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Review of vaccine hesitancy: Rationale, remit and methods

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ABSTRACT

Despite a wide array of safe and effective vaccines in use globally, with major impacts on health worldwide, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization has been repeatedly confronted with reports of hesitancy towards accepting specific vaccines or vaccination programmes. This paper summarizes the rationale for a SAGE review of the issue of vaccine hesitancy, its impact and ways to address it, and the convening of a Vaccine Hesitancy Working Group in March 2012 to prepare for the SAGE review. It describes the methods used and mode of operations, and advances in the relatively new field of research on vaccine hesitancy. It further elaborates and references the work conducted, including a series of products, conclusions and recommendations that emerged from the SAGE review in October 2014.

1. Background

The Strategic Advisory Group of Experts (SAGE) on Immunization, established by the Director-General of the World Health Organization (WHO) in 1999, provides guidance on the work of WHO concerning vaccines and immunization, and is the principal advisory group to WHO in this field. It is charged with advising WHO on overall global policies and strategies, ranging from vaccines and technology, research and development, to implementation of immunization and its linkages with other health interventions. SAGE is concerned with all vaccine-preventable diseases as well as cross-cutting issues related to immunization. SAGE Working Groups are convened on an ad hoc basis to assemble and review the available data on specific topics and propose draft conclusions and recommendations for SAGE's consideration during its bi-annual meetings.

Since its establishment, SAGE has been repeatedly confronted with reports of decreased acceptance of vaccines and/or immunization programmes by individuals or communities. This recurrent theme, spanning different vaccines and immunization issues, has emerged in both developed and developing countries. Presented with a report from the Global Advisory Committee on Vaccine Safety, in June 2001 SAGE noted that although scientific reports stated that there was no evidence of adverse events following immunization (AEFI), the public remained unsatisfied and wanted to be convinced that vaccines had been proven safe. A discrepancy between scientific evidence and perception of risk and difficulties in communication were highlighted. SAGE then endorsed the proposal for the development of a communication strategy to address public concern about AEFI in general, although it was acknowledged that there would always be a marginal yet influential group of people who would not trust information on immunization [1]. In the SAGE June 2002 report, thiomersal safety concerns, which were noted to be mostly driven by perceptions rather than by established scientific facts, were raised [2]. In November 2006, the WHO Regional Office for Europe (WHO/EURO) reported that, in response to negative publicity about immunization, it was prioritizing information and advocacy initiatives such as the expansion of the Global Vaccine Safety Net initiative and European Immunization Week [3]. The November 2008 SAGE report emphasized that misinformation about vaccine safety and AEFI had had negative effects during recent measles and rubella vaccination campaigns. Mistrust and fear of vaccines and immunization have led to a lack of support by some health professionals. Politicization of vaccination recommendations and decisions, as well as commercial interests of the pharmaceutical industry, have further exacerbated the situation in some countries.

The need for a methodical and proactive communication strategy to respond to misinformation and anti-immunization activities was recognized by WHO/EURO [4]. Particular challenges

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to eliminating measles including a lack of political and societal support for the goal, propaganda by anti-vaccine groups, contrary religious and philosophical beliefs, competing health priorities, and problems created by the reform of health systems in some eastern European countries were recognized by SAGE in October 2009 [5]. The October 2010 report stated that WHO/EURO had also been asked to use the European immunization week as a platform for increasing public awareness of the benefits of immunization and countering the false messages disseminated by anti-vaccination movements [6]. In April 2011, continued non-compliance with vaccination in several areas in Nigeria at high risk of wild poliovirus transmission was noted as a cause of concern by SAGE [7]. In November 2011 SAGE acknowledged that it would be crucial to address vaccine hesitancy in India, classified as a polio-endemic country at that time, as hesitancy was hampering the country's efforts to eliminate polio [8].

Given the continuous reappearance of a broad range of issues related to mistrust and non-acceptance of vaccines and the concerns expressed by different countries, the use of effective communication about vaccines with vaccine-hesitant populations was listed in April 2011 as a priority topic for SAGE to address [7]. SAGE expressed concern that the way forward to tackle hesitancy was not clear and felt that the global challenge of vaccine hesitancy, which posed a major threat to the integrity and acceptance of vaccines and immunization programmes worldwide, should be assessed and dealt with. Based on these concerns about vaccine hesitancy, its impact on vaccine uptake rates and the performance of national immunization programmes, SAGE established the SAGE Working Group on Vaccine Hesitancy in March 2012 with the following terms of reference [9].

2. Terms of reference

- Prepare for SAGE a review and advice on how to address vaccine hesitancy and its determinants.
- Define vaccine hesitancy and its scope.
- Undertake a review of vaccine hesitancy in different settings including its context-specific causes, its expression and its impact.
- Suggest one or several indicator(s) of vaccine hesitancy that could be used to monitor progress in the context of the Decade of Vaccines Global Vaccine Action Plan.
- At global, regional and national levels:
  - Perform a landscape analysis of who/what organizations are working on this issue in various settings/countries;
  - Identify existing activities and strategies that have had or could have a positive impact including examination of successful strategies that are not specifically related to vaccines or even medicines;
  - Identify strategies and activities that did not work well;
  - Identify new activities and strategies that could have a positive impact;
  - Prioritize existing and new activities/strategies based on an assessment of their potential impact;
  - Outline the specific role of WHO in addressing vaccine hesitancy; and
  - Identify the specific role of regional and country advisory committees.

3. Working Group on Vaccine Hesitancy and its Secretariat

A total of 11 international experts actively participated in the proceedings and deliberations of the Working Group. Following an open call for nominations, the experts were selected based on their experience in the field of vaccine hesitancy and to represent a wide array of expertise including social anthropology, communication and media, immunization programme delivery, knowledge of vaccination and experience in addressing vaccine hesitancy at a community level. Broad representation was assured from all WHO regions and from diverse contexts and backgrounds, as well as balanced membership from developing and developed countries. As for all SAGE working groups, transparent processes for assessment of conflicts of interest were put in place. Potential conflicts of interest of members were assessed and made publicly available on the WHO website [9].

The Working Group was supported by a joint WHO–UNICEF Secretariat, which included several departments, not only those directly involved with immunization, at both the headquarters and regional levels.

4. Methods and activities

The general approach of the Working Group on Vaccine Hesitancy was guided by the terms of reference set by SAGE. Initial deliberations of the Working Group specified the requested deliverables and identified appropriate methods. These methods included:

1) Conducting relevant de novo systematic literature searches of evidence on vaccine hesitancy in order to explore vaccine hesitancy in different settings including its context-specific causes, its expression and its impact: studies to be included were peer-reviewed publications, gray literature, reviews of published systematic reviews, and field reports;
2) Reviewing and assessing models characterizing vaccine hesitancy developed by different organizations;
3) Discussing personal observations reported from the field by different organizations and Working Group members;
4) Conducting an immunization managers' survey of vaccine hesitancy;
5) Conducting a de novo systematic literature search to generate data on vaccine hesitancy intervention strategies, including review of peer-reviewed studies and gray literature. This review also took into consideration successful strategies from beyond the field of immunization, within the area of reproductive health. The quality of the retrieved evidence was assessed using the GRADE methodology. A literature review of existing systematic reviews complemented the retrieved evidence;
6) Compiling vaccine hesitancy survey questions extracted from the published and gray literature and developing questions de novo with input from the Working Group members;
7) Developing and pilot testing of vaccine hesitancy indicators in the WHO–UNICEF Joint Reporting Form (JRF) in 2012 and 2013 and at Inter-country Support Team South, East and Central African Regional Immunization Managers' meetings in 2013, in view of the Global Vaccine Action Plan Strategic Objective 2 "that individuals and communities understand immunization as their right and responsibility"; and
8) Consultations to discuss hesitancy and its impact with the Global Polio Eradication Initiative (GPEI), United States National Vaccine Advisory Committee (NVAC), communications and marketing experts from industry, and other working groups and advisory committees, such as the SAGE Global Vaccine Action Plan (GVAP) Working Group, the SAGE Measles and Rubella Working Group, the Global Advisory Committee on Vaccine Safety (GACVS), and the Immunization and Vaccine Related Implementation Research Advisory Committee (IVIR-AC).

Beyond the Working Group's Secretariat, diverse departments in WHO and UNICEF were asked to identify additional staff from their departments able to contribute to specific discussions.

Other organizations not involved in immunization were also consulted including programmes, academic and research groups working on related topics. Attempts were made to draw upon experiences from beyond the field of immunization and beyond the health sector that relate to hesitancy/refusal to accept certain services and/or products or behavioural changes.

Discussions took place via email, monthly conference calls and three in-person meetings of the Working Group.

5. Processes

The Working Group began its work in March 2012 and continued until the final presentation to SAGE in October 2014.

Two in-person meetings in October 2012 and February 2013, in addition to the monthly teleconferences, facilitated the development of a definition of vaccine hesitancy, a workable model of factors impacting vaccine hesitancy [10] and indicators of vaccine hesitancy [11], which were pilot tested in the WHO Region of the Americas and the European Region in the 2013 JRF. By April 2013, the commissioned systematic review on vaccine hesitancy [12] had been finalized, and based on the retrieved evidence, the systematic review on interventions to address vaccine hesitancy had been initiated. A landscape analysis of organizations working on vaccine hesitancy was conducted.

These products and the preliminary results, as well as an interim report on the status of the proceedings, were presented to SAGE in April 2013 [13].

SAGE endorsed the effort to review successful interventions in health-related fields beyond immunization, aiming at improving confidence and increasing demand for vaccination, and supported the development of diagnostic tools to identify the context-specific cause(s) of hesitancy and to differentiate hesitancy from the many other reasons why children are not vaccinated or under-vaccinated, as such tools would help guide strategies to address the underlying causes. SAGE noted that the proposed indicators on vaccine hesitancy were currently being field-tested and that recommendations should be developed regarding demand creation and proactive interventions. SAGE recommended close linkages and interaction with key WHO and UNICEF initiatives to address the unvaccinated or under-vaccinated groups and relevant interventions.

Following the SAGE interim recommendations, the Working Group carried out the Immunization Programme Managers' Survey in 2013[14] including interviews with selected programme managers, and revised the definition of vaccine hesitancy [10].

Based on the matrix of determinants of vaccine hesitancy, in response to requests from countries, a standard list of survey questions was prepared by the Working Group with questions developed de novo or retrieved from published literature, acknowledging that few of these questions have been validated, and that none of the questions had been validated in settings other than high-income countries [11]. The systematic review on strategies was finalized prior to the October 2014 SAGE meeting [15]. The Working Group reviewed the 2013 Guide to Tailoring Immunization Programmes (TIP) developed by WHO/EURO. The TIP framework is based on evidence from behavioural economics, the medical humanities, psychology, and neuroscience. It may be a useful tool in understanding and addressing vaccine hesitancy, though further evaluation is needed [16].

A final in-person meeting of the Working Group took place in December 2013. This meeting focused on interaction with partners and reaching out to other initiatives to examine their experiences and how these might be relevant in addressing vaccine hesitancy and creation of demand. In addition to the Working Group members, participants attending this meeting included WHO and UNICEF technical staff from headquarters, regional and country offices and marketing experts from industry via the International Food & Beverage Alliance (IFBA) [17].

The Working Group discussed the findings and lessons learned from each of the initiatives and incorporated the conclusions in their deliberations and recommendations based on the retrieved evidence [18]. Final Working Group conclusions and recommendations as well as the various developed or reviewed products were reviewed and endorsed by SAGE in October 2014 [19].

6. Discussion

The iterative approach followed by the Working Group throughout its work has both strengths and limitations. The inclusion of a diverse group of experts from different disciplines proved to be very important for critical discussions of the nuances revealed in the reviews, surveys and consultations. Representation of geographic and socioeconomic diversity from all WHO regions was necessary in order to understand the issues from a global perspective, without which the report could have placed undue emphasis on findings from high-income countries, such as those retrieved from the systematic review of evidence.

The main limitation of the approach was the context in which the work was carried out. This was a period in which much new information was coming forward and the understanding of vaccine hesitancy was evolving. Having a clear and practical accepted definition for vaccine hesitancy was critical for the systematic reviews and consultations, so that like could be compared with like. As the term 'vaccine hesitancy' was still emerging, this presented some initial problems for the Working Group, as reflected in the lengthy process to reach the accepted definition.

The recognition that vaccine hesitancy is complex with many different determinants that vary with context, vaccine, setting and time infers that it is unlikely that any single strategy would be effective in addressing all determinants of vaccine hesitancy.

The systematic reviews, studies and consultations revealed many gaps in knowledge about vaccine hesitancy, with a paucity of work in particular from middle and low-income settings, but also revealed useful strategies for moving forward.

The volume of work carried out by the Working Group was necessarily compressed in the report to SAGE and the related annexes [20]. This supplement on vaccine hesitancy is intended to present the issues and findings that were reported to SAGE and expand the audience for this information, in order to raise awareness of vaccine hesitancy as an important modern public health problem, in a readily accessible publication for the public health and scientific communities and the general public.

As was emphasized by SAGE, ongoing evaluation of the deliverables developed by the Working Group is essential. And beyond the scope of the SAGE review, validation of the developed tools and assessment of future and current research and strategies are also needed.

These contributions to understanding, defining and communicating on the topic are seen as an initial step in tackling the continuing and evolving challenges in the field of vaccine hesitancy. The conclusions and recommendations endorsed by SAGE in October 2014 [18] may contribute to efforts to address vaccine hesitancy, particularly by national immunization programmes in all regions of the world when considering the introduction of new vaccines or counteracting the dwindling uptake of well-established vaccines.

Conflict of interest statements

The LSHTM research group "Project to monitor public confidence in Immunization Programs" has received research funding

from Novartis as well as funding from GSK to host a meeting on vaccine confidence. Heidi Larson has done consulting on vaccine confidence with GSK.

None of the other authors had any potential conflict of interest.

Some of the authors are World Health Organization staff members. The opinions expressed in this article are those of the authors and do not necessarily represent the decisions, official policy or opinions of the World Health Organization.

Appendix. SAGE Working Group on Vaccine Hesitancy

Juhani Eskola, National Institute for Health and Welfare, Finland (Chair of Working Group since April 2014); Xiaofeng Liang, Chinese Center for Disease Control, China (Member of SAGE until 2014, Chair of Working Group from March 2012 to April 2014); Mohuya Chaudhuri, Independent Journalist and Documentary Filmmaker, India; Eve Dubé, Institut National de Santé Publique du Québec, Canada; Bruce Gellin, Department of Health and Human Services, U.S.A; Susan Goldstein, Soul City: Institute for Health and Development Communication, South Africa; Heidi Larson, London School of Hygiene and Tropical Medicine, U.K.; Noni MacDonald, Dalhousie University, Canada; Mahamane Laouali Manzo, Ministry of Health, Niger; Arthur Reingold, University of California at Berkeley, U.S.A.; Kinzang Tshering, Jigme Dorji Wangchuck National Referral Hospital, Bhutan; Yuqing Zhou, Chinese Center for Disease Control, China with the WHO/UNICEF Secretariat: Robb Butler, World Health Organization, Denmark; Philippe Duclos, World Health Organization, Switzerland; Sherine Guirguis, UNICEF, U.S.A; Ben Hickler, UNICEF, U.S.A; Melanie Schuster, World Health Organization, Switzerland.

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