EVALUATION OF THE STRATEGIC ADVISORY GROUP OF EXPERTS (SAGE) ON IMMUNIZATION

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2 LIST OF ABBREVIATIONS

The following abbreviations can be found in the document:

AC – Advisory Committee
AMR – Antimicrobial Resistance
BMGF – Bill & Melinda Gates Foundation
CoI – Conflict of Interest
CSO – Civil Society Organization
DG – Director General
EAGSE – Expert Advisory Group on SAGE Evaluation
ECDC – European Centre for Disease Prevention and Control
EtR – Evidence to Recommendations
GACVS – Global Advisory Committee on Vaccine Safety
Gavi – Gavi, the Vaccine Alliance
GPEI – Global Polio Eradication Initiative
GRADE – Grading of Recommendations Assessment, Development and Evaluation
GVAP – Global Vaccine Action Plan
HIC – High Income Country
HSS – Health System Strengthening
IPAC – Immunization Practices Advisory Committee
IT – Information Technology
IVB – Immunization Vaccines & Biologicals
IVIR-AC – Immunization and Vaccines Related Implementation Research Advisory Committee
LC – Low-income Country
LMIC – Lower Middle-Income Country
M&R – Measles and Rubella Initiative
MIC – Middle-Income Country
MNCAH – Maternal Neonatal Child and Adolescent Health
MOV – Missed Opportunities for Vaccination NGO – Non-Governmental Organization
NITAG – National Immunization Technical Advisory Group
PDVAC – Product Development of Vaccines Advisory Committee
PHC – Primary Health Care
R&D – Research and Development
RITAG – Regional Immunization Technical Advisory Group
SAGE – Strategic Advisory Group of Experts on Immunization
SDG – Sustainable Development Goals
SIVAC – Supporting Independent Immunization and Vaccine Advisory Committees
SOP – Standard Operating Procedure
ToR – Terms of Reference
UHC – Universal Health Coverage
UMIC – Upper Middle-Income Country
UNICEF – United Nations International Children Emergency Fund
US CDC – United States Centers for Disease Control and Prevention
VPD – Vaccine Preventable Disease
WASH – Water, Sanitation and Hygiene
WER – Weekly Epidemiological Records
WG – Working Group
WHA – World Health Assembly
WHO – World Health Organization
The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 2005 to provide high-level guidance on vaccines and immunization to the Director-General of the World Health Organization (WHO). A first review of the overall advisory committee structure of WHO was done in 2007 confirming SAGE as the principal advisory committee which reviews and makes recommendations on all aspects pertaining to vaccine and immunization policies and strategies.

The present evaluation of SAGE was timed to coincide with the launch of the 13th WHO General Programme of Work and with the planning process for the post-2020 global immunization strategy. It set out to review the appropriateness of the current Terms of Reference (ToR) and working processes of SAGE, including those of its Working Groups and to assess whether SAGE was fit for purpose in view of the evolving immunization and global health agenda. The evaluation covered SAGE’s relationship with key actors in the immunization field, including National Immunization Technical Advisory Groups (NITAGs) and Regional Immunization Technical Advisory Groups (RITAGs), other WHO immunization advisory committees, major partners, donors and stakeholders, as well as current approaches for disseminating SAGE outputs.

The evaluation was performed under the guidance of the Expert Advisory Group on SAGE Evaluation (EAGSE) from April 2018 to April 2019 and supported by MMGH Consulting Group. The evaluation process was kicked-off during a workshop with SAGE members and senior WHO staff, followed by a fact-finding and desk review period including comprehensive interviews with SAGE Secretariat staff. Global, regional and country stakeholder views on SAGE were collected through anonymized online surveys and in-depth interviews. Based on this information, the EAGSE identified 14 key areas for potential improvement which were further discussed and validated with key stakeholders in a final Action Lab, before being submitted for consideration to the Director of the WHO Department on Immunization, Vaccines and Biologicals (IVB).

Overall, the immunization stakeholders’ community considered SAGE as extremely valuable, well respected, playing a critical and leadership role for global immunization and strong in providing evidence-based recommendations. At the same time an opportunity was seen for fine-tuning its scope in light of the evolving immunization space and for better balancing scientific advice with programmatic issues and implementability. In this way, and with some further adaptation of its modus operandi and composition, SAGE could be ready to accommodate future challenges and to fulfil its role in shaping and monitoring the future global immunization strategy.

More systematic consideration of regional and country needs was indicated as an area of attention with the goal of ensuring adequate focus on all WHO member states and of providing regionally differentiated guidance. The need for strengthening communication links between SAGE, RITAGs and NITAGs was emphasised so that region-specific questions could be taken up at SAGE and appropriate feedback provided on how SAGE recommendations are considered, adjusted and implemented.

Room for clarification was also seen with respect to the positioning of other WHO immunization advisory committees in the SAGE decision-making process and to the potential overlap of their roles and responsibilities.

The overall SAGE modus operandi including the use of WGs, the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach and the Evidence-to-Recommendations framework was considered effective, with the consensus-based decision-making process seen as adequate and resulting in appropriate and timely
recommendations. However, several areas for improvement were highlighted, including the agenda-setting process, the role of the chair and vice-chair, the use of modern communication technology and the fact that too many sessions were held ‘for information’ only.

Some concerns were raised about the role of key technical partners and the potential risk of their disproportionate influence. The need was expressed for a more precise definition of what constitutes a conflict of interest (CoI) in this setting.

The value and quality of SAGE position papers were considered very high. The efficacy and breadth of dissemination of SAGE output beyond scientific publications was seen as an area for improvement and suggestions were made for a constituency-tailored approach, adapting means and channels of communications to specific stakeholder groups.

Finally, the need for adequate financial and human resources for the SAGE Secretariat was highlighted as key to avoid rendering SAGE vulnerable.

In view of the above findings, the EAGSE issued a set of recommendations to WHO IVB, to the Regional Offices and to SAGE itself.

WHO IVB was recommended to:

- modify the SAGE ToR and objectives to more clearly reflect the primary goals and scope of SAGE as part of the post-2020 global immunization strategy and of emerging health issues in the context of the SDGs;
- ensure the complementary mandates, functions, roles and responsibilities of all WHO immunization-related advisory groups;
- more clearly define the rules of engagement with relevant stakeholders;
- improve the SAGE modus operandi by ensuring access of SAGE to all relevant expertise, establishing or updating the ToR for the SAGE chair and vice-chair, ensuring appropriate preparation of meetings and curation of topics, establishing longer briefing sessions for SAGE members and a process of immediate assessment of SAGE meetings and ensuring the use of state-of-the-art communication and IT technologies;
- consider establishing a Steering Committee for the prioritization of the SAGE agenda topics;
- refine the scope of what constitutes a CoI in full respect of WHO policies and upgrade the process for the CoI management;
- explore additional communication channels and appropriately tailor communication messages and tools to the different target audiences;
- assess the resources required to implement the proposed recommendations and ensure a sufficiently staffed SAGE Secretariat resourced from the WHO core funding;
- establish a follow-up mechanism to oversee that these recommendations are implemented.

WHO IVB in collaboration with the Regional Offices were recommended to:

- ensure appropriate consideration of regional and country needs and define a framework of describing roles, responsibilities and linkages with the RITAGs and NITAGs;
- set up an institutional mechanism or platform for country-specific questions, feedback and identification of topics for the SAGE agenda;
- include a standing agenda item on SAGE recommendations in the RITAG and regional EPI Manager meetings.

SAGE was recommended to:

- shorten the lead times for the establishment of WGs, update their operating procedures and assure their functioning independently of donor support and more clearly communicate the decision-making criteria used;
- focus the SAGE agenda on ‘for decision’ and ‘for discussion’ items and more often revise and update the SAGE position papers;
- establish mechanisms to better identify knowledge gaps requiring further upstream and operational research.

The swift implementation of these recommendations and adjustments to the current SAGE modus operandi were considered adequate to ensure that SAGE retains its prominent role and status in global health and continues to provide its important contributions to the achievement of the global immunization goals.
Over the past decade there have been major changes in the global context in which immunization occurs. The health field moved into the area of the SDGs and of Universal Health Coverage (UHC) necessitating a further integration of health services. With the development of the Global Vaccine Action Plan (GVAP) came an acceleration of immunization activities in countries and by major immunization stakeholders. There was unprecedented growth of support through Gavi, the Vaccine Alliance (Gavi), with a substantial number of additional vaccines introduced in national immunization programs. The target groups for vaccination are expanding, countries are able to strengthen immunization systems, the quality of data has improved, the number of NITAGs have increased, while the RITAGs have grown in importance. Towards the end of the decade, however, some reversal of these successes was also seen in different countries, there has been a rise in vaccine hesitancy, and many countries now face the necessary transition from Gavi and Global Polio Eradication Initiative (GPEI), support to self-financing.

The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 2005 as the principal advisory group to the WHO for vaccines and immunization. The group is charged with advising the Director General (DG) of the WHO on overall global vaccination policies and strategies, ranging from vaccines and technology, research and development, to delivery of vaccination and its linkages with other health interventions. SAGE’s remit extends to the “control of all vaccine-preventable diseases as part of an integrated, people-centred platform of disease prevention that spans the human life-course and in the context of health systems strengthening”.

The first evaluation of SAGE was published in 2007 as part of a broader exercise looking at the overall immunization advisory architecture in support of the WHO IVB department. With specific reference to SAGE, the outcome of that review was synthesized into the following five recommendations:

2. SAGE Terms of Reference - February 2016.
3. “Report of the Independent Review Team examining the Advisory Committees of the WHO Department of Immunization”, Vaccines and Biologicals, January 2007, World Health Organization, p.6-7. The report included an additional 5 recommendations related to more general issues or which did not refer to the SAGE.
• “That SAGE be recognized as the key committee which reviews and/or makes recommendations to the DG of WHO on all aspects pertaining to immunization policies.

• That SAGE and its WGs be adequately supported in order to meet the expectations placed upon it, including and especially the need for SAGE to have the necessary multidisciplinary expertise.

• That a much stronger connection be established between the regional Technical Advisory Groups (TAGs) and SAGE (along with the rest of the IVB’s advisory structure). Immediate steps should be taken in this regard that would include strengthening of the regional TAGs.

• That IVB should implement a comprehensive communication strategy.

• That the independence of advisory committees be affirmed as essential for their success, including the independence of committees from donors and from the advocacy functions of WHO itself”.

Since its creation, the scope and expectations for normative and strategic guidance by SAGE have expanded considerably in response to the expanding contribution of immunization to global health and global health security and to the evolving goals and objectives of the WHO. For instance, SAGE also assumes advisory functions for the GPEI, SAGE recommendations are essential to inform Gavi policies and SAGE exerts an oversight function for the GVAP. Over time, SAGE has progressively adapted its functions and processes. Today, the group is widely recognized as a model for other WHO advisory bodies and is highly influential with a number of different stakeholders, some of whom use the SAGE recommendations to frame their own organizational policies and strategies (see figure 1 for a schematic of the present WHO immunization advisory structure).

After a decade of operations, with a common impression that SAGE is performing well, the Director of IVB, the SAGE Secretariat and SAGE members agreed on the need to ensure that SAGE is not only fit for today’s challenges but also well-prepared to fulfil its mission into the next decade. In early 2018, it was decided that an evaluation of SAGE be conducted, aimed at appraising the committee’s functions and priorities and at identifying areas where processes may require improvements.

This second evaluation of SAGE was carried out starting in April 2018 and ending in April 2019 (ref. appendix 91. for the evaluation ToR). A set of initial scoping questions was developed by the Director of WHO IVB with input provided by WHO regional staff during a kick-off consultation in April 2018, to steer the evaluation process.
Figure 1: Overview of key areas of work and advisory input from vaccine development through to WHO policy

<table>
<thead>
<tr>
<th>Preclinical development</th>
<th>Early stage clinical development</th>
<th>Late stage clinical development</th>
<th>Positive regulatory assessment/licensure</th>
<th>Policy recommendations</th>
<th>WHO prequalification</th>
</tr>
</thead>
</table>

**KEY AREAS OF WORK**

- Supporting and facilitating product development
- Transparent and comprehensive evidence reviews
- Global policy and access to quality products

**ADVISORY INPUT**

- **PDVAC**
  - Class specific guidance to product development
- **ECBS**
  - Norms and standards
- **IPAC & PSPQ-SC**
  - Programmatic suitability
- **IVIR-AC**
  - Implementation research
- **GACVS**
  - Dedicated risk assessment
- **Ad hoc experts**
  - NRA joint reviews
- **SAGE**
  - Full evidence review
- **WHO**
  - Vaccine position paper


Abbreviations: PDVAC: Product Development for Vaccines Advisory Committee; ECBS: Expert Committee on Biological Standardization; IPAC: Immunization Practices Advisory Committee; PSPQ-SC: Programmatic Suitability of Vaccine Candidates for WHO Prequalification Standing Committee; IVIR-AC: Immunization and Vaccine-Related Implementation Research Advisory Committee; GACVS: Global Advisory Committee on Vaccine Safety; SAGE: Strategic Advisory Group of Experts on Immunization.
4.1. Objective and scope of the 2018-2019 SAGE Evaluation

The evaluation reviewed the appropriateness of the current ToR\(^5\) and working processes of SAGE, including those of the SAGE WGs\(^6\). It included SAGE’s relationship with key actors in the immunization community, including country Ministries of Health and NITAGs, WHO Regions and RITAGs, major partners, donors and other stakeholders. It also included a review of the approaches currently used for communicating and disseminating SAGE outputs. The scope of the evaluation did not include the functioning of RITAGs and NITAGs. However, it covered the functioning of other WHO committees advising the Director of WHO IVB as they are related directly to SAGE.

SAGE’s role and function was assessed, taking into consideration key strategies within, e.g., GVAP, and beyond the immunization field e.g., the focus on UHC, Health Security, and non-communicable diseases of the 13th Global Programme of Work and of the SDGs, as well as emerging themes of the post-2020 immunization strategy. Special emphasis was placed on the role that SAGE should play in a likely future scenario where immunization policies and services will be integrated to a greater extent with other health services.

4.2. Desired outputs of the SAGE evaluation

The Director of WHO IVB, considering input provided by WHO senior regional staff, advised that the evaluation should aim at:

a. ascertaining SAGE’s role in relation to the evolving immunization and health agenda;

b. identifying the optimal interfaces with other WHO immunization and public health decision making and advisory bodies;

c. ensuring the optimal coordination with WHO Regions and regional immunization committees, as well as key partners and stakeholders;

d. ensuring that SAGE works effectively and is able to meet the highest quality standards;

e. ensuring the effective presentation and dissemination of SAGE and WHO recommendations;

f. revisiting the WHO SAGE Secretariat composition and resource needs.

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5 METHODOLOGY OF THE EVALUATION

5.1. Evaluation governance

The evaluation was performed under the guidance and oversight of the EAGSE, tasked with the appraisal of the evaluation’s methodology and findings and with the development of recommendations (ref. appendix 9.2 for the EAGSE ToR). The group, established in June 2018, provided technical and strategic input and guidance throughout the evaluation process. Its membership was constituted by invitation from the Director of WHO IVB, with a balanced representation of experience, skills, regions, gender and background.

The EAGSE specifically reviewed the evaluation methodology, including the selection and adaptation of the appropriate tools, and guided the interaction of the evaluation team with identified stakeholders. The EAGSE reviewed summaries of results and of interim reports across the phases of the evaluation and developed the set of final recommendations. The EAGSE held two face-to-face meetings – in July 2018 and in February 2019 – and ten teleconferences in August, September, and November 2018, as well as in January, February and March 2019.

MMGH Consulting, a consulting and advisory group with specific knowledge and experience of the SAGE functions and processes and familiarity with the key immunization stakeholders, was selected through a competitive bidding process to support the EAGSE in the evaluation (ref. appendix 9.3 for the ToR of the consulting group). Under the supervision of the WHO SAGE Secretariat and guided by the EAGSE, the consulting group was tasked with preparing and facilitating meetings, administering online surveys, questionnaires and interviews, analysing the data and drafting documents.


Figure 2: SAGE evaluation timeline

KICK-OFF
• High-level survey
• SAGE retreat

SET UP
• Project kick-off
• EAGSE setup

EVALUATION
• Desk review
• Secretariat interviews
• 2 stakeholder surveys
• 40 in-depth interviews

RECOMMENDATIONS
• Analysis of findings
• Action Lab
• Draft report
• SAGE discussion

IMPLEMENTATION
• Final report
• Action Plan
5.2. Evaluation design

After definition of the evaluation’s goals and ToR, the evaluation process was formally launched in April 2018 during a retreat with participation of the members of SAGE, the chairs of other WHO immunization advisory committees, the chairs of the RITAGs and senior WHO staff at Headquarters and regional levels. The meeting served to identify the critical areas to be analysed and provided input on the evaluation’s design, tools and timelines. Based on those inputs, and in consultation with the EAGSE and the SAGE Secretariat, the consultants refined the evaluation design, identified the appropriate tools, and defined a detailed project timeline. The approach was endorsed by the EAGSE during a 2-day face-to-face meeting in early July 2018. The evaluation process started thereafter and consisted of 4 phases.

An initial fact-finding and insight generation phase took place between August and December 2018 and was comprised of multiple activities:

- **a desk review** based on an adaptation and extension of the standard NITAG self-evaluation tool developed by the Strengthening of Immunization and Vaccines Advisory Committees (SIVAC) Initiative, including the review of the prior SAGE evaluation, the review of all SAGE outputs between 2010 and 2017 and the resulting products (ref. appendix 9.4. for the SAGE product table), a descriptive analysis of SAGE agenda items, recommendations and position papers and decisions on cross-cutting issues, including the dissemination of outputs and the reach or influence of these – to the extent that this could be assessed – on initiatives, partners, and countries;

- **an in-depth interview** process with the WHO SAGE Secretariat, including a review of the SAGE ToR; guidance documents, standard operating procedures (SOP) and other specific working processes as well as of the WHO Secretariat support, aimed at identifying areas where SAGE processes could benefit from improvements (ref. appendix 9.4. for the desk review summary);

- the administration of two **online anonymized surveys** via a dedicated survey tool (off-the-shelf tool Qualtrics™) sent to 110 key technical partners closely involved with SAGE (defined as SAGE members and stakeholders regularly and directly impacted by SAGE’s work including staff from WHO Headquarters, WHO regional and country offices, UNICEF, Gavi, Bill & Melinda Gates Foundation (BMGF), as well as RITAG and NITAG representatives) and to 120 additional immunization and Global Health stakeholders. The surveys, based on an adaptation and extension of the standard SIVAC evaluation tools, aimed at collecting views on SAGE performance in different areas of work. A total of 58% of the key technical partners (n=64) and 37% of Global Health stakeholders (n=42) responded to the survey.

- **conducting interviews** with a subset of SAGE members and key technical partners as well as the wider stakeholder group, selected in agreement with the EAGSE with respect to global, regional/country as well as institutional representation, who provided additional in-depth insights into thematic areas that were emerging as critical for the evaluation. A total of 40 interviews were performed during the months of December 2018 and January 2019, equivalent to 65% of the sample of targeted respondents.

A second phase was aimed at identifying areas for improvement. The EAGSE reviewed the findings arising from the first phase and defined 14 thematic areas for potential improvements to be analysed during the subsequent phase. The six desired outputs of the evaluation (see 4.2.) are fully covered by these themes (see table 1):

Table 1: Thematic areas for intervention and desired outputs of the evaluation

<table>
<thead>
<tr>
<th>Desired Outputs of the Evaluation</th>
<th>Thematic Areas Identified for Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Ascertaining SAGE’s role in relation to the evolving immunization and health agenda.</td>
<td>1. SAGE goals, mandate, mission and scope</td>
</tr>
<tr>
<td></td>
<td>2. SAGE in the next decade</td>
</tr>
<tr>
<td></td>
<td>3. Research and development</td>
</tr>
<tr>
<td>b. Identifying optimal interfaces with other WHO immunization and Public Health decision-making and advisory bodies.</td>
<td>4. SAGE and other WHO Advisory Committees</td>
</tr>
<tr>
<td>c. Ensuring the optimal coordination with WHO Regions and regional committees, as well as key partners and stakeholders.</td>
<td>5. Principles of working with Regions and countries</td>
</tr>
<tr>
<td></td>
<td>6. SAGE – RITAG – NITAG policy making chain</td>
</tr>
<tr>
<td></td>
<td>7. Relations with global stakeholders</td>
</tr>
<tr>
<td>d. Ensuring the SAGE working mechanisms’ effectiveness and ability to meet the highest quality standards.</td>
<td>8. Membership and chair selection</td>
</tr>
<tr>
<td></td>
<td>9. SAGE agenda setting</td>
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<tr>
<td></td>
<td>10. Decision-making and WG processes</td>
</tr>
<tr>
<td></td>
<td>11. SAGE meeting setup and modus operandi</td>
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<tr>
<td></td>
<td>12. CoI management</td>
</tr>
<tr>
<td>e. Ensuring effective presentation and dissemination of SAGE and WHO recommendations.</td>
<td>13. Communication and dissemination of SAGE output</td>
</tr>
<tr>
<td>f. Revisiting the WHO SAGE Secretariat composition and resource needs.</td>
<td>14. Secretariat role and resources</td>
</tr>
</tbody>
</table>

A third phase, in February 2019, during which a subset of 28 experts including SAGE Members, former SAGE Chairs, WHO Regional Advisors, RITAG and NITAG chairs, and major immunization partners (UNICEF, Gavi) – i.e. the group most intimately involved in all practical dealings of SAGE and as such considered ‘process owners’ – came together by invitation of WHO IVB. Together with the EAGSE this group reviewed the 14 identified areas for improvement, prioritized those areas requiring focused attention and suggested potential organizational and process changes. These activities were carried out as part of an Action Lab, a two-day facilitated meeting focused on identifying concrete and actionable interventions. The approach consisted of an iterative facilitated process that moved between the broader global policy dimensions, the goal of SAGE’s work, and the technical details of the chosen interventions with a strong focus on their implementation. During the Action Lab, the group confirmed the thematic areas and extensively discussed interventions across a number of topics which had emerged in those areas.

A fourth and last phase focused on the prioritization of recommendations. During this phase, the EAGSE reconvened, during a face-to-face meeting in February 2019, to critically review the numerous recommendations emerging from the Action Lab and from the prior phases. The EAGSE performed a prioritization of those recommendations across the thematic areas, taking into account their relative impacts, their implementability and the urgency for their implementation. Detailed recommendations were thereafter prepared by the EAGSE for consideration by the Director of WHO IVB.

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9. The Action Lab is an approach to organizational redesign developed originally for the private sector – Richard T. Pascale and Anne H. Miller, “The Action Lab. Creating a greenhouse for organizational change”, Strategy, Management and Competition, Issue 17, Fourth Quarter 1999. In the last 10 years, the approach has been applied successfully in the public sector by its creator.

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Figure 3: Evaluation process steps
The initial desk review provided an overview of the topics discussed in the SAGE meetings over the period from 2010-2017. The analysis of the 17 SAGE meetings during this period highlighted that two categories of topics - vaccine-specific topics and reports (see tables 2 and 3) - were the most frequently discussed, representing 72% of sessions in that period. When reviewing the type of sessions, there was an almost equal split between topics “for decision”, “for discussion” and “for information” with a slight predominance of topics for decision (38% of sessions) - (Ref. appendix 9.4. for the desk review summary).

Polio was the most frequent agenda item, with at least one session devoted to this topic in each of the 17 meetings, emerging as de-facto standing agenda item. Measles-rubella and influenza vaccine issues were each discussed five times.

Table 2: Topics discussed at SAGE meeting 2010-2017

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>NUMBER OF SESSIONS N (%)</th>
<th>TOPIC CATEGORY</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>'FOR DECISION' N (%)</td>
<td>'FOR DISCUSSION' N (%)</td>
<td>'FOR INFORMATION' N (%)</td>
</tr>
<tr>
<td>Vaccine-specific</td>
<td>68 (40%)</td>
<td>51 (75%)</td>
<td>14 (21%)</td>
<td>3 (4%)</td>
<td></td>
</tr>
<tr>
<td>Reports</td>
<td>54 (32%)</td>
<td>0</td>
<td>7 (13%)</td>
<td>47 (87%)</td>
<td></td>
</tr>
<tr>
<td>Programmatic</td>
<td>20 (12%)</td>
<td>5 (25%)</td>
<td>14 (70%)</td>
<td>1 (5%)</td>
<td></td>
</tr>
<tr>
<td>challenges</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GVAP</td>
<td>12 (7%)</td>
<td>7</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Financing</td>
<td>4 (2%)</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Vaccine safety</td>
<td>4 (2%)</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>General policy</td>
<td>3 (2%)</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>SAGE process</td>
<td>2 (1%)</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Surveillance</td>
<td>2 (1%)</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>169 (100%)</td>
<td>64 (38%)</td>
<td>50 (30%)</td>
<td>55 (32%)</td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Vaccine specific topics and numbers of sessions

<table>
<thead>
<tr>
<th>NUMBER OF SESSIONS</th>
<th>VACCINE-SPECIFIC TOPICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 sessions</td>
<td>Polio</td>
</tr>
<tr>
<td>5 sessions each</td>
<td>Measles–rubella, influenza</td>
</tr>
<tr>
<td>3 sessions each</td>
<td>Ebola, Pertussis, Pneumococcal disease</td>
</tr>
<tr>
<td>2 sessions each</td>
<td>Cholera, Dengue, Hepatitis A, Human Papillomavirus, Meningococcal disease,</td>
</tr>
<tr>
<td></td>
<td>Tuberculosis, Typhoid, Yellow Fever</td>
</tr>
<tr>
<td>1 session each</td>
<td>Diphtheria, Hepatitis B, Hepatitis E, Haemophilus influenza type b, Human Immunodeficiency Virus, Japanese Encephalitis, Malaria, Measles, Rabies, Respiratory Syncytial Virus, Rotavirus, Rubella, Smallpox, Tetanus, Tick-borne Encephalitis, Varicella</td>
</tr>
</tbody>
</table>

With regard to the second most frequently discussed category of topics, i.e., reports, those from the IVB Director, Gavi and other advisory committees were again de-facto standing-agenda items during the entire period. In addition, regular annual sessions on GVAP were held (see table 2) for 5 years in preparation of World Health Assembly (WHA) discussions.

Table 4: Reports and numbers of sessions, n=54

<table>
<thead>
<tr>
<th>NUMBER OF SESSIONS</th>
<th>SUBJECT MATTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 sessions each</td>
<td>Reports from WHO IVB Director, Gavi, other Advisory Committees</td>
</tr>
<tr>
<td>3 sessions each</td>
<td>Reports from Regions on regional priorities and updates and from international immunization partners</td>
</tr>
</tbody>
</table>

Finally, with reference to the programmatic challenges, 2 sessions each were dedicated to (a) impact of new vaccine introduction on health and immunization systems; (b) humanitarian emergencies; (c) vaccine hesitancy; and (d) immunization supply chain and logistics. One session each was focused on the following topics: epidemiology of the unimmunized and gender-related issues; integration of immunization and child health care services; administration of multiple injections; reducing pain at the time of vaccination; maternal vaccination; implementation in the context of health systems strengthening and UHC; strengthening NITAGs; pre-empting responding to vaccine shortages; missed opportunities for vaccination (MOV); second year of life platform; national immunization programme management; and private provider engagement in immunization.
Across the four phases of the evaluation and as previously stated, findings, derived from the desk review, the surveys and the in-depth interviews were organised into 14 thematic areas which constituted the basis for the formulation of recommendations (see table 1). Details of findings by theme are provided below.

### 7.1. SAGE goals, mandate, mission and scope

The ToR of SAGE were last updated in February 2016 in the context of GVAP with a revision planned for 2020 in light of the emerging priorities of the evolving post-2020 global immunization strategy.

SAGE is considered by the stakeholders surveyed as extremely valuable, well-respected and playing a critical support role for global immunization. It has a direct and relevant influence on multiple areas of work for almost all key stakeholders: WHO, UNICEF, Gavi, BMGF, health ministries of low- (LIC) and middle-income countries (MICs) and for manufacturers. Its influence is deemed slightly less impactful, but still important for high-income countries (HICs), for non-governmental organizations (NGOs) and civil society organizations (CSOs), and for research and regulatory agencies.

SAGE is considered strong in accomplishing its main tasks of providing evidence-based recommendations even for complex issues. However, in light of the evolving global immunization space, there is a general consensus among the stakeholders for revisiting SAGE’s scope of work as well as the committee’s mission statement.
In this respect, the majority of key technical partner respondents (57%) are concerned about an expansion of the role and scope of SAGE since this may dilute its impact, while there is some appetite by the wider stakeholder group (52% of the survey respondents) to extend SAGE’s scope beyond immunization, i.e. in linking with the Primary Healthcare (PHC) and UHC agenda and with broader health issues such as antimicrobial resistance (AMR). At the same time, there is general consensus among both groups that SAGE should consider both vaccines and immunization programmes and all types of vaccination strategies against vaccine preventable diseases (VPDs).

There is agreement across stakeholder groups on the need for a better synthesis and balance between scientific advice on vaccines and immunization and policy guidance on overall programmatic issues, with the latter to be especially focused on the efforts necessary to reach vulnerable populations and strengthening capacities of the weaker systems. Any increased consideration of such programmatic issues should, however, be done without reducing the scientific rigor of present SAGE deliberations. Issues related to the practical implementation of recommendations are considered by respondents beyond the scope of SAGE and best dealt with by other Advisory Committees, e.g., the Immunization Practices Advisory Committee (IPAC) and the Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC) as well as the RITAGs and NITAGs.

## Recommendation 1

A. WHO IVB to modify the SAGE ToR to more clearly reflect the primary goals and scope of SAGE as part of the broader WHO Programme of Work and the global post-2020 immunization strategy. This should include a focus on:

- immunization across the life course;
- impact at country level;
- achieving high and equitable vaccination coverage;
- integration into UHC and PHC.

B. WHO IVB to modify SAGE’s objectives for enhanced focus and clarity with specific reference to:

- Evidence-based recommendations on the use of vaccines and immunization to reduce the burden of vaccine-preventable disease over the human life course;
- The use of vaccines and immunization to respond to public health priorities, including the use of vaccines in the context of vaccine shortages and public health emergencies;
- Challenges to achieving and sustaining high and equitable vaccination coverage, including vaccine-preventable disease (VPD) surveillance, data quality and birth registration;
- Monitoring and evaluation of the adequacy of progress towards the achievement of the goals of VPD control worldwide in light of GVAP and the post-2020 strategy and establishment of an accountability framework;
- Engagement of WHO in partnerships that will enhance the achievement of global immunization goals;
- Integration of immunization into the broader context of Sustainable Development Goals, UHC and PHC.
7.2. SAGE in the next decade

There is general agreement (80% of key technical partner respondents and 74% of the broader stakeholder group respondents) that SAGE can accommodate future immunization challenges. At the same time there is consensus that SAGE will need some adaptation in its composition and modus operandi to address emerging needs and trends. In the next decade, the field of immunization will undergo significant changes to the context within which it operates, including urbanization, humanitarian emergencies, ageing populations, climate change and a shift of focus from mortality to morbidity reduction. These changes will necessarily require SAGE functioning and expertise to adapt. In addition, a variety of immunization-specific issues are on the horizon: legal and social frameworks for vaccination to address immunization as a human right, the growing focus on vaccine hesitancy as well as the arrival of additional new vaccines and new technologies to advance delivery. All of these are issues, that SAGE will need to consider and for which adaptations in mission and operations will likely be required.

In this changing world, there is consensus among stakeholders of the need for SAGE to further enhance its “brand” to become the entity to which the world looks for guidance across a broad spectrum of strategic topics. To do so, respondents saw a need for better alignment of the SAGE agenda, role and processes with the SDGs and for addressing major shifts in the health agenda of UHC. SAGE will also need to deal with aspects of integration of immunization with other primary care programmes, particularly in Maternal Neonatal Child and Adolescent Health (MNCAH), including life-course vaccination approaches. Also, further intensified interactions will be needed within the WHO with departments dealing with health systems strengthening (HSS), emergencies, non-communicable diseases, water, sanitation and hygiene (WASH), cervical cancer, malaria, rabies, tuberculosis, neglected tropical diseases, and regulatory aspects, including prequalification.

Finally, it was stated that there will likely be even more demand for monitoring and accountability, with the present role of SAGE in translating and monitoring the GVAP to be aligned with the post-2020 global immunization strategy.

Recommendation 2

SAGE to ensure that emerging systemic issues in the context of the sustainable development goals such as urbanization, humanitarian emergencies, migration, ageing populations, climate change and a shift of focus from mortality to morbidity reduction are taken into account in its work of making evidence-based recommendations.

7.3. Research and development

There is general consensus among those surveyed that SAGE is not a committee focusing or advising on research and development (R&D) in immunization. However, as part of the development of recommendations and position papers, SAGE is dependent on research results generated or assessed by other WHO advisory groups (see 7.4.). When collating available evidence, or when discussing policy recommendations, SAGE often identifies knowledge gaps which require further R&D, i.e., including results emanating from upstream vaccine research as well as from operational research and implementation science.

Recommendation 3

SAGE to establish mechanisms to ensure the identification of knowledge gaps requiring further upstream vaccine and operational research to enable SAGE to fulfil its functions. This is to be done in close alignment with other WHO immunization advisory groups (e.g., on product development, implementation research and immunization practices), and with relevant immunization partners.
7.4. SAGE and other WHO immunization advisory committees

While the role of the other WHO Headquarters Advisory Committees (ACs) to SAGE functioning and their complementarity is acknowledged, the general perception is that there is a lack of clarity about SAGE’s relationship with these advisory bodies (47% of the key technical partner respondents). In particular, their mandates, functions and activities as well as their positioning in relation to the SAGE decision-making processes (e.g., their reporting lines to the Director of WHO IVB as well as their reporting to SAGE during meetings) appear not to be well understood by many stakeholders.

A lack of clarity is also felt by stakeholders on a possible overlap of roles and responsibilities of the ACs themselves and on how SAGE could benefit more from their work. In particular, there seems to be space for better alignment of topics and for joint management of critical issues between SAGE and the ACs. Workplans between SAGE and ACs seem not to be harmonized and linkages are not immediately apparent.

As a result, SAGE seems not to utilize the AC mechanism effectively and the possibility of delegating responsibility to specific committees is not being fully exploited.

Recommendation 4

WHO IVB to ensure complementary mandates, functions, roles and responsibilities of all WHO HQ immunization advisory groups as well as their contribution to the SAGE process of evidence review for recommendations.

In particular:

- SAGE to proactively seek technical inputs from the relevant WHO immunization advisory groups through the IVB Director or the SAGE Secretariat.
- SAGE to ensure that the relevant reports of the immunization advisory groups to SAGE be integrated into the corresponding SAGE sessions and linked to SAGE recommendations.

10. Product Development for Vaccines Advisory Committee (PDVAC); Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC); Immunization Practices Advisory Committee (IPAC); Global Advisory Committee on Vaccine Safety (GACVS)
General consensus emerged among the stakeholders that SAGE should be more systematic in considering regional and country needs (54% of the key technical partner respondents), and in particular in ensuring that its focus extends to all countries, recognizing that, increasingly, some of the greatest needs may not necessarily be concentrated in the LICs and lower middle-income countries (LMICs). For this purpose, the strengthening of existing channels or the definition of new ones (such as more direct country participation with SAGE or more effective translation of SAGE output via WHO Regional Offices) is suggested to ensure that appropriate consideration is given to country needs in defining the SAGE agenda and in formulating SAGE guidance or specific recommendations.

Country-level dimensions such as local disease burden evidence of VPDs, HSS, country decision-making processes, financial and political priorities including Gavi eligibility, and local acceptance and handling of vaccine hesitancy are all context-specific themes that will require additional attention to ensure that SAGE recommendations remain relevant for countries. Respondents saw WHO Regional Offices as having the main responsibility for ensuring that appropriate visibility of country specific issues is achieved.

It was also pointed out that low-income, middle-income and high-income countries will require a differentiation of recommendations and a sweeping approach will no longer be useful in the future. Increasingly, country choices and adaptations from a broader menu of options will likely be required. SAGE will therefore increasingly need to provide guidance for decision-making rather than off-the-shelf recommendations.

The ability to synthesize best practices in the delivery of vaccines and addressing any emerging challenges with the implementability of SAGE decisions are also seen as important tasks of SAGE, necessitating a more functional feedback-loop from countries.

**Recommendation 5**

WHO IVB in collaboration with Regional Offices to strengthen existing channels or develop new ones to ensure appropriate consideration of all regional and country needs in defining the SAGE agenda and in formulating SAGE guidance, including those for low, middle- and high-income countries.
7.6. SAGE – RITAG – NITAG policy-making chain

Relations between SAGE, RITAGs and NITAGs are key to the success of SAGE. The implementability of SAGE recommendations is dependent on the RITAGs’ ability to tailor SAGE outputs to the specifics of each Region and on the NITAGs’ ability to effectively advise Ministries of Health on applying these recommendations in the management of country immunization programmes. There is a general consensus that SAGE’s relationship with RITAGs and NITAGs should be rendered more functional (64% of the key technical partner respondents and 54% of the broader stakeholder group respondents) and roles, responsibilities and interactions further clarified with the aim of a more effective bidirectional engagement and information sharing across the three levels.

The fact that SAGE and the RITAGs occasionally operate in parallel was indicated as a source of concern: technical discussions happening at the SAGE meetings appear to sometimes be repeated at RITAG meetings. While there are established communication links between SAGE, RITAGs and NITAGs, with SAGE members participating in RITAG meetings (albeit not sufficiently), and RITAG and some NITAG chairs attending SAGE meetings, it was suggested by survey respondents that these links could be better used to align committee operations. This should allow for informing the SAGE agenda setting and for taking up region-specific questions at SAGE, while ensuring each committee’s respective level of responsibility and independence. At the same time, these links could be used to ensure that SAGE output is taken up in RITAG deliberations without necessarily repeating the technical discussions preceding these outputs.

Respondents also asked for a mechanism of systematic feedback on how SAGE and RITAG recommendations have been considered, adjusted to local needs and implemented to assist with SAGE’s continuous quality improvement.

Recommendation 6

A. WHO IVB in collaboration with Regional Offices to define a framework describing roles, responsibilities and linkages between SAGE, RITAGs and NITAGs.

B. WHO IVB to work with Regional Offices to set up an institutional mechanism or platform for regular interaction with RITAGs and NITAGs to allow for country and region-specific questions to be proposed for SAGE advice and for provision of feedback on the implementability of SAGE recommendations.

C. WHO IVB to encourage Regional Offices and RITAGs to include a standing agenda item for discussion of SAGE recommendations in RITAG and inter-country EPI managers meetings.
7.7. Relations with global stakeholders

SAGE’s role is known in the global immunization community and the reach of its engagement with stakeholders is seen as a key strength of the committee. A variety of stakeholders in and outside of the field of immunization refer to SAGE decisions and use them as key triggers or inputs for their decisions. Gavi, UNICEF, the GPEI and the Measles and Rubella Initiative (M&RI) operations are directly advised by SAGE deliberations. SAGE, in addition, exerts influence on other stakeholders, including BMGF, the US Centers for Disease Control and Prevention (US CDC) the European CDC (ECDC), the World Bank, bilateral donors, academia, industry, regulators, ministries, NGOs, CSOs and professional associations.

A clearer definition of the role of ‘key technical partners’ – e.g. the ones directly impacted by SAGE decisions and that depend on the downstream policy implementation processes – was called for to clarify the modalities and the extent of their contributions to the SAGE meetings. Suggestions were made by survey respondents that the purpose, method and process of obtaining their views and that of other stakeholders participating in the meetings should be more clearly differentiated and clarified.

The potential risk of disproportionate influence directly or indirectly exerted by some stakeholders and by WHO focal points on SAGE and WG dealings and decisions was indicated by many as an area of concern. This applies in particular to the engagement of representatives of donors, funders and of industry, with participation of the latter in SAGE sessions considered as particularly critical for discussions about vaccine products. However, such an engagement demands utmost transparency and pre-defined terms of engagement.

Finally, there is consensus that SAGE could further benefit from the establishment of a more formal stakeholder feedback process.

**Recommendation 7**

**A.** WHO IVB to define rules of engagement of SAGE with stakeholders and individual subject matter experts, including the ‘key technical partners’ and WHO focal points, to ensure the provision of highest quality input while avoiding undue influence.

**B.** SAGE to engage in regular dialogue with relevant global immunization stakeholders to have a current understanding of their priorities, plans, and challenges. Such dialogue should ensure timeliness and relevance of SAGE recommendations, as well as optimizing the ability of recommendations to shape stakeholder planning and commitment of resources, and to be implemented.
7.8. SAGE membership and chair selection

There is consensus that the fundamental areas of expertise needed for SAGE operations are well covered (70% of the broader stakeholders group survey respondents), however a need was voiced for additional skills and competencies in areas such as primary healthcare, ethics, health economics, social science, communication science, obstetrics and maternal health. This would not necessarily require an extension of SAGE membership, as WGs potentially play an important role in providing the SAGE decision-making process with such added competencies.

Moreover, SAGE membership is considered adequate by most stakeholders (75% of key technical partners and broader stakeholder group respondents indicate SAGE membership as consistent with its goals and functions), with appropriate technical, geographic and gender diversity. However, a potential area for attention is the need for regional representation while maintaining the greatest technical expertise. The latter can lead to some regions (Americas and Europe in particular) and high-income countries (HICs) to be overrepresented in SAGE. Furthermore, an increased representation from implementers and CSOs, particularly from LICs & LMICs, was seen as desirable. The opportunity for establishing a mentoring programme for SAGE members or future members was proposed as an option for creating a more diversified membership, capable of participating fully and contributing to all discussions.

The current practice of rotating membership was perceived by the stakeholders as appropriate to ensure the dynamic adaptation of the mix of expertise represented in the committee and to allow for transition in case of performance issues.

The very high workload of the chair and the currently ill-defined role of the vice-chair were seen as problematic by several stakeholders. The chair’s role – and the time necessary to dedicate to SAGE – is widely recognized as critical to the success of the committee, hence there is a need for realistic requirements in terms of time commitment so that the widest pool of strong candidates may retain an interest in the position. In this respect the clarification of the role of the vice-chair – for which ToR do not yet exist – was indicated as an area worth exploring.

Recommendation 8

A. SAGE to ensure access to all relevant expertise in its decision-making process in light of the enlarged scope of the immunization agenda, specifically covering the fields of ethics, health economics, social sciences, communication sciences and maternal health.

B. WHO IVB to establish ToR for the SAGE chair and vice-chair to address the issue of high work load and the need to delegate some of the chair’s tasks.
7.9. SAGE agenda setting

Although the topics included in the agenda of SAGE meetings are considered adequate and relevant by the large majority of stakeholders, some stakeholders perceive the agenda setting to not be fully transparent and not to result from a thorough approach to prioritization (55% of the key technical partner survey respondents). Specifically, concerns were raised by some respondents about the possible influence of some stakeholders and about the limited consideration given to country delivery needs. Consultation with Regional Offices and RITAGs appears not to be functioning as required (see 7.6.), considering the limited input provided to the agenda from regions. A more transparent SAGE agenda-setting process was also suggested as providing an opportunity for positively influencing similar exercises in the regions.

Overall, the agenda topics selection was felt to be lacking a prescribed process (e.g., SOP). There is consensus that this process should be part of a structured work planning exercise, taking into account need, urgency, and expected impact.

There were suggestions that a more open consultation process involving other stakeholders in a formalized manner could be beneficial, however, in those circumstances care would be required to avoid the agenda-setting being driven or influenced by individual stakeholders’ interests.

On the operational side it was noted that a large part of SAGE meetings is spent on sessions ‘for information’ and reports, that SAGE sessions are often very long, and that presentations are sometimes not clear or harmonized.

Recommendation 9

A. WHO IVB to ensure systematic interaction with Regional Offices and RITAGs for identification of topics for the SAGE agenda in close consultation with NITAGs and country offices.

B. WHO IVB to consider establishing a Steering Committee for the collection, triaging and prioritization of agenda topics.

C. SAGE to focus its agenda on ‘for decision’ and ‘for discussion’ items and to reduce the time spent on ‘for information’ sessions.
### 7.10. Decision-making and Working Group processes

The current consensus-based SAGE process of decision-making is deemed optimal by the vast majority of stakeholders (88% of the key technical partner respondents). However, some concerns exist about the process of formulating SAGE recommendations (52% of the key technical partner respondents): several stakeholders pointed out that the decision-making process does not always appear transparent and raised concerns that, at times, ‘influential’ or ‘vocal’ stakeholders exercise unjustifiable influence (see 7.12.). In particular, clearer summary decisions and remaining questions at the end of every ‘for decision’ session are thought to be needed as well as increased transparency on the decision-making criteria used by SAGE.

WGs are seen as a key feature in the SAGE decision-making architecture, allowing the committee to expand its expert knowledge and competencies beyond its membership and as a major mechanism for the synthesis of evidence using the GRADE and Evidence to Recommendations (EtR) framework. Overall, WGs are considered as working well and appropriately structured. The standard composition with one or two SAGE members and a number of experts identified by a selection panel is considered appropriate, allowing geography as well as gender and expertise to factor in even if efforts for further improvement regarding diversity are recommended. There is full consensus on their time-limited nature (100% of SAGE members and key technical stakeholder respondents) and on the fact that standing WGs (such as the ones on polio, measles-related issues and GVAP) have a member rotation policy. During the interviews, the process of setting up WGs was indicated by some stakeholders as an area where improvements can be made, in particular related to the occasionally long lead-time required for their establishment. Some concerns were raised about the lack of uniformity of the functioning of various WGs. In addition, the role of other partner and donor agencies in this process should be clarified on certain aspects, e.g., their active involvement in funding or conducting research for WGs.

The GRADE approach is considered adequate by the vast majority of respondents (79% of the key technical partner and 87% of the broader stakeholder respondents), as is the use of the EtR framework. The publication of the GRADE tables is deemed appropriate with a request made to present them during the meetings where recommendations are discussed.

However, questions were raised by some stakeholders during the interview process on the suitability of GRADE for the assessment of observational studies with a call for alternative mechanisms to be explored.

Most respondents felt that SAGE’s recommendations were appropriately timely (79% of the key technical partner survey respondents) and, as a result, SAGE is seen as providing sensible answers to emerging issues and to be adequately responsive to urgent matters. Nevertheless, a more regular update of the position papers to remain current on evolving vaccine developments was solicited by several stakeholders, with the request for SAGE to seamlessly implement minor reviews of earlier decisions with minimal delay.

#### Recommendation 10

**A.** SAGE to communicate more clearly the decision-making criteria used for the development of SAGE recommendations and to more clearly link GRADE and Evidence to Recommendation tables to specific sessions and resulting reports.

**B.** WHO IVB to shorten the lead times for establishment of WGs and to update their SOPs to allow for comparable functionality.

**C.** WHO IVB to assure that the establishment and functioning of SAGE WGs is done independently of donor and funder support.

**D.** SAGE to establish a process for the timely revision of and update to its position papers in case of minor policy changes.
7.11. SAGE meeting setup and modus operandi

There is a general consensus (86% of the key technical partner and 75% of the broader stakeholder respondents) that the present SAGE modus operandi works reasonably well, allowing opportunities for participation of the key technical partners and of other stakeholders, including the invitation of comments from a wider audience.

Specifically, while the overall setup with plenary meetings and consensus voting is considered appropriate in terms of transparency, modifications that can possibly facilitate a more ‘honest and robust’ discussion were indicated as an area for improvement. Despite the fact that SAGE is seen as working effectively as a team, not all SAGE members actively participate in all ‘for decision’ sessions. Members may, at times, be hesitant to speak up in public on highly technical issues. A more active role for the chair in engaging all key technical partners during the public discussion was suggested, as well as the adoption of a more structured approach to engage members before the meeting. The establishment of longer closed-door sessions, during which SAGE members could preview detailed findings ahead of the open sessions and have frank discussions on controversial topics, was suggested by several parties during the interview process.

The limited proactive regional participation (WHO Regional Advisors and RITAGs) during the SAGE meetings was also pointed out during the interviews as an area to be addressed. Short regional presentations related to specific issues could be valuable to raise the profile of regional needs and priorities. Similarly, input from countries, private sector providers and civil society should be increased, creating specific appropriate spaces for their public comments.

Concerns were voiced by some interview participants that during SAGE meetings advocacy efforts may occur and that SAGE members should be shielded from any such lobbying to the extent possible.

The communication technology in use is widely perceived as not appropriate to enable good preparation of SAGE members or to promote high quality member interaction. The use of state-of-the-art video and audio technology was requested by most stakeholders in their comments in the survey and during the interviews, highlighting the positive impacts that such a move would allow, including a wider participation of experts from a distance and possibly reducing the need for travel.

Finally, suggestions were made for the establishment of an evaluation process for SAGE meetings providing immediate feedback for their further improvement.

**Recommendation 11**

**A.** The SAGE Secretariat to ensure appropriate preparation of meetings, curation of topics and presentations, e.g., by use of standard templates, and strengthened time management.

**B.** The SAGE Secretariat to establish longer closed briefing sessions for SAGE members allowing for in-depth review of more complex issues prior to the open SAGE meetings.

**C.** The SAGE chair to proactively encourage participation of all SAGE members in plenary discussions.

**D.** The SAGE Secretariat to establish a procedure to assess the meeting agenda and process, including the quality of presentations, materials and discussions immediately after a meeting, e.g., through a representative survey of registered meeting participants.

**E.** The SAGE Secretariat to explore and pilot utilization of state-of-the-art communication and IT technologies for SAGE and its Working Groups to improve efficiencies, allow for better and more frequent interaction and potentially reduce the need for travel.

**F.** WHO IVB to explore holding a third SAGE meeting per year via web-conference to allow discussion of matters of importance and to decompress the SAGE face-to-face meeting agenda.
7.12. Conflict of Interest management

The *Conflict of Interest* management is considered appropriate by the vast majority of the stakeholders (78% of the key technical partner respondents). However, the opportunity for and desirability of even more transparency was highlighted.

The precise *definition of what constitutes a CoI* was seen as an area deserving special attention to uphold SAGE independence. There is consensus on the need for extending the scope of CoI beyond simple financial interests and a focus on commercial enterprises. Other institutions beyond industry (e.g., public health, academia, donors) and other interests beyond the financial ones (e.g., research and policy) carry a relevant risk of undue influence on SAGE decisions and ought to be disclosed and appropriately managed. Any revision of CoI will need to encompass WGs. It was noted that sufficient attention should be paid to the need for any revised CoI mechanism to be consistent with the general WHO CoI practices, and to being applicable to all other WHO IVB advisory committees. Additionally, caution was voiced against too strict a CoI management, which would make it difficult to find subject-matter experts and to have meaningful discussion with all stakeholders concerned.

**Recommendation 12**

WHO IVB to refine the scope of what constitutes a CoI according to WHO-wide CoI policies, including interests beyond industry relationships, e.g., academic, intellectual, regional, and national interests, and upgrade the process for CoI management.
7.13. Communication and dissemination of SAGE output

There is general consensus (80% of the key technical partner respondents) on the need for improvement of the dissemination of SAGE decisions. The main output of SAGE work, the Weekly Epidemiological Records (WER) position papers and Vaccine publications, and the SAGE meeting notes and presentations are well known in the immunization field. Detailed background documents are considered as highly valuable but less well known with broader availability to be sought.

While the quality of position papers is rated as very high by most stakeholders, there are voices which consider SAGE outputs as being ‘too difficult’ and not easily ‘digestible’ by many immunization practitioners. Use of more effective communication tools and approaches as well as the generation of documents using more plain language was indicated by many as a possible way forward to achieve a broader reach. This would also require a constituency-tailored approach that goes beyond the traditional focus on immunization stakeholders and extends to policy and decision-making bodies including finance ministries, donors, CSOs, academics and media. Policy briefs for decision-makers, guidelines for implementers and additional communication channels to medical associations are suggested.

An improved communication and dissemination strategy would thus need to be more proactive to allow a wider audience in regions and countries to benefit from the SAGE output. Such a strategy will have to consider a number of components such as an improved WHO website, a smarter use of social media, and the partial webcasting of SAGE sessions (or at least a possibility for download of some sessions). It was highlighted that RITAGs and NITAGs will also have an instrumental role in enhancing communication of key recommendations to Ministries of Health.

The briefing with WHO DG and the higher-level WHO management is deemed important by those surveyed and should be continued. More direct involvement at the Assistant DG level in WHO could allow for tighter links with areas beyond immunization.

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**Recommendation 13**

A. WHO IVB to explore additional communication channels in collaboration with Regional Offices and RITAGs, i.e., in addition to ‘Weekly Epidemiological Records’ and ‘Vaccine’ publications, for dissemination of SAGE outputs.

B. WHO IVB to broaden its engagement and communication with multiple stakeholders including e.g., national immunization programme directors, professional associations and other immunization partners, and ensure the appropriate tailoring of communication messages and tools according to target audiences.
7.14. Secretariat role and resources

While there is wide consensus on the adequacy of the support provided by the SAGE Secretariat (71% of the key technical partner survey respondents), several comments were provided about the currently available financial resources for the SAGE Secretariat and its various WGs being inadequate and – as only partly coming from WHO core funding – potentially rendering SAGE vulnerable to influence from selective funders. The support of donors and funders for SAGE is welcome but needs to be managed – e.g., not being earmarked to a specific WG or topic – to avoid any possibility of undue influence. Specific budgets were suggested to be allocated to all WGs to ensure their effective functioning.

The ability of the SAGE Secretariat to provide sufficient data collection and analysis prior to SAGE deliberations (e.g., by performing or overseeing systematic reviews) appears to be inadequate in view of its limited size and large administrative burden. It was noted that the Secretariat will likely be even more stretched once some of the areas for improvement identified in this evaluation are addressed. Most stakeholders called for an increase in size of the SAGE Secretariat in the context of the further refinement of SAGE’s roles and modus operandi.

Recommendation 14

A. WHO IVB to perform an assessment of the resources required to implement the recommendations proposed by the EAGSE and to ensure a sufficiently staffed SAGE secretariat to facilitate the necessary processes.

B. WHO IVB to ensure that SAGE, SAGE Working Groups and SAGE Secretariat resources come from WHO core funding.

8 NEXT STEPS

The findings and recommendations were presented to SAGE for information in its April 2019 meeting. The WHO IVB Department is invited to develop an action plan with short term and longer-term activities to act upon these recommendations in each of the 14 thematic areas.

9 APPENDICES

The following reference documents are made available on the WHO website as background material of this report: [https://www.who.int/immunization/policy/sage/sage_evaluation_annexes.pdf](https://www.who.int/immunization/policy/sage/sage_evaluation_annexes.pdf)

- ToR of the SAGE evaluation
- ToR of the EAGSE
- ToR of the Consulting Group supporting the EAGSE
- Desk review summary with SAGE product and impact tables 2010-2017
- Online survey summary results
- In-depth interview summary themes