans, annual budgets and medium-term expenditure frameworks). Ideally the timing should be fully synchronized with the health sector planning process. If not fully synchronized, a new cMYP should be prepared.
a year before the expiry of the current multi-year plan, and should not extend beyond the limit
of the health sector plan.
In addition, the objectives, strategies, cost and financing information
Source: WHO-UNICEF guidelines for developing a comprehensive multi-year plan (cMYP)
WHO/IVB/05.20

As of 2008 in total 69 countries developed cMYP and 56 us using cMYP costing tool.

<table>
<thead>
<tr>
<th>WHO region</th>
<th>N of countries with cMYP</th>
<th>Costing tool included</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>36</td>
<td>34</td>
</tr>
<tr>
<td>AMR</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>EMR</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>EUR</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>SEAR</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>WPR</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>69</strong></td>
<td><strong>56</strong></td>
</tr>
</tbody>
</table>

Source: cMYP immunization database, as of January 2009 be the appropriate source
(K:\Jenner_Public\EPI_new\Functional Groups\cMYP Functional Group\FunctionalMYPs Final)

Data is not available prior to the guidelines.

**Safety**

Standard disposable syringes should no longer be used for immunization.

WHO, UNICEF and UNFPA urge that, by the end of 2003, all countries should
use only auto-disable syringes for immunization.

Source: WHO, UNICEF and UNFPA joint statement on the use of auto-disable syringes in
immunization services, 1999

**Number of countries using: AD syringes**

<table>
<thead>
<tr>
<th></th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
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<td>27</td>
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<tr>
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<td><strong>97</strong></td>
<td><strong>113</strong></td>
<td><strong>113</strong></td>
<td><strong>119</strong></td>
<td><strong>118</strong></td>
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</tbody>
</table>

**Number of countries using: Sterilizable syringes**

<table>
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<th></th>
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<th>2002</th>
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<tbody>
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<td>1</td>
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<tr>
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<tr>
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<td>1</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
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</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>WPR</td>
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<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>31</strong></td>
<td><strong>27</strong></td>
<td><strong>16</strong></td>
<td><strong>8</strong></td>
<td><strong>7</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>
Number of countries where safety boxes distributed with all vaccine deliveries.

<table>
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<th></th>
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<th>2002</th>
<th>2003</th>
<th>2004</th>
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</thead>
<tbody>
<tr>
<td>AFR</td>
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<td>AMR</td>
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<td>19</td>
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<tr>
<td>EMR</td>
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<td>13</td>
<td>11</td>
<td>14</td>
<td>16</td>
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</tr>
<tr>
<td>EUR</td>
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<td>17</td>
<td>21</td>
<td>26</td>
<td>27</td>
<td>26</td>
<td>24</td>
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<tr>
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<td>9</td>
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<td>9</td>
</tr>
<tr>
<td>WPR</td>
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<td>19</td>
<td>19</td>
<td>22</td>
<td>21</td>
<td>21</td>
<td>20</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
<td>100</td>
<td>107</td>
<td>129</td>
<td>132</td>
<td>132</td>
<td>137</td>
<td>139</td>
</tr>
</tbody>
</table>

Reasons for lack of adherence with WHO policy recommendations:
There is no systematic collection of information on reasons why some recommendations are not followed and the reasons certainly defer depending on the type of recommendation. Lack of adherence could mean delays to implement a new policy or a definite choice not to implement a WHO policy recommendation. The cause can be multi-factorial. We have some idea of the reasons through interaction with the countries. For many of the policy recommendations financial constraints are an issue. For others such as use of booster dose of BCG, this is very regional and deeply anchored in the culture and history of the scientific establishment and the fact that some industrialized and or historically influential countries were continuing booster doses did not help.

The global survey of national immunization decision making processes implemented in 2008 brings some indirect information as highlighted in the following figure.

Figure 1: The main challenges countries encountered when making immunization policy decisions in descending order. (Global immunization policy making processes. Bryson M, et al. to be submitted for publication)

1) Securing funding  
2) Capturing the epidemiology of disease in home country  
3) Coordination or government and stakeholders  
4) Implementation of immunization policies  
5) Introduction of new vaccines or scheduling of vaccines  
6) Coverage rates and reaching target groups  
7) Lack of human resources  
7) Lengthy policy making process  
9) Lack of technical expertise  
9) No active Immunization Technical Advisory Group (ITAG)  
11) Need to strengthen ITAG to work more effectively  
12) Lack of immunization legislation

For some of the policy recommendations such as with respect to vaccine introduction the decision/or delay to implement a policy recommendation may be a logical one for a country in view of overall health priorities and opportunity cost.

It is unknown to what extent the relevance and credibility of WHO recommendations, the lack of clarity in the recommendations, or absence of communication of the policy recommendations impact the acceptance and or their implementation. This should be
informed by the results of the Country survey of the awareness and use of WHO recommendations and standards being implemented by McKinsey Inc.
Executive summary (1/2)

The overall objective of the survey was to understand the impact on key decision makers in-country of WHO normative/policy guidance on vaccines and immunisation. In addition, we sought to hear suggestions for improvement in content, communication, and access.

Our approach was to understand country perspectives through an online survey with questions on awareness, understanding, and use of WHO normative and policy guidance:

- We selected a set of 24 representative countries to ensure that a broad range of perspectives were heard. The countries (18 primary countries and 6 alternatives) were randomly selected within income and regional categories to ensure balance.
- There were 35 respondents from 19 countries. Respondents were primarily EPI managers, but we also received responses from others in the Ministry of Health, NRA, and those on technical advisory groups.
- We followed up online survey results with several phone interviews to delve deeper to understand impact.

Results from survey highlighted several key findings:

- Overall, WHO Vaccine Position Papers are seen as excellent quality and useful tools for low income and middle income countries alike. A high percentage of decision makers in the survey sample were aware of VPPs and have read and considered them.
- Though respondents felt VPPs were of excellent quality, particularly in terms of scientific information on disease and vaccines, there are several areas for potential improvement:
  - On content, the biggest gap perceived in the VPPs is on cost effectiveness. The major barrier to implementing a vaccine or a VPP for most countries is cost, and cost-effectiveness was seen as the lowest quality aspect of VPP content.
  - On communication, there were many suggestions for WHO to write a summary using call-outs and bullet points that could accompany the VPPs so that they can be more easily digested and shared.
  - Distribution and access of the recommendations can also be improved. Currently only people within health and immunisation departments read and discuss the papers. This is despite the fact that the Ministry of Finance is cited as one of the most important influencers in vaccine adoption decisions.
Executive summary (2/2)

- Most people are familiar with the Global Advisory Committee on Vaccine Safety and consider the statements, though there is no difference in familiarity between National Regulatory Authority focal points and other Ministry of Health staff.
- However, less than 50% of respondents are aware of Expert Committee on Biological Standardization, and only a few extensively consider the statements.

Lessons learned through the process and results raise potential implications and recommendations for SAGE and WHO:

- On cost effectiveness, VPPs could potentially try to incorporate high-level cost-benefit tradeoffs for countries to consider. If the VPPs are not the best way to address cost effectiveness, are there ways to address it? For example, at a regional level could WHO give guidelines to countries? Is there a tool that countries could use?
- Communication methods should broaden to convey the recommendations in multiple ways to supplement the Weekly Epidemiological Record (WER)
  - WHO should supplement the WER with high-level bullet points in an email or through summaries in powerpoint that could be distributed/shared with others at a country level
  - WHO could also collaborate with others-- e.g., could the World Bank include flash news of VPP recommendations in their communications to MOF? What about press releases?
  - The committee should also consider members of SAGE making themselves available to key policy making bodies.
- Distribution format should ensure up-to-date contact lists and find creative ways to reach senior officials in the MOH and relevant contacts in the MOF
  - The distribution list should be kept current-- SAGE could work with WRs or with partners like GAVI to keep lists updated more frequently. WHO could potentially dedicate more admin time to this
  - Right now the WER is not 'pushed' to EPI managers or others. WHO could potentially could broaden the distribution list specifically for VPPs and GACVS/ECBS guidance to be able to disseminate more broadly
  - There may be other ways to distribute recommendations to those outside EPI-- perhaps could WR distribute printed summaries directly to Minister of Health or MOF
- The process of getting feedback from countries should be one that is conducted more regularly to understand use of guidance and get suggestions for improvement.

Contents

- Approach and methodology
  - Survey results
  - Questions raised
Objectives of effort

Overall objective:
To understand the impact of WHO normative and policy guidance on vaccines and immunisation on key decision makers in-country and to hear suggestions for improvement in content, communication, and access

Goals

- Assess the usefulness of the WHO reports and recommendations and assess any perceived recent changes
- Assess access and credibility of the recommendations and determine what is and what is not working
- Get suggestions for ways to improve impact, which would include the identification of gaps in WHO policy recommendations and norms and standards development framework

Approach

- Hear country perspectives through an online survey with questions designed to achieve goals
- Choose a set of representative countries randomly to ensure that perspectives are heard outside the usual vocal countries
- Follow up online survey results with phone interviews to delve deeper to understand impact of WHO guidance on vaccines

Methodology for choosing countries and decision makers to complete survey

Country selection

1. Removed countries that **did not report** whether or not an advisory committee existed at country level (44 of 194 countries removed)
2. Split remaining countries into 6 WHO regions
3. Within each region, split countries into 3 categories:
   - High / Upper Middle Income
   - Lower Middle Income
   - Low Income
4. Within these 18 groups, selected a country at random using the RANDDBETWEEN function in Excel
5. For each region, selected one alternate country for a total of 24 countries
6. Reviewed list to ensure balance between selected countries reporting that an advisory committee did or did not exist

Specific contacts to complete survey

- WHO IVB generated a list of contact info for EPI managers and NRA contacts for the selected countries
- An email was sent in mid-December to EPI managers to ask for suggestions of immunisation decision makers in their country to fill in survey
  - For those who did not respond, Philippe and team followed up with emails, phone calls, and requests to WRs to provide names
- As contacts were collected, each decision maker (including EPI managers and NRA contacts; 94 total) was sent a personalised link to the survey and several reminders to complete the survey (between Dec 19 and Jan 30)
- Every contact with a phone number received a call between Jan 20-23 asking if they would prefer to fill in survey on phone
# Outline of survey questions (1/2)

<table>
<thead>
<tr>
<th>Level of specificity</th>
<th>Summary of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccine status in country</strong></td>
<td>Status of vaccine in country</td>
</tr>
<tr>
<td>- Ask for all 4 vaccines aligned with the VPPs being tested</td>
<td>- Is vaccine currently part of national schedule?</td>
</tr>
<tr>
<td></td>
<td>- If no, how important are the following factors in preventing introduction?</td>
</tr>
<tr>
<td><strong>Consideration of VPPs</strong></td>
<td>Awareness of recommendation</td>
</tr>
<tr>
<td>- These questions were asked for specific VPP recommendations:</td>
<td>- To what level are aware of the recommendations in this VPP?</td>
</tr>
<tr>
<td>- Pneumococcus (March 2007)</td>
<td>- Did you read this VPP?</td>
</tr>
<tr>
<td>- Rotavirus (August 2007)</td>
<td>- How did you become aware of the VPP and its recommendations?</td>
</tr>
<tr>
<td>- Updated VPP on Haemophilus influenzae type b (Hib) (November 2006)</td>
<td>- Consideration of recommendation (only asked if aware of the VPP recommendations)</td>
</tr>
<tr>
<td>- Hep B (July 2004)</td>
<td>- Did you consider the recommendations in this Vaccine Position Paper?</td>
</tr>
<tr>
<td></td>
<td>- When considering this Vaccine Position Paper, did you find the following aspects useful?</td>
</tr>
<tr>
<td></td>
<td>- Did you discuss the VPP with any of the following groups?</td>
</tr>
<tr>
<td></td>
<td>Decision on recommendation (only asked if considered the VPP recommendations)</td>
</tr>
<tr>
<td></td>
<td>- Did you accept, modify, or not adopt the VPP recommendation?</td>
</tr>
<tr>
<td></td>
<td>- What were the most important components of this decision?</td>
</tr>
<tr>
<td></td>
<td>Delay of recommendation (only asked if accepted / modified VPP recommendation)</td>
</tr>
<tr>
<td></td>
<td>- What are / were the primary barriers, if any, that delayed implementation of these recommendations?</td>
</tr>
<tr>
<td><strong>General WHO recommendations</strong></td>
<td>General questions on VPPs and in-country decision making for vaccine adoption</td>
</tr>
<tr>
<td>- These questions were asked on a general basis for different types of WHO recommendations</td>
<td></td>
</tr>
<tr>
<td>- VPPs</td>
<td>- How important is immunization program relative to other health priorities in your country?</td>
</tr>
<tr>
<td>- GACVS</td>
<td>- How important are the following in making a decision to introduce a new vaccine?</td>
</tr>
<tr>
<td>- ECBS</td>
<td>- Overall, how do you view the quality of the WHO Vaccine Position Papers?</td>
</tr>
<tr>
<td></td>
<td>- How would you rate the quality of specific VPP components?</td>
</tr>
<tr>
<td></td>
<td>- Going forward, what would be the most effective vehicles for communicating and distributing the information in VPPs?</td>
</tr>
<tr>
<td></td>
<td>- What are the reasons you would not read a VPP?</td>
</tr>
<tr>
<td></td>
<td>- How do you use the WHO VPPs?</td>
</tr>
<tr>
<td></td>
<td>- In which language do you most prefer to read the VPPs? Is it useful?</td>
</tr>
<tr>
<td></td>
<td>- Overall, how could the WHO VPPs be improved?</td>
</tr>
<tr>
<td></td>
<td>GACVS and statement on Hepatitis B and multiple sclerosis (2008)</td>
</tr>
<tr>
<td>- How familiar are you with GACVS?</td>
<td>- How much do you rely on recommendations from GACVS?</td>
</tr>
<tr>
<td>- How much do you rely on recommendations from the ECBS?</td>
<td>- To what level are you aware of the GACVS statement on Hepatitis B and Multiple Sclerosis?</td>
</tr>
<tr>
<td></td>
<td>- Overall, how could the statements from GACVS be improved?</td>
</tr>
<tr>
<td></td>
<td>Expert Committee on Biological Standardization</td>
</tr>
<tr>
<td>- How familiar are you with ECBS?</td>
<td>- How much do you rely on recommendations from the ECBS?</td>
</tr>
<tr>
<td>- What is missing from the ECBS written or physical standards and how could they be improved?</td>
<td></td>
</tr>
</tbody>
</table>
We surveyed 18 primary and 6 alternate countries and received 35 responses from 19 of these countries.

Countries randomly chosen for survey:

<table>
<thead>
<tr>
<th>Regions</th>
<th>WB income status</th>
<th>Alternate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High/upper middle</td>
<td>Lower middle</td>
</tr>
<tr>
<td>AFRO</td>
<td>Seychelles</td>
<td>Swaziland</td>
</tr>
<tr>
<td>AMRO</td>
<td>Jamaica</td>
<td>Guyana</td>
</tr>
<tr>
<td>EMRO</td>
<td>Bahrain</td>
<td>Sudan</td>
</tr>
<tr>
<td>EURO</td>
<td>Romania</td>
<td>Albania</td>
</tr>
<tr>
<td>SEARO</td>
<td>n/a</td>
<td>Sri Lanka</td>
</tr>
<tr>
<td>WPRO</td>
<td>New Zealand</td>
<td>Philippines</td>
</tr>
</tbody>
</table>

*Since no High/upper middle income countries existed in the region, a second country was selected in lower middle income.

For analysis we used two of the alternates given fragile situation in Haiti and Nigeria (though we did get a response from Nigeria).

AMRO participation was lower since no response from Guatemala.

Respondents were predominantly from immunisation department and were spread out by region and income level:

Breakdown of respondents:

Percent, 100%=35 respondents

- 40% of respondents were from countries with a technical advisory committee.
- 37% of respondents eligible for GAVI funding.

1 Romania had six respondents out of ten EURO respondents and nine Upper Middle Income respondents.
2 Respondent from the MOF in Albania only filled out responses for sections 1 and 2 of the survey.

Source: WHO vaccine guidance survey 2009
Lessons learned from the process

1. Immunisation staff (including EPI managers) in many countries have high turnover. In some countries we surveyed (Haiti, Nigeria) the whole immunisation department is in transition. This impacted the number of survey responses and our ability to communicate with these countries.

2. Given this high turnover, the WHO lists with contact information for EPI managers and NRA focal points need to be updated more regularly to ensure that contacts, email address, and phone numbers are current.

3. NRA focal points and those outside MOH were often disengaged—many NRAs said they had no involvement with vaccine decisions or did not respond to any requests. More broadly, those outside the MOH were very difficult to engage, potentially highlighting collaboration and responsiveness issues.

4. There is a need to better understand how specific VPP recommendations are interpreted to prevent inconsistency in feedback. This is particularly true for how people ‘implemented’ or ‘modified’ VPPs (e.g., respondents saying they implemented recent Hep B VPP with the comment that they have had vaccine in schedule for 15 years).
Overall, respondents felt that WHO VPPs were high quality and very important for country decision making

- **Overall, decision makers think VPPs are of a very high quality**

<table>
<thead>
<tr>
<th>Quality Level</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely high quality</td>
<td>36</td>
<td>11</td>
</tr>
<tr>
<td>Neutral/sufficient</td>
<td>61</td>
<td>19</td>
</tr>
<tr>
<td>High quality</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

- **However, usefulness of the VPPs differs by role of respondent**

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOH</td>
<td>36</td>
<td>11</td>
</tr>
<tr>
<td>NRA</td>
<td>61</td>
<td>19</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Almost all respondents are aware of VPPs and have read and considered them**

<table>
<thead>
<tr>
<th>VPP Type</th>
<th>Aware of VPP recs</th>
<th>Read VPP</th>
<th>Considered VPP recs</th>
<th>Implemented VPP recs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal</td>
<td>4</td>
<td>6</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>3</td>
<td>7</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Hib</td>
<td>4</td>
<td>5</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Hep B</td>
<td>4</td>
<td>1</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>

- **Almost all respondents were aware of the WHO VPPs**

- **Moreover, those that are aware tend to also read and consider the VPPs—few people know of them but then do not consider them**

- **No real correlation between role (MOH vs. outside MOH) and how extensively VPPs were read and considered**

- **NZ was the only OECD country and respondents were less aware of VPPs; further work needed to see if similar across OECD**

*Consistently, the respondents who were not aware of VPPs were from New Zealand, Namibia, and Swaziland

**SOURCE:** WHO vaccine guidance survey 2009
Of those who implemented, many said they modified the recommendations

**Pneumococcal**
- Albania
- Bahrain*
- Cambodia
- Guyana
- Pakistan
- Romania*
- Sudan
- Vietnam*

**Rotavirus**
- Albania
- Bahrain*
- Cambodia
- Guyana
- Nederland
- Pakistan
- Romania* 
- Sri Lanka
- Sudan
- Vietnam*

**Hib**
- Albania
- Bahrain*
- Cambodia
- Jamaica
- Nepal
- Pakistan
- Philippines
- Romania*
- Sri Lanka
- Sudan
- Vietnam*

**Hep B**
- Albania
- Bahrain*
- Cambodia
- Jamaica
- Nepal
- Nigeria
- Pakistan
- Philippines
- Romania*
- Sri Lanka
- Sudan
- Thailand
- Vietnam*

* Bold = Countries who already have vaccine in schedule

For Cambodia, “implemented” meant an EPI endorsement of the VPP, even if the country had not yet introduced the vaccine (e.g., pneumo, Hib)

For Seychelles, “modified” meant adapting the Hib schedule to introduce pentavalent vaccine with the current DTP schedule

* Country for which one respondent replied “implemented” and other replied “modified”

** Cost is the primary reason for preventing vaccine adoption in general **
Percent of respondents rating factor as ‘very’ or ‘most’ important in preventing introduction of vaccine

<table>
<thead>
<tr>
<th>Pneumo</th>
<th>Rotavirus</th>
<th>Hib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness of vaccine</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Insufficient disease burden</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>Unsure of disease burden</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>Concern about supplier</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>Availability of alternatives</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Safety/side effects</td>
<td>17</td>
<td>25</td>
</tr>
<tr>
<td>Local surveillance requirements</td>
<td>30</td>
<td>25</td>
</tr>
<tr>
<td>Logistical requirements</td>
<td>27</td>
<td>31</td>
</tr>
<tr>
<td>Cost of vaccine</td>
<td>80</td>
<td>75</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>19</td>
</tr>
</tbody>
</table>

1 All respondents indicated that they have adopted Hep B, so no results for this question

SOURCE: WHO vaccine guidance survey 2009, Interviews with country decision makers
There are a variety of reasons for not implementing VPP recommendations
Percent of respondents rating factor as ‘very’ or ‘most’ important in choosing not to implement VPP recs

### Pneumo VPP recommendations
n=7 respondents have not implemented

- Effectiveness of vaccine: 29
- Insufficient disease burden: 29
- Unsure of disease burden: 14
- Concern about supplier: 0
- Availability of alternatives: 29
- Safety/side effect info: 43
- Local surveillance requirements: 43
- Logistical requirements: 43
- Cost of vaccine: 71

### Rotavirus VPP recommendations
n=10 respondents have not implemented

- Effectiveness of vaccine: 20
- Insufficient disease burden: 40
- Unsure of disease burden: 30
- Concern about supplier: 0
- Availability of alternatives: 80
- Safety/side effect info: 40
- Local surveillance requirements: 40
- Logistical requirements: 30
- Cost of vaccine: 80

### Hib VPP recommendations
n=2 respondents have not implemented

- Effectiveness of vaccine: 50
- Insufficient disease burden: 50
- Unsure of disease burden: 50
- Concern about supplier: 0
- Availability of alternatives: 50
- Safety/side effect info: 50
- Local surveillance requirements: 50
- Logistical requirements: 50
- Cost of vaccine: 50

1 All respondents indicated that they have implemented Hep B VPP, so no results for this question

SOURCE: WHO vaccine guidance survey 2009

---

A significant number of countries who implemented the VPPs reported delays of over a year in implementation

**Respondents who implemented VPP**

<table>
<thead>
<tr>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumo</td>
</tr>
<tr>
<td>Rotavirus</td>
</tr>
<tr>
<td>Hib</td>
</tr>
<tr>
<td>Hep B</td>
</tr>
</tbody>
</table>

- Implementation delayed by over a year
- Implementation not delayed

- Reasons for delay are similar to those that prevent adoption of a vaccine—primarily cost
- Most of respondents who report a delay are from EPI/MOH
- This may suggest that when EPI managers “implement” a VPP, they are endorsing it and recommending it to the government
- The actual adoption of vaccine into schedule may be a separate process involving MOF and others, in which potentially VPP plays less of a role

In both Seychelles and Cambodia, concerns about the cost of introducing a new vaccine resulted in delayed vaccine introduction

- Cambodia, though receiving GAVI funding, is concerned about co-financing costs for new vaccines while trying to finance more of their traditional vaccines
- Seychelles is waiting for Hib price quotes from the supplier; if the price is too high they may not be able to introduce in 2009 as planned
While decision makers think many aspects of VPPs are very high quality, cost effectiveness comes up as important but lower quality

**“Cost effectiveness information” is the aspect of VPPs with the lowest quality rating**

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Percent of respondents citing aspect as high quality or extremely high quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunisation schedule</td>
<td>82</td>
</tr>
<tr>
<td>Target populations</td>
<td>79</td>
</tr>
<tr>
<td>Background on disease</td>
<td>74</td>
</tr>
<tr>
<td>Relevance of scientific evidence for my country</td>
<td>68</td>
</tr>
<tr>
<td>Info on vaccine use (e.g. cold chain)</td>
<td>68</td>
</tr>
<tr>
<td>Safety and side effect info</td>
<td>65</td>
</tr>
<tr>
<td>Cost effectiveness information</td>
<td>53</td>
</tr>
</tbody>
</table>

... but cost is one of the most important factors in choosing to introduce a vaccine

<table>
<thead>
<tr>
<th>Factor</th>
<th>Most important or “very important” in deciding on vaccine introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Political support</td>
<td>91</td>
</tr>
<tr>
<td>Cost of vaccine</td>
<td>88</td>
</tr>
<tr>
<td>Disease burden in my country</td>
<td>88</td>
</tr>
<tr>
<td>Effectiveness for my recommendation</td>
<td>88</td>
</tr>
<tr>
<td>WHO recommendations</td>
<td>85</td>
</tr>
<tr>
<td>Safety and side effects</td>
<td>82</td>
</tr>
<tr>
<td>Infra-structure/logistics</td>
<td>64</td>
</tr>
<tr>
<td>Local surveillance reqs.</td>
<td>50</td>
</tr>
<tr>
<td>Supplier of vaccine</td>
<td>38</td>
</tr>
<tr>
<td>Alternative treatments</td>
<td>26</td>
</tr>
</tbody>
</table>

**Elements that were useful in specific VPPs are broadly similar**

<table>
<thead>
<tr>
<th>VPP</th>
<th>Highest usefulness</th>
<th>Lowest usefulness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal VPP</td>
<td>n=31 respondents aware</td>
<td>n=31 respondents aware</td>
</tr>
<tr>
<td>Immunisation schedule</td>
<td>77</td>
<td>58</td>
</tr>
<tr>
<td>Background on disease</td>
<td>74</td>
<td>52</td>
</tr>
<tr>
<td>Safety/side effects info</td>
<td>71</td>
<td>45</td>
</tr>
<tr>
<td>Target populations</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>Rotavirus VPP</td>
<td>n=30 respondents aware</td>
<td>n=30 respondents aware</td>
</tr>
<tr>
<td>Immunisation schedule</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Safety/side effects info</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Background on disease</td>
<td>83</td>
<td>63</td>
</tr>
<tr>
<td>Target populations</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Hib VPP</td>
<td>n=30 respondents aware</td>
<td>n=30 respondents aware</td>
</tr>
<tr>
<td>Background on disease</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Immunisation schedule</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Relevance of evidence</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Target populations</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Hep B VPP</td>
<td>n=30 respondents aware</td>
<td>n=30 respondents aware</td>
</tr>
<tr>
<td>Target populations</td>
<td>90</td>
<td>77</td>
</tr>
<tr>
<td>Background on disease</td>
<td>90</td>
<td>73</td>
</tr>
<tr>
<td>Relevance of evidence</td>
<td>87</td>
<td>67</td>
</tr>
<tr>
<td>Immunisation schedule</td>
<td>87</td>
<td>67</td>
</tr>
</tbody>
</table>

SOURCE: WHO vaccine guidance survey 2009

McKinsey & Company  | 18

SOURCE: WHO vaccine guidance survey 2009

McKinsey & Company  | 19
In addition to content in the VPP, some issues emerge about its format

<table>
<thead>
<tr>
<th>Reason</th>
<th>Primary reason not to read</th>
<th>Often reason not to read</th>
<th>Sometimes reason not to read</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper is too long</td>
<td>0</td>
<td>6</td>
<td>40</td>
</tr>
<tr>
<td>I can get paper summarised elsewhere</td>
<td>6</td>
<td>16</td>
<td>28</td>
</tr>
<tr>
<td>Don’t know how to get paper</td>
<td>6</td>
<td>10</td>
<td>26</td>
</tr>
<tr>
<td>VPP too late: country already made decision</td>
<td>0</td>
<td>6</td>
<td>21</td>
</tr>
</tbody>
</table>

7 free text comments suggest that VPPs can be improved through an executive summary or bullet point highlights.

Several countries, including Viet Nam, New Zealand, Uzbekistan, Bahrain and Pakistan indicated that VPPs were issued after country made a decision on vaccine.

Few cited “paper is confusing or complicated” or “paper is not translated into a language I can easily read” as a barrier.

SOURCE: WHO vaccine guidance survey 2009

Almost all of responding countries prefer WHO normative guidance in English, but potential bias prevents conclusions on language preference

Most survey respondents are from countries that are likely to prefer WHO normative guidance in English*

<table>
<thead>
<tr>
<th>Language</th>
<th>% countries n=19</th>
</tr>
</thead>
<tbody>
<tr>
<td>English is an official language</td>
<td>53</td>
</tr>
<tr>
<td>English is spoken</td>
<td>25</td>
</tr>
<tr>
<td>Another WHO language is spoken</td>
<td>11</td>
</tr>
<tr>
<td>A non-WHO language is spoken</td>
<td>11</td>
</tr>
</tbody>
</table>

Potential for bias:
- The introduction email and survey were sent in English only
- Follow-up calls were conducted in English or French only
- Non-English speakers may have not have been able to respond to the survey or suggest additional or alternative decision makers

Survey results showed a strong preference for English:
- All respondents who wrote in their preferred language submitted “English”
- Four respondents wrote in a second language preference in addition to English:
  - 2 wrote French
  - 2 wrote Arabic

* English is not an official language but is spoken in Sri Lanka, Nepal, Thailand, Cambodia and Vietnam; another WHO language is spoken in Bahrain (Arabic) and Uzbekistan (Russian); non-WHO language is spoken in Albania (Albanian) and Romania (Romanian)
**Improved communication channels could be tested**

<table>
<thead>
<tr>
<th>How did you become aware of this WHO VPP?</th>
<th>What would be the most effective vehicles for communicating information in VPPs?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percent citing source (average across VPPs)</strong> n=30</td>
<td><strong>Percent rating ‘very’ or ‘most’ effective N=34</strong></td>
</tr>
<tr>
<td>Communication from in-country WHO</td>
<td>Increased communication from WHO staff</td>
</tr>
<tr>
<td>Communication from regional/other WHO</td>
<td>Regional WHO meetings</td>
</tr>
<tr>
<td>EPI manager meetings</td>
<td>Online</td>
</tr>
<tr>
<td>Online search</td>
<td>Newsletters</td>
</tr>
<tr>
<td>Other conference/meeting</td>
<td>E-mail updates</td>
</tr>
<tr>
<td>Subscribe to WER</td>
<td><strong>Current channel of email WER is least effective</strong></td>
</tr>
<tr>
<td>Other access to WER (downloaded, obtained print version)</td>
<td></td>
</tr>
</tbody>
</table>

**Source:** WHO vaccine guidance survey 2009

**Though respondents rarely discussed VPPs with the Ministry of Finance, they report the MoF as one of the most influential decision makers**

<table>
<thead>
<tr>
<th>Who did you discuss the WHO VPP with?</th>
<th>How influential are the following groups in making a decision to implement a vaccine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>% (average across VPPs), n=30</td>
<td>%, n=34</td>
</tr>
<tr>
<td>Those within MoH</td>
<td>· Most influential · Very influential</td>
</tr>
<tr>
<td>Those within MoF</td>
<td>26</td>
</tr>
<tr>
<td>Natl Advisory Group</td>
<td>63</td>
</tr>
<tr>
<td>Other government groups</td>
<td>50</td>
</tr>
<tr>
<td>International 3rd party</td>
<td>54</td>
</tr>
<tr>
<td>International donors</td>
<td>45</td>
</tr>
<tr>
<td>Private sector</td>
<td>54</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
</tbody>
</table>

**Source:** WHO vaccine guidance survey 2009
There are many suggestions for how to improve vaccine position papers

**Selection of quotes from free text answers**

**Content**
- “More country-specific applicable. More information per WHO region in regard to disease burden and relevance of the vaccine”
- “More information on logistics and cost effectiveness issues”
- “Some aspects of cost-effectiveness and also the use of vaccines in immunodeficient and HIV groups should be always included”
- “The extensive cost effectiveness study base on developing countries data / context should be considered”

**Communication**
- “Executive summary at the beginning”
- “Summarise the key recommendations in a list or box”
- “More bullet points of the important issues or boxes with the main summary points which can be used as job aids or teaching tools or as slides in powerpoint presentations”

**Distribution/Access**
- “Every person directly involved in vaccine management should be oriented on WHO vaccine position papers. Workshops should be conducted frequently to ensure that every person is updated”
- “Improve communication between WHO and MoH, NRA, NCL, Manufacturer”
- “WER should be send regularly to EPI managers even if they didn't subscribe”
- “Send as a newsletter to the key vaccine decision makers in countries through the regional or local WHO office”
- “Main issue is to make things more widely available. Think outside the box for who this information could be useful to”
- “WHO position paper has very important role in the introduction of new vaccines in my country. It needs to be extensively circulated among different stakeholders. It needs to be shared in different forums, so that people who have not read the paper will be aware of the content and will start reading it regularly”
- “These should be specifically mailed to all EPI Managers and distributed through the WHO country offices to ensure dissemination. To encourage reading they should also be concise and summarized into shorter statements”

*Source: WHO vaccine guidance survey 2009, Quotes from open text fields*

---

Overall, decision makers are familiar with the Global Advisory Committee on Vaccine Safety

### Most decision makers are familiar with GACVS

<table>
<thead>
<tr>
<th>Percent of respondents</th>
<th>n=34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not very familiar</td>
<td>3</td>
</tr>
<tr>
<td>Not familiar</td>
<td>17</td>
</tr>
<tr>
<td>Somewhat familiar</td>
<td>41</td>
</tr>
<tr>
<td>Very familiar</td>
<td>44</td>
</tr>
</tbody>
</table>

### Percent of respondents aware of the GACVS statement on Hepatitis and MS

<table>
<thead>
<tr>
<th>Percent of respondents</th>
<th>n=34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not very aware</td>
<td>11</td>
</tr>
<tr>
<td>Somewhat aware</td>
<td>26</td>
</tr>
<tr>
<td>Very Aware</td>
<td>20</td>
</tr>
</tbody>
</table>

**Suggestions for improvement from survey respondents:**
- “More widely distributed- branch out from EPI, reach into other depts, areas eg. community health”
- “Making the decision makers more aware of the committee and sharing its statement in different meetings”
- “Any vaccine safety issues should be made aware by the National Program Manager through information sharing from Global or Regional Committee on Vaccine Safety”
- “By more communication with the EPI managers”

### More than half are aware of recommendations or statements from the group...

**Percent of respondents**

<table>
<thead>
<tr>
<th>Percent of respondents</th>
<th>n=34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not consider</td>
<td>3</td>
</tr>
<tr>
<td>Somewhat consider</td>
<td>44</td>
</tr>
<tr>
<td>Extensively consider</td>
<td>53</td>
</tr>
</tbody>
</table>

**No difference between high and low income, countries with/without technical advisory group, type of decision maker**

**SOURCE:** WHO vaccine guidance survey 2009

---

McKinsey & Company
Decision makers are less familiar with the Expert Committee on Biological Standardisation

<table>
<thead>
<tr>
<th>Most decision makers are not very familiar with ECBS</th>
<th>Of those familiar, few extensively consider the statements from this group</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of respondents</td>
<td></td>
</tr>
<tr>
<td>n=34</td>
<td></td>
</tr>
<tr>
<td>Very familiar</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Somewhat familiar</td>
<td></td>
</tr>
<tr>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Not very familiar</td>
<td></td>
</tr>
<tr>
<td>29</td>
<td></td>
</tr>
<tr>
<td>No idea</td>
<td></td>
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<tr>
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<tr>
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<tr>
<td>Somewhat consider statements</td>
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<td>47</td>
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<tr>
<td>Do not consider statements</td>
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<td>35</td>
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Suggestions for improvement

- “Expert representative for developing countries”
- “The ECBS written or physical standards should be regularly reviewed and kept up to date in order to cover the new advanced technology as well as products”
- “Too narrow audience, too ‘scientific’ approach”
- “The ECBS written or physical standards should be widely shared and distributed to Member State via NRA”
- “I shall be grateful if the WHO could send… a free copy of the TRS series on Biological Standardization”

SOURCE: WHO vaccine guidance survey 2009

Contents

- Approach and methodology
- Survey results
- Possible implications
Questions discussed at stakeholder meeting

- **Understanding of VPPs**—are all decision makers truly understanding the main point of VPPs, especially updates on existing vaccines?

- **Modifying VPP recommendations**. What does it mean that so many countries “modified” their implementation of the recommendations?

- **Cost effectiveness**. Is this a gap in the content of VPPs today, and how could this be addressed in a country-relevant way?

- **Better publicity and dialogue** of the recommendations—why are EPI managers not discussing VPPs with MoF colleagues? Would better cost effectiveness information help facilitate these discussions?

- **Communication of the VPPs**. Potentially could supplement WER with bullet points in email or summaries that could be distributed/shared

- **Distribution format**. What is the best way to reach people with the VPPs? Is email working?

Possible implications to pursue

- **Cost effectiveness**
  - Potentially VPPs could try to incorporate high-level cost benefit tradeoffs for countries to consider
  - If the VPPs are not the best way to address cost effectiveness, are there other people at WHO that are better placed? For example, at a regional level could WHO give guidelines to countries? Is there a tool that countries could use that might be effective?

- **Communication methods**
  - Should supplement WER with high-level bullet points in email or summaries in powerpoint that could be distributed/shared with others at a country level
  - Could collaborate with others—e.g., could World Bank include flash news of VPP recommendations in their communications to MOF? What about press releases?
  - Should also discuss value of members of SAGE making themselves available to key policy making bodies

- **Distribution format**
  - Keeping distribution list current—could work with WRs or with partners like GAVI to keep lists updated given high turnover at country level. Potentially dedicate more admin time to this
  - Right now WER is not ‘pushed’ to EPI managers or others. Potentially could broaden the distribution list specifically for VPPs and GACVS/ECBS guidance to be able to disseminate more broadly
  - Potentially should consider other ways to loop in MOF—could WR distribute printed summaries directly to Minister of Health or MOF?

- **Further follow-up**
  - Need to better understand when decision makers are looking at recommendations—is it when SAGE recommendations come out, or do they wait until VPPs are issued?
  - There can be further work done on specific guidance outside VPPs (safety, ADS) and how those can be communicated more effectively
Annex 4: Feedback from Vaccine Advisory Committee Chairs

Each of the chairs of three key vaccine advisory committees was interviewed by telephone for 30 – 45 minutes. Conversations were informal, but guided by questions on the eight topics below. Key feedback points are listed under each of these items below.

General effectiveness:
- Overall good satisfaction.
- Filling a very important niche; “no other competition”.
- Making a difference at both national and global level.
- A sense of being taken more seriously by WHO.
- Increased inclusion of partners, for example GAVI and UNICEF.
- A clear sense of pride

Assessment of recent process improvements:
- In general, functioning including quality, timeliness and relevance has increased.
- Members are now experts rather than merely representatives of regions.
- Transparent and clear appointment criteria; improved relevant expertise, competence and engagement.
- Issues now get a good hearing dispute and revision. There is no longer a “free ride”

Strengths:
- Timeliness of release of Committee recommendations.
- Relevance
- Serve as a bridge between developing countries and other important constituencies, for example industry.

Specific example of effective work:
- Response to concerns about yellow fever vaccination in Peru.
- BCG recommendations.
- Small pox vaccine requirements.
- HPV recommendations
- Pneumococcal recommendations

Weaknesses/Suggestions for improvements:
- Lack of resources to initiate or conduct studies or carry out a research agenda.
- The process to generate position papers is slow.
- Appropriate representation from relevant WHO departments not always present.
- An improved process with active “talent scouting” is needed for identifying candidates from some WHO regions.

Adequacy of staffing:
- Good people.
- WHO is getting a big bang for its buck.
- There is a huge burden on a competent but limited secretariat.
• “Overwhelmed”.
• Additional resources should be a priority

**Agenda prioritization:**
• Improved by good intermeeting communication and good secretarial support.
• Remains an *ad hoc* process.
• An emerging problem as “We are becoming victims of our own success” and issues are stacking up.
• Alternatives for increased efficiency are limited by distances and need for transparency.
• We need a more effective “horizon scan” process.

**Other:**
• Lack of country infrastructure and information, for example on disease burden or to assess adverse events.
• Concern about the time it takes for the prequalification process.
• WHO priorities are unclear
Annex 5: Key material available as background information

Report of the Independent Review Team examining the advisory committees of the WHO Department of Immunization, Vaccines and Biologicals

Reports of SAGE meetings of November 2007 and April 2008; detailed agenda for SAGE meeting of November 2008; list of agenda items for SAGE meetings of 2009


GACVS


Vaccine position papers on PPV23 http://www.who.int/wer/2008/wer8342.pdf

Executive summary of “A better way to speed the adoption of vaccines”, published in the McKinsey Quarterly in August 2008
http://www.mckinseyquarterly.com/A_better_way_to_speed_the_adoption_of_vaccines_2173


A descriptive analysis of immunization policy decision-making in the Americas - Immunization Newsletter of the Pan American Health Organization


Annex 6: List of persons interviewed, who delivered presentations or participated in the preparation of background information or in the panel's meetings

WHO staff

IVB Department
- Mrs Alison Brunier, Communications Officer,
- Dr Thomas Cherian, Coordinator, Expanded Programme on Immunization
- Mr. Mario Conde, Documentalist
- Dr Philippe Duclos, Senior Health Advisor
- Dr. Rudi Eggers, Group Leader, Immunization Services Strengthening, Expanded Programme on Immunization
- Mrs. Marta Gacic-Dobo, Information Systems Technical Officer, Expanded Programme on Immunization
- Dr Joachim Hombach, Coordinator, Implementation Research, Initiative for Vaccine Research
- Dr. Marie-Paule Kieny, Director, Initiative for Vaccine Research
- Dr. Ivana Knezevic, Group Leader, norms and standards, Quality, Safety and Standards
- Ms. Emily Lewis, informatics clerk
- Dr. Jean-Marie Okwo-Bele, Director
- Ms Caroline Scudamore, assistant to the Senior Health Adviser
- Dr David Wood, Coordinator, Quality, Safety and Standards
- Mr Simon Wreford-Howard, External Relations Office
- Dr Patrick Zuber, Group Leader, Global Safety, Quality, Safety and Standards

Other departments
- Dr Tim Evans, Assistant Director-General, Information, Evidence and Research
- Dr Suzanne Hill, Scientist, Policy, Access and Rational Use, Chair of the Guideline Review Committee
- Dr Ulysse Panisset, Scientist, Research Policy and Cooperation, Information, Evidence and Research
- Dr Ian Smith, Adviser to Director-General, Office of the Director-General

McKinsey and Company
- Michael Conway,
- Manisha Gulati
- Farhad Riahi

Oliver Wyman
- Adam Sabow
- Graeger Smith

Chairs of advisory committees
- Professor David Salisbury, Director of Immunisation, Department of Health, London, Chair of SAGE
- Professor Paul-Henri Lambert, University of Geneva, Chair of GACVS
- Dr Phil Minor, National Institute for Biological Standards and Control, Potters Bar, Chair of ECBS
- Professor Pierre van Damme, Vaccine and Infectious Diseases Institute, University of Antwerp, Antwerp, Chair of ETAGE