

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

Initial draft report of the
Expert Advisory Group on SAGE Evaluation (EAGSE)

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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
DoV – Decade of Vaccines
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
GPEI – Global Polio Eradication Initiative
GPW – Global Programme of Work
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
IVB – Immunization Vaccines & Biologicals
IVIR-AC – Immunization and Vaccines Related Implementation Research Advisory Committee
LIC – Low-income Country
LMIC – Lower Middle-Income Country
M&RI – Measles and Rubella Initiative
MIC – Middle-Income country
MNCAH – Maternal Neonatal Child and Adolescent Health
NCD – Non-communicable Disease
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
TAG – Technical Advisory Group
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

3. Introduction and background

The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 2005 as the principal advisory group to the World Health Organization (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"*¹.

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 Immunization, Vaccines and Biologicals (IVB) department. With specific reference to SAGE, the outcome of that review was synthesized into the following five recommendations²:

- *"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 working groups 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 Global Polio Eradication Initiative (GPEI), SAGE recommendations are essential to inform Gavi policies and SAGE exerts an oversight function of the Global Vaccine Action Plan (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.

After a decade of operations, and a common overview that SAGE is performing well, the Director IVB, the SAGE Secretariat and SAGE members agreed on the need to ensuring 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 has been carried out starting in April 2018 and ending in June 2019. (ref. Appendix 8.3 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 (ref. Appendix 8.1 for the scoping questions and appendix 8.4 for the notes of the consultation).

¹ SAGE Terms of Reference - February 2016.

² "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 did not refer to the SAGE

3.1. Objective and scope of the 2018-2019 SAGE Evaluation

The evaluation reviewed the appropriateness of the current Terms of Reference (ToR)³ and working processes of SAGE, including those of the SAGE Working Groups (WGs)⁴. It included SAGE's relationship with key actors in the immunization community, including country Ministries of Health and National Immunization Technical Advisory Groups (NITAGs), WHO Regions and Regional Immunization Technical Advisory Groups (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 IVB department as they are related directly to SAGE.

SAGE's role and function was assessed taking into consideration key strategies within e.g., Global Vaccine Action Plan (GVAP), and beyond the immunization field e.g., the focus on Universal Health Coverage (UHC), Health Security, and non-communicable diseases of the 13th Global Programme of Work and of the Sustainable Development Goals (SDG), as well as emerging themes of the post-2020 immunization agenda. 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.

3.2. Desired outputs of the SAGE Evaluation

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

- Ascertaining SAGE's role in relation to the evolving immunization and health agenda.
- Identifying the optimal interfaces with other WHO immunization and public health decision making and advisory bodies.
- Ensuring the optimal coordination with WHO Regions and regional immunization committees, as well as key partners and stakeholders.
- Ensuring that SAGE works effectively and is able to meet the highest quality standards.
- Ensuring the effective presentation and dissemination of SAGE and WHO recommendations.
- Revisiting the WHO SAGE Secretariat composition and resource needs.

4. Methodology of the evaluation

4.1. Evaluation governance

The evaluation was performed under the guidance and oversight of the Expert Advisory Group on SAGE Evaluation (EAGSE)⁵, tasked with the appraisal of the evaluation's methodology and findings and with the development of recommendations (ref. Appendix 8.2 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 IVB, and to ensure a balanced representation of experience, skills, regions, gender and background.

³ https://www.who.int/immunization/sage/SAGE_TORs_Full_21_11_08.pdf

⁴ https://www.who.int/immunization/sage/SAGE_Working_Groups_general_information.pdf?ua=1

⁵ https://www.who.int/immunization/policy/sage/sage_wg_evaluation_may2018/en

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 video or teleconferences in August, September, and November 2018, as well as in January, February and March 2019.

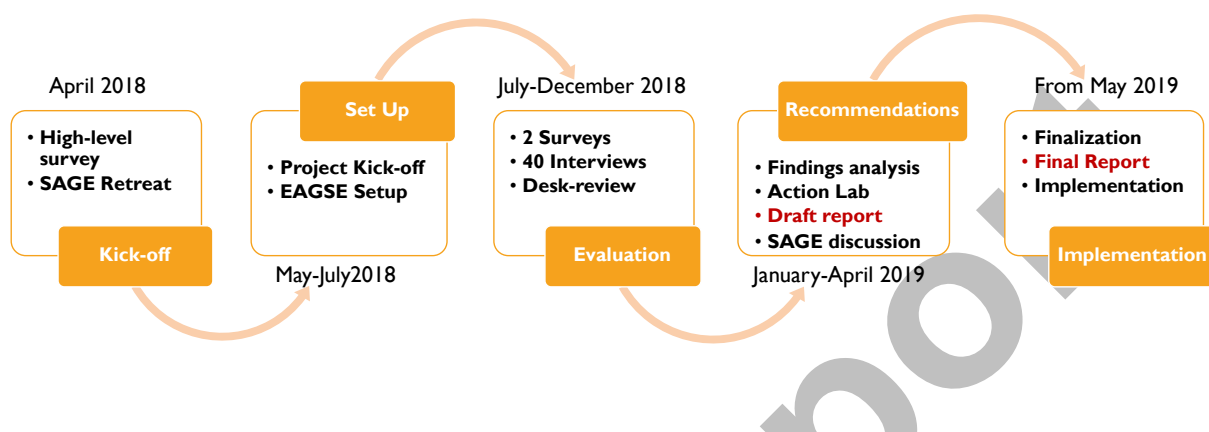


Figure 1: SAGE Evaluation Timeline.

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 8.7 for the ToR of the consulting group). Under the supervision of the WHO SAGE Secretariat and guided by the EAGSE, the consulting firm was tasked with preparing and facilitating meetings, administering online surveys, questionnaires and interviews, analysing the data and drafting documents.

4.2. 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** including the review of the prior SAGE evaluation, the review of all SAGE outputs between 2010 and 2017 and the resulting products (ref. appendix 8.5. 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;

- c) the administration of two **online anonymized surveys** via a dedicated survey tool (off-the-shelf tool Qualtrics™) sent to 110 stakeholders closely involved with SAGE, those forming the ‘inner circle’ during SAGE meetings (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 NITAG evaluation tool developed by the Strengthening of Immunization and Vaccines Advisory Committees (SIVAC) Initiative⁶, aimed at collecting views on SAGE performance in different areas of work. Some 58% of the ‘inner circle’ stakeholders (n=64) and 37% of Global Health stakeholders (n=42) responded to the survey.
- d) conducting **interviews** with a subset of stakeholders of both the ‘inner circle’ 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 3.2.) are fully covered by these themes (see table 1):

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

Table 1: Thematic Areas for Intervention and desired outputs of the evaluation

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

⁶ SIVAC tool for evaluating NITAGS - <http://www.nitag-resource.org/media-center/document/3473>

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 **prioritized the areas requiring focused attention** and suggested potential organizational and process changes. These activities were carried out as part of an Action Lab⁷, a two-day facilitated meeting focused on identifying concrete and actionable interventions for the 14 thematic areas for intervention identified in the prior phase. 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 are currently being prepared by EAGSE for consideration by the Director of IVB.

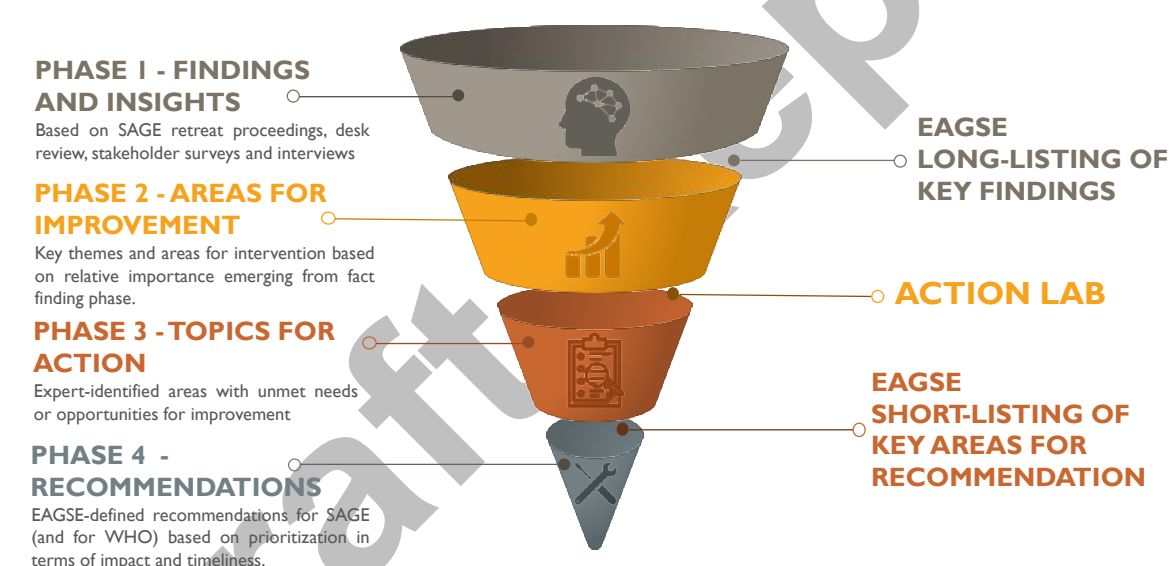


Figure 2: Evaluation Process Steps

5. SAGE retrospective: a descriptive analysis

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 3 and 4) - 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 8.6. for desk review questions).

Topic	# sessions	%	# for decision	# for discussion	# for information
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⁷ 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.

Vaccine-specific	68	40	51 (75%)	14 (21%)	3 (4%)
Reports	54	32	0	7 (13%)	47 (87%)
Programmatic challenges	20	12	5 (25%)	14 (70%)	1 (5%)
DoV/GVAP	12	7	7	1	4
Financing	4	2	0	4	0
Vaccine safety	4	2	1	3	0
General policy	3	2	0	3	0
SAGE process	2	1	0	2	0
Surveillance	2	1	0	2	0
TOTAL	169	100%	64 (38%)	50 (30%)	55 (32%)

Table 2: Topics discussed at SAGE meeting 2010-2017

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.

Number of sessions	Vaccine-specific topics
17 sessions	Polio
5 sessions each	Measles – rubella, influenza
3 sessions each	Ebola, Pertussis, Pneumococcal disease
2 sessions each	Cholera, Dengue, Hepatitis A, Human Papillomavirus, Meningococcal disease, Tuberculosis, Typhoid, Yellow Fever
1 session each	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

Table 3: Vaccine specific topics and numbers of sessions

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 DoV / GVAP were held (see table 1) for 5 years in preparation of World Health Assembly (WHA) discussions.

Number of sessions	Subject matter
16 sessions each	Reports from IVB Director, Gavi, other Advisory Committees
3 sessions each	Reports from Regions on regional priorities and updates and from international immunization partners

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

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.

6. Evaluation findings by thematic areas

Across the four phases of the evaluation and as previously stated, findings, derived from the desk review, the surveys and the in-depth interviews had been organised into 14 thematic areas which were the basis for the formulation of recommendations (see table 1). Details of findings by theme are provided in the following.

6.1. SAGE goals, mandate, mission and scope

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 or 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 inner circle respondents (57% of the survey respondents) 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).

Finally, 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 and the "implementability" of SAGE's recommendations. Any increased consideration of 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).

6.2. SAGE in the next decade

There is general agreement (80% of the 'inner circle' survey 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 for 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 to better align the SAGE agenda, role and processes with the Sustainable Development Goals (SDGs) and to address 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.

6.3. 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 as generated or assessed by other WHO advisory groups (see 6.4.). 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.

6.4. SAGE and other WHO Advisory Committees

While the role of the other WHO Advisory Committees (ACs)⁸ to SAGE functioning and their complementarity is acknowledged, the general perception is a lack of clarity about SAGE's relationship with these advisory bodies (by almost half, 47% of the 'inner circle' 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 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 a 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.

6.5. Principles of working with regions and countries

General consensus emerged among the stakeholders that SAGE should be more systematic in considering **regional and country needs** (54% of the 'inner circle' 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 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 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 regional offices to have the main responsibility in 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. This is becoming more

⁸ 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)

important as a result of the trend in which major donors appear to be reducing their engagement, increasing sustainability risks in some countries.

Finally, 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.

6.6. 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 relationships with RITAGs** and NITAGs should be rendered more functional (64% of the 'inner circle' survey 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. 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.

6.7. 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 the BMGF, the US Centers for Disease Control and Prevention (CDC) the European CDC (ECDC), the World Bank, bilateral donors, academia, industry, regulators, NGOs / CSOs and professional organizations.

A clearer **definition of the role of 'inner circle' stakeholders** – 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 contours of engagement.

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

6.8. 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 both inner circle and broader stakeholders 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 (in particular Americas and Europe) 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.

Finally, 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 post. In this respect the clarification of the role of the vice-chair – for which ToR do not yet exist – is indicted as an area worth exploring.

6.9. 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 inner circle survey respondents to the survey). Specifically, concerns are raised by some survey respondents about the 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 6.6.), 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.

Finally, 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.

6.10. 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 'inner circle' survey respondents); however, some concerns exist about the process of formulating SAGE recommendations (52% of the 'inner circle' respondents): several stakeholders pointed out that the decision-making process does not always appear transparent and raised concerns on, at times, 'influential' or 'vocal' stakeholders exercising unjustifiable influence (see 6.11.). In particular, more clarity on how SAGE arrives

at its decisions is thought to be needed with increased transparency by the immunization community on the decision-making criteria used.

Working Groups (WG) 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 Grading of Recommendations Assessment, Development and Evaluation (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 Secretariat-identified panel of experts is considered appropriate, allowing to factor-in geography as well as gender and expertise even if efforts for further improvement regarding diversity are recommended. There is full consensus on their time-limited nature (100% of 'inner circle' survey 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 has been 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. Finally, the role of other partner and donor agencies in this process can 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 'inner circle' and 87% of the broader stakeholder group 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 operational studies with a call for alternative mechanisms to be explored.

Most respondents felt that **SAGE's recommendations** were appropriately timely (79% of the 'inner circle' 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.

6.11. SAGE meeting setup and Modus Operandi

There is a general consensus (86% of the 'inner circle' and 75% of the broader stakeholder respondents) that the present SAGE modus operandi works reasonably well, allowing opportunities for **participation** of the 'inner circle' 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 '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 inner circle members 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) 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.

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.

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 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 and possibly obviating 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.

6.12. Conflict of Interest management

The **Conflict of Interest (Col) management** is considered appropriate by the vast majority of the stakeholders (78% of the 'inner circle' survey respondents). However, the opportunity for and desirability of even more transparency was highlighted.

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

6.13. Communication and dissemination of SAGE output

There is general consensus (80% of the 'inner circle' 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 practitioners in the immunization world. 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.

Finally, 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 Director General level in WHO could allow for tighter links with areas beyond immunization.

6.14. Secretariat role and resources

While there is wide consensus on the adequacy of the support provided by the SAGE Secretariat (71% of the inner circle survey responders), 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 will be 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.

7. Next steps

The EAGSE is presently preparing detailed recommendations related to SAGE's mission and scope, relations and modus operandi in each of the 14 thematic areas for consideration by the Director IVB. These recommendations will be presented to SAGE for information in its April 2019 meeting.

8. Appendixes

The following reference documents will be made available on the SAGE website for background materials in advance of the April 2019 meeting:

8.1. Evaluation scoping questions

8.2. TOR of the EAGSE

8.3. TOR of the SAGE evaluation

8.4. SAGE product table 2010-2017

8.5. Desk review impact table

8.6. TOR of the Consulting Group