REPORT OF THE SAGE WORKING GROUP ON VACCINE HESITANCY

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List of Abbreviations

AFR- WHO African Region AMR- WHO American Region EMR- WHO Eastern Mediterranean Region **EUR- WHO European Region GPEI-** Global Polio Eradication Initiative **GVAP- Global Vaccine Action Plan** GACVS- WHO Global Advisory Committee on Vaccine Safety **HIC- High Income Country** IVIR-AC – WHO Immunization and vaccines related implementation research advisory committee LIC- Low Income Country LMIC- Low and Middle Income Countries NVAC- National Vaccine Advisory Committee (USA) MIC- Middle Income Country SAGE: Strategic Advisory Group of Experts on Immunization SEAR- WHO South East Asian Region **UNICEF-** United Nations Children's Fund WHO- World Health Organization

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Section 1: Introduction

Unlike other medicines, vaccines work at both the individual and community level. While no vaccine is 100% effective, when used broadly in communities, several vaccine preventable diseases could be eliminated and some may be eradicated. High vaccine uptake rates, specific to each vaccine preventable disease, are needed for community-level immunity to be achieved and sustained in order that disease risk can lowered beyond what would be predicted by vaccine coverage alone. Even in countries with overall high national vaccine uptake rates, there may be clustered pockets or subgroups where the rates of uptake are lower than required for protection of the community. In the past decade, such pockets have been associated with outbreaks or resurgence of measles, mumps, *Haemophilus influenzae* b, pertussis and polio in countries where these diseases had previously been controlled.

At the November 2011 meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization, SAGE noted with concern the impact of reluctance to accept immunization on the uptake of vaccines reported from both developed and developing countries. These reports led SAGE to request the establishment of a working group on vaccine hesitancy¹.

Background

The evidence demonstrating the benefits of immunization are overwhelming. It is one of the most successful and cost-effective interventions to improve health outcomes. Vaccines have saved countless lives and improved health and well-being around the globe. However, to prevent the morbidity and mortality associated with vaccine preventable diseases and their complications, and optimize control of vaccine preventable diseases in communities, high uptake rates must be achieved. In 2011, SAGE noted the growing recognition of the negative impacts of hesitancy on vaccine uptake rates and program efficiency². Through a survey of SAGE members in 2011, communication with vaccine hesitant populations was identified as one of the new priority topics for SAGE³. If the high uptake rates needed for herd immunity are to be achieved and sustained, individual and community hesitation and reluctance to be immunized must be better understood and addressed. SAGE also observed that the problem did not appear to be restricted to one region or subset of the population. For example during the pH1N1 influenza pandemic, SAGE highlighted that while many countries in the Americas successfully deployed influenza pandemic vaccine to the general public, many had difficulty in convincing pregnant women to accept the vaccine. Even when faced with strong evidence of increased morbidity and mortality caused by influenza, many pregnant women hesitated to obtain pandemic influenza vaccination despite the recommendation by their health care provider and their country's immunization program leaders. Even improved access to receive vaccine did not reliably overcome this. Similarly, reluctance to accept measles vaccine in parts of Europe, HPV vaccine in Japan and

¹ http://www.who.int/wer/2012/wer8701.pdf, accessed 16.09.2014

² http://www.who.int/wer/2011/wer8601_02.pdf, accessed 16.09.2014

³ http://www.who.int/wer/2011/wer8621.pdf, accessed 16.09.2014

India, polio vaccine in parts of Nigeria and Pakistan, are just a sample of the episodes that are appearing around the world. Because the root causes of these events are complex and not always straight forward, SAGE also expressed concern that the path forward to address hesitancy was not clear.

Based upon the concerns about hesitancy and its impact on vaccine uptake rates and the performance of national immunization programs, SAGE established the SAGE Working Group on Vaccine Hesitancy in March 2012 with the following terms of reference⁴:

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 looking at successful strategies that have worked and 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;
 - Identify the specific role of regional and country advisory committees.

The Working Group on Vaccine Hesitancy was composed of:

- a) Juhani Eskola, National Institute for Health and Welfare, Finland (Chair of Working Group since April 2014)
- b) Xiaofeng Liang, Chair of Working Group, Chinese Center for Disease Control, China (Member of SAGE until 2014, Chair of Working Group from March 2012 to April 2014)
- c) Arthur Reingold, University of California at Berkeley, U.S.A. (Member of SAGE until 2012)
- d) Mohuya Chaudhuri, Independent Journalist and Documentary Filmmaker, India
- e) Eve Dubé, Institut National de Santé Publique du Québec, Canada

⁴ http://www.who.int/immunization/sage/sage_wg_vaccine_hesitancy_apr12/en/, accessed 16.09.2014

- f) Bruce Gellin, Department of Health and Human Services, U.S.A.
- g) Susan Goldstein, Soul City: Institute for Health and Development Communication, South Africa
- h) Heidi Larson, London School of Hygiene and Tropical Medicine, England
- i) Noni MacDonald, Dalhousie University, Canada
- j) Mahamane Laouli Manzo, Ministry of Health, Niger
- k) Dilian Francisca Toro Torres, Congress of the Republic of Colombia (was only able to join the working group proceedings for the first teleconference and had to withdraw for personal reason)
- 1) Kinzang Tshering, Jigme Dorji Wangchuck National Referral Hospital, Bhutan
- m) Yuqing Zhou, Chinese Center for Disease Control, China

The Working Group was supported by a SAGE and UNICEF Secretariat, including participation and support from WHO's SAGE Secretariat, the WHO Global Vaccine Safety Group, the WHO Expanded Program on Immunization, the WHO Director General Central communication team, the WHO Polio Department, and WHO regional offices as well as UNICEF headquarters, UNICEF polio communications and the UNICEF AFR regional office.

Report Structure

This Report deals with the deliverables established in the SAGE Terms of Reference for the Working Group. Each Section begins with the deliverables to be addressed followed by the conclusions of the Working Group and then the detailed discussion of the work done to address the deliverables. In the final Section (Section 7), the Working Group's recommendations to SAGE are presented. The Appendices to this report will be posted on the SAGE share point.

Section 2: General Approach and Methods

The general approach of the SAGE Working Group on Vaccine Hesitancy was guided by the deliverables set out by SAGE. This was accomplished through discussion of 1) commissioned and published relevant systematic reviews of evidence on vaccine hesitancy, including published studies, grey literature, and field reports; 2) models characterizing vaccine hesitancy developed by different organizations; 3) personal observations reported from the field by different organizations and Working Group members; 4) an immunization managers' survey of vaccine hesitancy; 5) a review of systematic reviews of vaccine hesitancy intervention strategies; 6) vaccine hesitancy survey questions extracted from the published and gray literature and developed, in part, with Working Group member input; 7) pilot testing of vaccine hesitancy indicators in Joint Reporting Form (JRF) (2012, 2013) and at Intercountry Support Team South & East and Central African Regional Immunization Managers' meetings in 2013; 8) consultations to discuss hesitancy and its impact with WHO regional offices, UNICEF (HQ and regional offices), the Global Polio Eradication Initiative (GPEI), United States National Vaccine Advisory Committee (NVAC), communications and marketing experts within 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). Other organizations not involved in immunization were also consulted including programs and research groups working on related topics. Attempts were made to draw from experiences from beyond the immunization and the health fields.

The Working Group consulted on the findings and lessons learned from each of these outlined initiatives and embedded the conclusions into their deliberations and recommendations.

In developing a workable model of factors impacting on vaccine hesitancy, literature and reports from other relevant organizations including both published and unpublished findings were reviewed and discussed to inform the final Working Group Vaccine Hesitancy Matrix of Determinants (See Section 3). To ensure a comprehensive approach, the developed Matrix of determinants was reviewed against the findings of the systematic review of determinants, a 2014 review of hesitancy focused on low and middle income countries (LMIC), and the Immunization Program Managers' Survey conducted in 2013.

Section 3: Definition of Vaccine Hesitancy, its Scope and Vaccine Hesitancy Determinants Matrix

SAGE Deliverable: Define vaccine hesitancy and its scope

The Working Group reviewed vaccine hesitancy definitions and models, discussed the nuances of demand versus hesitancy and the role of communication in hesitancy, and determined that:

Definition: Vaccine Hesitancy

Vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccine services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence.

- 1. The scope of vaccine hesitancy does not apply to situations where vaccine uptake is low because of poor availability e.g. lack of vaccine (stock outs), lack of offer or access to vaccines, unacceptable travel/distances to reach immunization clinics, poor vaccine program communication, etc.
- 2. In low uptake situations where lack of available services is the major factor, hesitancy can be present but is not the principle reason for unvaccinated and undervaccinated members of the community. In these settings, improving services is the priority.
- 3. As the Complacency, Convenience and Confidence ("3Cs") model of vaccine hesitancy determinants succinctly categorized many factors it was embedded in the definition.
- 4. The more complex Working Group Vaccine Hesitancy Determinants Matrix (see below), with determinants in three main categories (contextual, individual and group and vaccine/vaccination specific influences) was more useful for guidance on development of vaccine hesitancy indicators, survey questions, diagnostic tools, and strategies for intervention, and research.
- 5. Concerns about vaccine safety may be associated with vaccine hesitancy. However, it is important not to equate vaccine hesitancy and vaccine safety. Safety is only one driver of vaccine hesitancy. Nevertheless, in situations where vaccine safety is one of the underlying causes of vaccine hesitancy, using appropriate best practices to address concerns over adverse events following immunization, can minimize the potential negative impact that may result.
- 6. Communication is a key tool for success of any immunization program but is not a specific determinant in vaccine hesitancy. However, inadequate or poor communication about vaccines (e.g., why they are recommended and their safety and effectiveness) can contribute to vaccine hesitancy.
- 7. To achieve vaccine demand as per GVAP Strategic Objective 2, not only must vaccine hesitancy be addressed, but communities must be supported in seeing value in vaccines for individuals

and for communities and in conveying their vaccine needs and perspectives on how vaccine programs are delivered to key decision makers. However, having communities demand current or new vaccines is a step beyond the scope of SAGE's desire to address vaccine hesitancy and increase vaccine acceptance.

Working Group Considerations on Definition and Scope of Vaccine Hesitancy

Section 3A: Definition

As there was no established definition of vaccine hesitancy, with input and suggestions from the Working Group, the definition selected as the starting point for discussion in 2012 was:

Vaccine attitudes can be seen on a continuum, ranging from total acceptance to complete refusal. Vaccine-hesitant individuals are a heterogeneous group in the middle of this continuum. Vaccine hesitant individuals may refuse some vaccines, but agree to others; delay vaccines or accept vaccines but are unsure in doing so.^{5,6}

While highlighting that vaccine hesitant individuals encompass a much larger group and are likely very different to those who outright refuse vaccines, the Working Group determined that this definition was not adequate as it neither defined the scope nor provided any concept of the many factors that influence hesitancy.

The Working Group determined that the definition of vaccine hesitancy and its scope must be practical (i.e. not too long and applicable to populations, subgroups and individuals). It needs to embed the assumption that vaccine(s) are available and affordable. It needs to be highlighted that equivocation on the decision on whether to accept vaccine(s) is the core issue, with many factors impinging on this complex decision i.e. context, time and specific vaccine.

Section 3B: Scope

The Working Group, based upon experience in different geographic settings and the emerging use of the term in the literature, agreed upon vaccine hesitancy being *present when vaccine acceptance in a specific setting is lower than would be expected, given the availability of vaccine services.* Thus vaccine hesitancy is a behavioural phenomenon that is vaccine and context specific and measured against an expectation of reaching a specific vaccination coverage goal, given the immunization services available. The Working Group also recognized that vaccine hesitancy occurs along a continuum between full acceptance, including high demand for vaccine, and outright refusal of some or all vaccines (Figure 1), though acceptance of vaccines is the norm in the majority of populations globally.

⁵ Opel et al Hum. Validity and reliability of a survey to identify vaccine-hesitant parents. Vaccine. 2011;7:419-25

⁶ Benin et al. Qualitative analysis of mother's decision-making about vaccines for infants: the importance of trust.Paediatrics 2006;117:1532-41

The Working Group agreed that although vaccine hesitancy may be present in situations where vaccine uptake is low because of any one of a number of system failures (lack of vaccine, stock-outs, lack of vaccine offer, infeasible travel/ distances to reach immunization clinics, missing vaccine program communication, or curtailment of vaccine services in the presence of conflict, natural disaster or similar situations), it is not the principle driver of unvaccinated or undervaccinated members of the population. These situations where individuals or communities lack the opportunity to accept or refuse vaccine(s) fall outside the scope of the Working Group definition of vaccine hesitancy; thus vaccine coverage estimates cannot be used as a reliable indicator of vaccine hesitancy. In low uptake situations where lack of available services is the major factor, hesitancy can be present but the priority is to address they system failure that limits vaccine access and availability.

Figure 1: The Continuum of Vaccine Hesitancy between Full Acceptance and Outright Refusal of all Vaccines



Defining the scope of vaccine hesitancy and differentiating hesitancy from other reasons children/adults are unvaccinated or under-vaccinated is of critical importance in assessment of whether interventions to specifically address vaccine hesitancy in a population or subgroup are or are not needed in order to improve vaccine uptake rates.

Section 3C: Vaccine Hesitancy versus Confidence in Vaccines

The Working Group, in its early meetings, discussed at some length whether hesitancy was the most appropriate word to describe this problem. Concerns were raised that hesitancy has a negative connotation and might send the wrong signal. The most commonly offered alternative in the literature is confidence, a more positive word. However, the Working Group noted that vaccine confidence was too narrow a term, covering only one category of factors that affect vaccine acceptance decisions (see discussion of Models and Matrix below).

Section 3D: Vaccine Hesitancy and Vaccine Demand

In the Global Vaccine Action Plan, approved by the World Health Assembly in May 2012⁷, Strategic Objective 2 states that "*individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility*" [GVAP p38].

Vaccine hesitancy occurs on the continuum between high vaccine demand and complete vaccine refusal i.e. one who is not demanding available and offered vaccines, but rather is equivocal about ever receiving some or all vaccines in accordance with the recommended schedule (Figure 1). Similarly, a vaccine hesitant community is one that does not accept vaccines at the rate expected, given that services and vaccines are available i.e. lower vaccine demand than expected. At both the individual and community level, if vaccine hesitancy is present, it undermines personal and community responsibility for immunization. Given these characteristics of hesitancy, achieving the GVAP Objective 2 will require better identification, understanding and addressing of both individual and community level vaccine hesitancy, as well as the encouragement of demand.

As noted in the GVAP, achievement of Strategic Objectives 2 will be "contingent upon all stakeholders having clearly defined and coordinated responsibilities." "Individuals and communities, as recipients of immunization, should do the following: Understand the risk and benefits of vaccines and immunization, viewing this as part of being a responsible citizen. Demand safe and effective immunization programmes as a right from their leaders and government, and hold leaders and government accountable for providing them. Participate in public-health discussions and be involved in key decisions about immunization processes. Participate and contribute to the immunization delivery process and convey the needs and perspectives of their communities to the policy-makers" [GVAP p95-96].

The working group noted that although it was crucial to address these demand-building approaches as outlined in this GVAP, tackling vaccine hesitancy needs more engagement and tailored approaches, beyond intention for demand generation (see Strategic Objective 2).

Hence, having communities and individuals demand vaccines differs from addressing vaccine hesitancy and increasing vaccine acceptance. The two examples in the box illustrate demand aspects that are beyond addressing hesitancy.

Two examples of community vaccine demand illustrate the aspect of demand not encompassed in vaccine hesitancy:

In Uttar Pradesh, India, the community demanded, through the courts, public access to Japanese Encephalitis vaccine to curb annual disease outbreaks associated with high morbidity and mortality (http://www.rishabhdara.com/sc/view.php?case=100927).

In Calgary, Canada where access to Human Papilloma Virus vaccine in Catholic schools was precluded in 2008 by a religious ban on in school delivery, citizens' demand in 2013 successfully overturned this religious ban. [Guichon JR, Mitchell I, Buffler P, Caplan A. Preventive Medicine 2013; 57:409–413].

['] Global Vaccine Action Plan: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en, accessed 16.09.2014

As hesitancy undermines demand, to achieve the in GVAP defined vaccine demand goal, countries will need to address hesitancy. High rates of hesitancy mean low demand. Thus the root causes and magnitude of vaccine hesitancy must be determined and addressed at both the individual and community level as a start to increasing demand. However, low rates of hesitancy do not mean that there will be high demand. To achieve high individual and community vaccine demand, context, community and vaccine specific strategies beyond those aimed at addressing hesitancy need to be developed.

Section 3E: Models of Vaccine Hesitancy: Vaccine Hesitancy Determinants

At its core, vaccine hesitancy is the behaviour that results from the decision-making process and reflects a constellation of factors that may influence the decision to accept some or all vaccines in accordance with the recommended schedule. In further refining the definition of vaccine hesitancy, the Working Group assessed a number of conceptual models for understanding and grouping of vaccine hesitancy determinants (See Appendix A3.1). Models were considered and reviewed for complexity and global applicability. Their factors were considered and assessed for potential usefulness in



informing the development of vaccine hesitancy indicators, survey questions and interventions for use at the global and country levels.

Figure 2: Confidence, Complacency, Convenience Model of Vaccine Hesitancy

Review of these models re-enforced that vaccine hesitancy is complex and is not driven by a simple set of individual factors. Two models were determined to be most useful. The Complacency, Convenience and Confidence ("3Cs")

model was intuitive and thus the easiest to grasp (Figure 2). In addition a more comprehensive Working Group Matrix that better captured the complexity of the contextual, individual, and group and vaccine /vaccination-specific influences (Table 1) was developed.

In the "3Cs" model, *confidence* is defined as trust in 1) the effectiveness and safety of vaccines; 2) the system that delivers them, including the reliability and competence of the health services and health professionals and 3) the motivations of the policy-makers who decide on the needed vaccines.

Vaccine *complacency* exists where perceived risks of vaccine-preventable diseases are low and vaccination is not deemed a necessary preventive action. Complacency about a particular vaccine or about vaccination in general is influenced by many factors, including other life/health responsibilities that may be seen to be more important at that point in time. Immunization program success may, paradoxically, result in complacency and ultimately, hesitancy, as individuals weigh risks of vaccines against risks of diseases that are no longer common. Self-efficacy (the self-perceived or real ability of

an individual to take action to vaccinate) also influences the degree to which complacency determines hesitancy.

Vaccine *convenience* is measured by the extent to which physical availability, affordability and willingness-to-pay, geographical accessibility, ability to understand (language and health literacy) and appeal of immunization services affect uptake. The quality of the service (real and/or perceived) and the degree to which vaccination services are delivered at a time and place and in a cultural context that is convenient and comfortable also affects the decision to be vaccinated and could lead to vaccine hesitancy.

The more complex Working Group Determinants of Vaccine Hesitancy Matrix has determinants arranged in three categories: *contextual*, *individual and group* and *vaccine /vaccination-specific influences* (Table 1). (See Appendix A3.1 for more detailed Matrix).

Table 1: Working Group Determinants of Vaccine Hesitancy Matrix

CONTEXTUAL INFLUENCES

Influences arising due to historic, socio-cultural, environmental, health system/institutional, economic or political factors

INDIVIDUAL AND GROUP INFLUENCES

Influences arising from personal perception of the vaccine or influences of the social/peer environment

VACCINE/ VACCINATION-SPECIFIC ISSUES

Directly related to vaccine or vaccination

- a. Communication and media environment
- **b.** Influential leaders, immunization program gatekeepers and anti- or pro-vaccination lobbies.
- **c.** Historical influences
- d. Religion/culture/ gender/socio-economic
- e. Politics/policies
- **f.** Geographic barriers
- g. Perception of the pharmaceutical industry
- a. Personal, family and/or community members' experience with vaccination, including pain
- b. Beliefs, attitudes about health and prevention
- c. Knowledge/awareness
- d. Health system and providers-trust and personal experience.
- e. Risk/benefit (perceived, heuristic)
- f. Immunisation as a social norm vs. not needed/harmful
- a. Risk/ Benefit (epidemiological and scientific evidence)
- b. Introduction of a new vaccine or new formulation or a new recommendation for an existing vaccine
- c. Mode of administration
- d. Design of vaccination program/Mode of delivery (e.g., routine program or mass vaccination campaign)
- e. Reliability and/or source of supply of vaccine and/or vaccination equipment
- f. Vaccination schedule
- g. Costs
- h. The strength of the recommendation and/or knowledge base and/or attitude of healthcare professionals

The Matrix includes determinants derived from a range of sources: research studies, from experience of Working Group members in the field, from discussions with experts working in the area, from the systematic review of determinants, and the findings from the Working Group's Immunization Managers Survey (Section 4).

Vaccine hesitancy is often equated with vaccine safety concerns. Whereas the Working Group acknowledged that vaccine safety concerns can be factors underlying hesitancy, safety concerns are just one of many determinants of vaccine hesitancy. Nevertheless, specific serious adverse events following immunization (AEFI), such as a death following a vaccination, can trigger hesitancy locally and at a distance if not well managed. Health care workers (HCW) need to be well trained to address serious AEFIs, including investigation, causality assessment, and communication. When AEFIs are well handled, the risk of increasing hesitancy can be minimized. The Vaccine Safety Net facilitates the access of public health authorities, health professionals and the public to reliable information on vaccine safety via the internet⁸.

Section 3F: Vaccine Hesitancy and Communication

The Working Group discussed whether poor communication was a determinant of vaccine hesitancy. The Working Group concluded that it was a tool not a determinant. While communication is not a specific factor, like confidence, complacency and convenience, when it is poor or inadequate it can negatively influence vaccine uptake and contribute to vaccine hesitancy. Poor quality services of any type, including poor communication, can undermine acceptance.

Poor, inadequate or misguided communication can be a problem in any setting. In HIC with wellresourced vaccine programs, inadequate or poor vaccine communications can increase vaccine hesitancy and outright refusal. For example, in 1999, the reason underlying the decision to minimize thimerosal as a preservative in some vaccines in the USA was poorly communicated. As a consequence, this impacted on public confidence in vaccines and the vaccine system, leading to increased vaccine hesitancy and refusal. In LMIC, scarce communication resources limit the capacity to counter negative information about vaccines and achieve community support for vaccination programs. For instance, the Independent Monitoring Board on Polio Eradication noted deep concern about "the Global Programme's weak grip on the communications and social mobilization that could not just neutralize communities' negativity, but generate more genuine demand. Within the Programme, communications is the poor cousin of vaccine delivery, undeservedly receiving far less focus. *Communications expertise is sparse throughout and needs to be strengthened*⁹". The WHO African Task Force on Immunization is collaborating with UNICEF on the development of a tool to improve vaccine program communications in the region because these deficiencies, especially during crises with poor quality communication, may result in significant vaccine hesitancy. Thus, regardless of the setting and causes of vaccine hesitancy, poor communication needs to be addressed generally, in addition to developing targeted communication to address hesitancy and improve vaccine uptake.

⁸ Vaccine Safety Net: <u>http://www.who.int/vaccine_safety/en/</u>, accessed 16.09.2014

⁹ WHO Weekly epidemiological record. <u>http://www.who.int/wer/2013/wer8828.pdf?ua=1</u>, accessed 16.09.2014

Section 4: Determinants and Impact of Vaccine Hesitancy in Different Settings

Deliverable: Undertake a review of vaccine hesitancy in different settings including its context-specific causes, its expression and its impact.

The Working Groups undertook a systematic review of literature on vaccine hesitancy, an immunization managers' survey, discussed examples of hesitancy in populations where measureable improvements had occurred following targeted intervention, and reviewed presentations and materials from other WHO groups, researchers and partners (such as WHO vaccine safety, UNICEF and others). After review and discussion, the Working Group observed that:

1. Vaccine Hesitancy is:

- *a)* A global problem that varies between and within countries;
- b) Context, time, place, program and vaccine specific;
- c) Not a new problem but a problem increasingly being recognized;
- d) More likely with:
 - o new or newly introduced vaccines than with older locally well-accepted vaccines
 - mass campaigns than with routine immunization.

2. The Impact of Vaccine Hesitancy is

- a) Reflected in lower than expected country vaccine uptake rates and within country
 subgroup uptake rates, though does not necessarily impact on the country's vaccination
 coverage if only in subgroups and pockets of unimmunized.
- b) Difficult to assess precisely across the globe and regionally due to country variations in the definition and a lack of data.
- c) A complex and multilayered, social behavioural phenomenon; however, the precise level when vaccine hesitancy has a harmful impact on individuals and communities is dependent on the background epidemiologic picture;
- 3. The Working Group Matrix of Determinants of Vaccine Hesitancy is (see Section 3).
 - a) Strongly supported by the systematic review and consistent with other findings.
 - b) Determinants may have opposite effects in different settings and regions e.g. higher education has been associated with higher and lower rates of hesitancy. Hence, one cannot assume the influence of a determinant.
 - c) While most research on determinants focused on social and cognitive factors, too narrow a research approach may constrict the spectrum of potential strategies conceived to address vaccine hesitancy at the individual, community and population levels.

d) While vaccine hesitancy studies with determinants were identified in all regions, the great majority were from the WHO EUR and AMR, with only a few from other regions. Published studies in LMIC were particularly scarce.

4. Like a differential diagnosis of a chief complaint in clinical medicine, understanding the Determinants of Vaccine Hesitancy and diagnosis of the root(s) of the problem in each specific setting is fundamental to the development of appropriate and targeted interventions. Moreover, because the evidence-base that supports the effectiveness of various interventions is thin, there is a need to advance this area through evaluation.

Section 4A: Systematic Review of Vaccine Hesitancy: 2007-2012

The findings of the commissioned systematic review of the published literature can be found in Larson HJ et al.¹⁰ (See Appendix 4A.1). The review team used the earlier, narrower draft Working Group definition of vaccine hesitancy and a spatial model with vaccine acceptance/hesitancy in middle and many spokes for different determinants (see Section 3, Appendix Figure 3A.2) developed by the Working Group in 2012- 2013. The search focused on routinely recommended childhood vaccines and covered the years 2007- 2012. With duplicates removed, of the slightly over 16,000 articles retrieved from the more than 30,000 articles identified, 1164 were included for full review.

Many factors were found to be associated with vaccine hesitancy, but this review reinforced that there was no simple universal or small group of determinants that influenced hesitancy in all circumstances. The independence and relative strength of each identified factor varied by context, setting and type of vaccine.

Figure 3 below illustrates barriers (B) and promoters (P) of childhood vaccination uptake, mapped onto the contextual component of the Vaccine Hesitancy Matrix of Determinants by WHO region.

Taking the example of education, the impact of a determinant may differ widely. In contrast to the social determinants of health, where a factor like education drives in one direction, better education resulting in better health, with vaccine hesitancy, higher education may be associated with either lower or higher levels of vaccine acceptance.

¹⁰ Larson HJ et al. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: A systematic review of published literature, 2007–2012. Vaccine 2014, 32: 2150-2159

Figure 3: Barriers (B) and promoters (P) of childhood vaccination by contextual influences



Does education predict vaccine acceptance?: Studies from China, Lebanon, Israel, Bangladesh and USA all identified higher education as a potential barrier to vaccine acceptance, whereas studies from Greece, The Netherlands, Nigeria and Pakistan identified it as a promoter of vaccine acceptance. Low education was cited as a barrier in studies from Nigeria, India, China and Kyrgyzstan, and both as a promoter and barrier to acceptance in the United States. In the DR Congo, both high and low education were barriers. Furthermore, low education had different reported effects in other countries. In India, low literacy was related to low vaccine knowledge but not anti-vaccine attitudes, while in Nigeria and Kyrgyzstan, low literacy was linked to higher likelihood of anti-vaccination attitudes.

These findings regarding education illustrate why individual determinants of vaccine hesitancy must not be viewed in isolation or always assumed to be acting in the same way in different settings. More importantly, the reviews made it clear that multiple factors shape vaccine acceptance. Therefore, in addressing vaccine hesitancy, the critical issue is to determine the principle factors that are collectively contributing as barriers to vaccine uptake and promoters of vaccine hesitancy.

Not all factors in the Working Group Matrix were identified in the systematic review. This may be a reflection of how determinants were selected for study. Most often, selection was based upon core theoretical constructs of classic social cognitive models (e.g. Health Belief Model, Theory of Planned Behaviour). These models do not adequately take into account the influence of broader contextual factors noted in the Working Group Matrix of Determinants of Vaccine Hesitancy. A gap identified was the dearth of studies on populations and subgroups. Most studies focused on addressing individuals not communities. Again, this gap may narrow conceptualization of intervention strategies. The Working Group recognized that while social cognitive determinants are important, in considering the future path of the research community, too narrow a research approach may constrict the spectrum of potential strategies conceived to address vaccine hesitancy at the individual, community and population levels.

As of July 2014, two other systematic reviews of parental vaccine-hesitancy and attitudes towards vaccines had been published^{11,12}. The review by Williams focused primarily on HIC and the one by Yaqub on studies from countries in Europe. Of note in the latter study, a paucity of papers from Eastern European countries was observed. Neither review uncovered new determinants for inclusion in the Matrix.

From these reviews, the Working Group concluded that the determinants of vaccine hesitancy in any setting are complex. Vaccine hesitancy is global, but the precise level at which it becomes a problem disrupting immunization programs and/or contributing to vaccine-preventable disease outbreaks – cannot be precisely determined with current measurement and diagnostic tools. As many of the studies in the systematic review were cross-sectional, extending inferences on vaccine hesitancy behaviour from one setting to another, even in same region, may be problematic and should be done cautiously. More studies, in particular qualitative studies, are needed from all regions in order to better understand

¹¹ Williams SE. What are the factors that contribute to parental vaccine-hesitancy and what can we do about it? Hum Vaccin Immunother. 2014 May 1;10(9) ¹² Yaqub O et al. Attitudes to vaccination: A critical review. Social Science & Medicine. 2014; 112

individual and community vaccine uptake behaviour if vaccine hesitancy drivers are to be better understood in specific contexts.

Section 4B: Immunization Managers' Survey on Vaccine Hesitancy

In April 2013, following the interim report of the Working Group, SAGE recommended that a survey of immunization managers be conducted on vaccine hesitancy in their respective countries to provide a snapshot of the breadth, perceived drivers and importance of vaccine hesitancy globally. The Working Group developed a telephone-based survey designed to qualitatively capture unanticipated responses whilst assessing known determinants of vaccine hesitancy (see Appendix A4.2 for full report). The survey was carried out in 2013, and consisted of semi-structured interview with 14 closed and open-ended questions. In collaboration with WHO Regional Office advisors, 13 country immunization managers (IM) in the six WHO regions were interviewed – and specifically included high, middle and

low-income countries to ensure a breadth of contexts for this vaccine hesitancy assessment.

The study results, not unexpectedly, revealed a wide variation in the reported basis for vaccine hesitancy across these countries. Vaccine hesitancy was identified as a concern in each of the 13 countries surveyed. The impact of vaccine hesitancy on immunization program vaccination uptake was considered as minor in 11 countries, while two noted it to be a major problem. Overall, the qualitative analysis identified religious beliefs as the most often cited determinant of hesitancy. Other commonly noted factors were lack of trust in the health system and/or in the health care provider, vaccine safety concerns, and a lack of perceived benefit of vaccines. Risk of adverse events leading to hesitancy occurred particularly in the context of mass campaigns, and was more likely with newly-introduced than established, more familiar vaccines. In eight of the 13 countries surveyed, interventions were implemented to address the vaccine hesitancy problem, although rigorous evaluation of these interventions had not been done.

The interviews did not identify any new determinants beyond those in the Working Group Matrix and reinforced that hesitancy is a global phenomenon whose impact varies across and within countries. The survey also highlighted that many of these countries lacked the capacity to identify and appropriately address vaccine hesitancy.

A limitation of the study was a lack of consistency in the definition of hesitancy across countries, posed as an open-ended question, and difficulties in quantifying the problem. Further, perceptions of the immunization managers might not represent the reality at the community level. The study also noted that poor service delivery problems can compound hesitancy. The survey also spotlighted the need for tools to diagnose local causes of vaccine hesitancy, as immunization managers are not equipped or trained to do these types of studies, and every country will have its own nuances.

In summary, vaccine hesitancy existed in all 13 countries surveyed. The causes of vaccine hesitancy were variable and context-specific, indicating the need to strengthen the capacity of countries to first identify local context-specific factors of vaccine hesitancy and then develop tailored strategies to address them.

Section 4C: Vaccine Hesitancy – Populations, Subgroups, Communities and Individuals

The Working Group also examined hesitancy within populations and subgroups. Working Group members brought forward examples where subgroups in a population differed in vaccine hesitancy from the main population and then changed their vaccine hesitancy behaviour as the context changed. One example from Israel highlighted this change, where an Orthodox Jewish community began accepting polio vaccine after the wild poliovirus was found in sewage and their local rabbis, who previously had shunned vaccination, started to recommend it¹³. Thus a vaccine hesitant community became vaccine compliant after a contextual change. The kinetics of the H1N1 influenza pandemic in many countries offered numerous examples of variation in vaccine uptake among subgroups in the population (e.g. uptake of vaccine by pregnant women versus uptake by children). As child mortality increased, demand for and acceptance of childhood influenza immunization rose steadily. In contrast, demand for and acceptance by pregnant women in spite of reported deaths from pandemic influenza mirrored these trends in some, but not all countries.

Section 4D: Working Group Observations on Determinants and Impact from Materials and Presentations by Experts from GVAP, GPEI, UNICEF, IVIR-AC, NVAC, WHO Regional Offices.

The Working Group also reviewed presentations and/ or materials from experts from GVAP, GPEI, UNICEF, IVIR-AC, NVAC, WHO Regional Offices and others to see if other determinants not in the Working Group Matrix of Determinants of Vaccine Hesitancy had been raised. No new factors were found, although several determinants not highlighted in the systematic review were noted. The reports did reinforce the findings in the review that a specific determinant may have an opposing effect in different settings, times and contexts. The GPEI highlighted that even when access to vaccination was difficult, many parents in Pakistan tried to have their children immunized. The locals' trust was higher in local health organizations (99% indicated trust) than in international health organizations (70% indicated trust), and was seen as a key factor for polio vaccine acceptance. The presentations from UNICEF, GPEI and IVIR-AC all emphasized the difficulty in accessing vaccine (i.e. convenience as determinant of vaccine hesitancy), even when vaccine outreach programs were in place. Of note, often programs may think that outreach programs address the access barrier, even when they may not (see Bulgaria Roma example page 35). Armed conflict was also noted as a contributor to hesitancy, as it did not only increase access problems, but also added political factors into the mix of determinants of vaccine hesitancy.

¹³ Kallner E. et al. Silent reintroduction of wild-type poliovirus to Israel, 2013 – risk communication challenges in an argumentative atmosphere. Euro Surv 2014; 19(7).

Section 5: Vaccine Hesitancy Monitoring and Diagnosis

Deliverable: 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).

The Working Group acknowledged that monitoring, diagnosing and segmenting issues that significantly contribute to vaccine hesitancy, needs to be the initial step in order to apply effective, targeted strategies. The Working Group suggests diagnostic tool to measure/diagnose vaccine hesitancy, yet these tools still need further evaluation and validation across different settings.

The Working Group reviewed and pilot tested several indicators and developed a compendium of vaccine hesitancy survey questions, as many countries had expressed need for this. The Guide to Tailoring Immunization Programmes (TIP), developed by WHO EUR, was also reviewed to assess its potential for diagnosing vaccine hesitancy factors in subpopulations.

Two indicators were developed in part to meet the requirment of the GVAP's goal of measuring and monitoring vaccine demand. The first set of indicators developed by the Vaccine Hesitancy Working Group in 2012 was reviewed by the GVAP Working Group. The provided feedback led to a revision of the indicators in 2013.

Indicators of Vaccine Hesitancy

Immunization programs need to regularly determine if and where pockets of under-immunized subgroups occur in the country as part of good program management practice. Then, the factors underlying this lower than expected uptake, given the vaccine services, need to be assessed.

a) Coverage (uptake rates) and/or immunization drop-out rates, although potentially appealing as proxy measures for hesitancy, are not valid single measures of hesitancy as they encompass non-hesitancy aspects (e.g. access, stockouts, program delivery obstacles, etc) not related to hesitancy.

b) Measuring demand for vaccination is problematic. There is no linear relationship between hesitancy and demand-low hesitancy does not necessarily mean communities are demanding vaccines. Addressing demand includes but goes beyond addressing hesitancy.

c) The GVAP working group overseeing the revision of the indicators acknowledged that the JRF could provide a practical, routine opportunity to collect information on vaccine hesitancy. WHO/UNICEF regions can decide whether they want to include one or both of the recent indicators into their regional JRF. Adequate translation into languages other than English of the questions and the term "vaccine hesitancy" needs to be ensured.

d) Given the limited validation of the relevance of these questions to predict and monitor vaccine hesitancy in a community, the Working Group concluded that only process indicators of vaccine

hesitancy are feasible at this time and that routinely assessing whether measurements of vaccine hesitancy have been conducted would emphasize the current need to identify vaccine hesitancy in the community when it exists and reinforced this approach to integrate vaccine hesitancy assessments into program assessments until better tools and more resources become available.

e) As vaccine hesitancy is not static and varies by vaccine, context and time, to obtain a clear picture at the country population level may require further refinement of the indicators, building on this JRF work.

Indicators of Vaccine Hesitancy proposed for inclusion in the JRF are:

Process and Etiologic Indicators (2013)

Etiologic Indicator: Reasons for vaccine hesitancy.

Question 1:

What are the top three reasons for not accepting vaccines according to the national schedule? *Question 2:*

Is this response based or supported by some type of assessment, or is it an opinion based on your knowledge and expertise?

Process Indicator: % of countries that have assessed the level of hesitancy in vaccination at a national or subnational level.

Question 1: Has there been some assessment of vaccine hesitancy or refusal among the public at national or sub-national level? Question 2: If yes, please provide assessment title(s) and reference(s) to any publication/report.

These Indicators need to be accompanied by the vaccine hesitancy definition and a note requesting a response to Indicator 2 regardless of the response to Indicator 1.

Vaccine Hesitancy Survey Questions

Countries using selected questions from the Working Group Compendium of sample Vaccine Hesitancy Questions to measure vaccine hesitancy must bear in mind that:

1. More research is needed to develop, validate and determine the utility of questions on determinants. i.e. are these helpful or should diagnosis of causes best be done using programs such as TIP. The majority of the questions in the survey have not been validated and for those that have, only in HIC.

2. Selecting questions from the compendium supports inter- country comparison of answers.

3. Refusal of vaccination is not the same as vaccine hesitancy which lies on a continuum between acceptance and refusal.

4. The current survey questions predominantly focus on identifying whether hesitancy is present, not on the determinants of hesitancy.

5. Question selection needs to fit the context.

6. Question sequencing matters. Leading questions may drive answers in a particular direction and make one factor appear to be more important than it might actually be.

7. Context also alters relevancy of specific questions and/or may influence the answers

8. Sample questions linked to the Working Group Determinants of Vaccine Hesitancy Matrix were developed.

9. Asking specific determinant questions rather than asking for hesitancy concerns must be approached with great caution, as they may trigger hesitancy issues not previously considered by survey participants e.g. bringing to their attention issues around alleged threats by MMR vaccine such as autism.

Diagnosis of Determinants of Vaccine Hesitancy in Specific Subgroups.

The 2013 Guide to Tailoring Immunization Programmes (TIP) developed by WHO EUR, based upon evidence from behavioural economics, the medical humanities, psychology, and neuroscience, is an example of a tool that may be useful in understanding and addressing vaccine hesitancy by helping to:

a) Identify and prioritize vaccine hesitant populations and subgroups

b) Diagnose the demand and supply -side barriers to vaccination in these populations

c) Support design of evidence –based responses to vaccine hesitancy appropriate to the setting, context and population.

Of Note- TIP does not promote one or more specific intervention strategies. Rather by segmenting the population it helps to validate the diagnosis of the relevant barriers and enablers of vaccine uptake in the subgroup(s); and can guide the development of an intervention tailored to fit the findings, context and available resources for each subgroup.

For TIP to be a useful tool globally, the following developments are needed:

To apply to vaccine hesitancy:

1. The 2013 TIP needs to be reshaped to better fit the varied needs and levels of expertise in the different regions.

2. TIP vaccine hesitancy=related resources/ expertise/ training are needed to support implementation in WHO regions.

3. Tip needs to be evaluated and assessed in a range of settings in HIC, MIC and LIC.

4. A means to share TIP successes, failures and lessons learned in addressing vaccine hesitancy is needed across regions and globally.

5. The TIP approach adapted to address other communicable and non-communicable diseases where behavioural decisions markedly influence outcomes needs to be tested and evaluated.

6. For application of TIP to hesitancy and other areas where behavioural decisions are key to health outcomes, to optimize use of resources and minimize costs, pulling together core behavioural insight teams at WHO headquarters and the regional level with the required integrated knowledge and skills of sociologists, behavioural psychologists, anthropologists, experts in social marketing and communication as well as specific disease experts is needed.

Section 5A: Indicators of Vaccine Hesitancy

One of the Terms of Reference for the SAGE Working Group on Vaccine Hesitancy was "to suggest one or several indicator(s) that could be used to monitor progress on a global and on a national level in the context of the Decade of Vaccines Global Vaccine Action Plan" However, as the Working Group noted in Section 3, vaccine hesitancy and vaccine demand are not synonyms.

The Working Group on Vaccine Hesitancy, therefore focused on developing indicators for assessing vaccine hesitancy. Demand indicators might utilize similar strategies but were beyond the scope of the Vaccine Hesitancy Working Group.

Although coverage and/or immunization drop-out rates are potentially appealing as proxy measures for hesitancy, they encompass non-hesitancy aspects, such as limited access due to vaccines stockouts and other program delivery obstacles not related to hesitancy.

The WHO/UNICEF Joint Reporting Form (JRF)¹⁴ is a questionnaire-based monitoring tool usually completed by national immunization managers designed to examine national immunization coverage, reported cases of vaccine-preventable diseases, immunization schedules and indicators of immunization system performances. This could provide a routine opportunity to capture hesitancy if indicators can be developed. In 2003-2006, the JRF had questions introduced about whether negative publicity concerning vaccines or immunization had been present. While 20% of member states reported the presence of negative publicity, these questions only captured one potential factor that might impact on hesitancy and demand (see Section 3).

¹⁴ <u>http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/, accessed 16.09.2014</u>

2012 Trial Indicators

Indicator 1: % of countries that have assessed (or measured) the level of confidence in vaccination at subnational level.

Question 1:

Has there been some assessment (or measurement) of the level of confidence in vaccination at subnational level in the past?

Question 2:

If yes, please specify the type and the year the assessment has been done.

Indicator 2: % of un- and under-vaccinated in whom lack of confidence was a fact or that influenced their decision.

Question 1:

What is the % of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision (this applies to all vaccines)?

Question 2:

Was this % measured or estimated?

Question 3:

Any comments or specific issue?

These two indicators were pilot tested in the 2012 JRF in the Americas (PAHO) and the European (EURO) regions. In addition, the two indicators were tested within a self-administered questionnaire distributed at the Inter-country Support Team South & East and Central African Regional Immunization Managers' meetings in 2013 in the African region (AFRO). Pilot testing within these three regions ensured coverage of a broad range of high, middle and low-income countries needed to assess response, comparability and feasibility of the indicators in different settings. The response rate of 14% (13/94)) was suboptimal (See Appendix 5A.1 for Report 2012 JRF Indicators). The analysis revealed that 19% of all participating countries had done an assessment of the level of confidence in their country, demonstrating that vaccine confidence was an issue in their country. Of note, lack of vaccine confidence ranged from 0% in Cuba, Dominica, Botswana and Sao Tomé & Principe, 1% in German and Brazil, 4% in Guatemala and Jamaica, 5% in Burundi, 8% in DR Congo, 10% in Romania, 18% In Czech Republic to 19% in Uganda. These results demonstrate that the lack of confidence can be significant problem, even in low-income settings, such as Uganda, where rather availability of services, not vaccine confidence might be presumed to be an issue.

Feedback from regions/countries revealed several concerns: a) misreporting, as current surveys did not actually measure vaccine hesitancy, b) surveys may only have been done in one part of a country not reflecting the whole, c) about a lack of a good translation for the term "vaccine hesitancy" in languages other than English and d) confusion about the definition because "access" was included. Many countries called for tools and questions to help them better assess vaccine hesitancy. Based on these concerns, the SAGE GVAP Working Group requested the Working Group to revisit the indicators during its December 2013 face-to-face meeting.

Modifications to the 2013 JRF included: refining the indicators to widen the scope of vaccine hesitancy to include not just confidence but also convenience and complacency, to link with the revised Working Group definition, and inclusion of a narrative description of Working Group definition of vaccine hesitancy in the JRF.

Revised JRF Vaccine Hesitancy Indicators 2013:

2013 Indicators

Indicator 1: % of countries that have assessed the level of hesitancy in vaccination at a national or subnational level.

Question 1: Has there been some assessment of vaccine hesitancy or refusal among the public at national or sub-national level?

Question 2:

If yes, please provide assessment title(s) and reference(s) to any publication/report.

Indicator 2: Reasons for vaccine hesitancy.

Question 1:

What are the top three reasons for **not** accepting vaccines according to the national schedule in the last year?

Question 2:

Is this response based or supported by some type of assessment, or is it an opinion based on your knowledge and expertise?

The indicator questions were accompanied by a narrative on vaccine hesitancy, including the Working Group definition of vaccine hesitancy (Section 3).

The WHO EUR region volunteered again to pilot test the revised vaccine hesitancy indicators in its 2013 JRF. This was sent in January 2014 to the 53 member countries in EUR, who were asked to return the completed forms by 15 April 2014. (See Appendix 5A. for Report on 2013 Indicators)

In brief, more countries (31/45) reported on indicator 1, which is a higher response rate to the indicator than in the JRF 2012 (25/48). Within the 2013 JRF, 10 countries indicated having undertaken an

assessment. This may be due to an increased number of assessments amongst the countries in the EUR region, better understanding of the question due to the inclusion of a revised narrative and/or as a result of the inclusion of both a national and a sub-national assessment in the indicator question in comparison to only a sub-national assessment in 2012. For those countries not responding to indicator 1, it remains unclear if non-response was a proxy for no assessment, lack of understanding, or lack of willingness to answer the question.

With regard to Indicator 2, 36% (16/45) of the countries responded to the question and provided reasons for vaccine hesitancy. The response rate to this newly revised indicator was higher compared to the previous indicator: only 6% (3 out of 48) of the European countries in 2012 had provided a measured or estimated percentage of un- or under-vaccinated in whom a lack of confidence in vaccination was a factor.

The top three reasons for vaccine hesitancy, categorized by the determinants within the Working Group Matrix were 1) beliefs, attitudes, motivation about health and prevention, 2) risk/benefit of vaccines (perceived risks, experiences (heuristics)), and 3) communication and media environment. Major issues were fear of side effects of vaccination and distrust in the vaccine, lack of perceived risk of vaccine-preventable diseases and the influence anti-vaccination reports in the media.

Interestingly, 3 countries mentioned unjustified medical contraindications, medical contraindications, or the child being ill the day of the vaccination as reasons for vaccine hesitancy. The issue of false contra-indications is noted in the Working Group Determinants of Vaccine Hesitancy Matrix under on the role of the health care professional (See Section 3 Table 1 (i.e. in Appendix)).

A plausible reason for the lower response rate on Indicator 2 compared to Indicator 1 may be linked to the current structural format of the indicators. Upon analysing the data, it was found that 67% (14 out of 21) countries that answered "No" to Indicator 1 failed to continue and answer indicator 2. Meanwhile, only one of the ten countries that answered "Yes" to Indicator 1 did not complete Indicator 2. This suggests that countries may have believed that if they answered "No" to Indicator 1, they were not required to continue and complete the remaining questions of the vaccine hesitancy indicator. Further tweaking of the JRF questionnaire is suggested by the Working Group to clarify that both Indicator 1 and Indicator 2 should be completed, regardless of the response in Indicator 1.

Based upon past experiences with the JRF, a time period of approximately 3 years are required to obtain an adequate response rate with newly introduced indicators. With further familiarity and adjustment, the vaccine hesitancy indicators on the JRF may prove to be beneficial in identifying key reasons for vaccine hesitancy. The Working Group acknowledged that the quality of the JRF responses could be enhanced if these are based on national or sub-national survey evidence using questions from the same question bank (see below). Data on vaccine hesitancy collected on an annual basis, pose only a limited burden on countries, could provide information on the global prevalence and monitor potential shifts in the drivers and importance of vaccine hesitancy. Further, the indicators may be a valuable advocacy tool to raise awareness of vaccine hesitancy.

Immunizations programs need to regularly determine if and where pockets of un- or underimmunized subgroups occur in the country as part of good program management practice. This is part of good immunization program practice. To facilitate this, the Working Group, at the request of many countries has assembled a series potential survey questions (see Section 5B).

The revised indicators and the feedback from the JRF 2013 pilot test were presented to the GVAP Working Group in September 2014. Their recommendation was that WHO/UNICEF regional offices should decide whether they wanted to include one or both of the proposed indicators into their regional JRF. The annual JRF indicator 1 at this stage determines if regular assessment of vaccine hesitancy is taking place and serves as a reminder of good program practices. The data deriving from indicator 2 will allow the monitoring of major concerns of immunization managers with regard to vaccine hesitancy and their potential shift over time. Use of country vaccine hesitancy survey findings will in the future lead to improvement of the quality of Vaccine Hesitancy indicators reported on in the annual JRF.

During the meeting of WHO and UNICEF HQ and regional offices to consult on the 2014 JRF, several suggestions were made on how to improve the collection of data using the two proposed indicators. Prerequisite of including the indicators in the JRF was an adequate translation by a knowledgeable interpreter in order to ensure the comprehensibility of questions in languages other than English. Furthermore, the accompanying narrative needs to be very clear to immunization managers to not report on issues beyond vaccine hesitancy e.g. linked to lack of vaccine services or lack of vaccines. Changing the order of the indicators was suggested as this would likely increase response rate to Indicator 2. Within the most 2013 pilot test, countries might have assumed that if they hadn't conducted a measurement of vaccine hesitancy they were not required to move on to the question on the top 3 reasons for vaccine hesitancy.

Section 5B: Standard Survey Questions to Assess Vaccine Hesitancy and Its Determinants

In the feedback from the regions and countries concerning the 2012 JRF Indicators and the Immunization Managers' Survey (Section 4), many countries called for a menu of survey questions to help them assess vaccine hesitancy. A compendium of universally validated survey questions is needed to identify vaccine hesitant populations at the national or subnational level across the globe. Questions are also needed to determine the most prominent factors underlying hesitancy so these can be monitored globally (See Section 3 and 4). A standardized compendium of both survey and determinant questions would further enable intra- and inter-country comparison of the prevalence of and the major determinants leading to vaccine hesitancy and support global assessment.

For **identifying vaccine hesitancy**, the Working Group developed a compendium of three different types of survey questions (see below: Table 2 (Core Closed Questions), 3 (Likert Scale Questions) and 4 (Open Ended Questions)). Some were derived from previously validated questionnaires (HIC only)¹⁵,

¹⁵ Freed GL, et al. Parental Vaccine Safety Concerns. Pediatrics. April 2010; 125(4):654-659

some came from experts in the field and others were newly proposed. The majority of the proposed general vaccine hesitancy survey questions are aimed at identifying vaccine-hesitant individuals not at identifying determinants of hesitancy.

Table 2: Potential Vaccine Hesitancy Survey Questions: Version 1.0

Potential questions to consider in assessing vaccine hesitancy at a community level

Core Vaccine Hesitancy Survey

To be asked to parents/caregivers about childhood vaccinations

- 1. Do you believe that vaccines can protect children from serious diseases? Yes/ No
- 2. Do you think that most parents like you have their children vaccinated with all the recommended vaccines? Y/N
- 3. Have you ever been reluctant or hesitated to get a vaccination for your child? Y/N
- 4. Have you ever refused a vaccination for your child? Y / N
- *a. Please indicate which one(s):*

	Hesitated	Refused
Chicken pox vaccine		
Haemophilus influenza b (HiB) Vaccine		
Hepatitis B vaccine		
Human papilloma virus (HPV) vaccine		
Influenza vaccine		
Polio vaccine		
Measles vaccine		
Meningococcal vaccine		
Mumps vaccine		
Rubella vaccine		

"Pentavalent" or other combination infant vaccine		
Pneumococcal vaccine		
Rotavirus vaccine		
Tetanus, diphtheria pertussis vaccine		
Chicken pox vaccine		

What was/were the reason(s)? (*Use list below to code response*)

Did not think it was needed	Heard or read negative media
Did not know where to get vaccination	Had a bad experience or reaction with previous vaccination
Did not know where to get good/reliable	Had a bad experience with previous
information	vaccinator/health clinic
Not possible to leave other work (at home	Someone else told me they/their child had a bad
or other)	reaction
Did not think the vaccine was effective	Someone else told me that the vaccine was not safe
Did not think the vaccine was safe/	Fear of needles
concerned about side effects	
Religious reasons	Other (explain)
Other beliefs/traditional medicine	

- 5. Has distance, timing of clinic, time needed to get to clinic or wait at clinic and/or costs in getting to clinic prevented you from getting your child immunized? Y / N If yes, please explain
- 6. Are there other pressures in your life that prevent you from getting your child immunized on time? Y / N If yes, specify

7. Are t	here any reasons you think children should not be vaccinated? Y / N
If yes	, specify
8. Do yo	ou think that it is difficult for some ethnic or religious groups in your community / region
•	vaccination for their children? Y / N
U U	is it because
a.	they choose not to vaccinate?
b.	they do not feel welcome at the health service?
c.	health services don't reach them?

9. Have you ever received	or heard negative information	about vaccination? Y / N
If yes, please give an exam	ple	

10. If yes, did you still take your child to get vaccinated after you heard the negative information? Y / N

11. Do leaders (religious, political, teachers, health care workers) in your community support vaccines for infants and children? Please indicate below

Religious Y/N	Political	Y / N
Teachers Y / N	Health care workers	Y / N
Other specify		

Table 3: Vaccine Hesitancy 5 point Likert scale questions

Vaccine Hesitancy 5 point Likert scale questions: scale 1 = strongly disagree to-scale 5 = strongly agree					
	1	2	3	4	5
L1. Childhood vaccines important for my child's health					
L2. Childhood vaccines are effective					
L3. Having my child vaccinated is important for the health of others in my community					
L4. All childhood vaccines offered by the government program in my community are beneficial.					
L5. New vaccines carry more risks than older vaccines					
L6. The information I receive about vaccines from the vaccine program is reliable and trustworthy.					
L7. Getting vaccines is a good way to protect my child/children from disease.					
L8. Generally I do what my doctor or health care provider recommends about vaccines for my child/children.					
L9. I am concerned about serious adverse effects of vaccines.					
L10. My child/children does or do not need vaccines for diseases that are not common anymore.					

Table 4: Vaccine Hesitancy Open Ended Survey Questions

Vaccine Hesitancy Open Ended Survey Quest	ions		
Name of respondent:	Reviewer:		
Respondent's Age: Resp	dent's Age: Respondent's Gender:		
Number of children under care of the respondent:			
Age of the youngest child under care of the responde	nt:		
Immunization status of the youngest child in the c Partially vaccinated for age/ Unvaccinated	are of the respondent: Fully vaccinated for age/		
Question 1: Dear Parent/ Guardian, what are the 3 Reviewer, please list them below in the order of prior	• • • •		
1.	Do you consider this as a priority?		
2.	\Box Do you consider this as a priority?		
3.	Do you consider this as a priority?		
Question 2: Dear Parent/ Guardian, Do you have an immunization? YES/NO If yes, what are they?	y worries or concerns when you take your child for		
Reviewer, please list them below in the order of prior	rity.		
1.	\Box Do you consider this as a priority?		
2.	\Box Do you consider this as a priority?		
3.	\Box Do you consider this as a priority?		
Question 3: (ask this question only for Parent/ Gu immunization in the last 1 year)	ardians who are known to have accepted		
Dear Parent/ Guardian, in your family the decision to year was based on Reviewer, please list them belo	o vaccinate your child (Name XYZ) last week/ month/ w in the order of priority.		
1.	Do you consider this as a priority?		
2.	\Box Do you consider this as a priority?		
3.	\Box Do you consider this as a priority?		
Question 4: (ask this question only for Parent/ Gu immunization in the last 1 year)	ardians who are known to have refused		
Dear Parent/ Guardian, in your family the decision N	OT to vaccinate your child (Name XYZ) last week/		

month/ year was based on Reviewer, please list them below in the order of priority.			
1.	\Box Do you consider this as a priority?		
2.	\Box Do you consider this as a priority?		
3.	\Box Do you consider this as a priority?		
Question 5:			
Dear Parent/ Guardian, in your personal opinion, why do some p Reviewer, please list them below in the order of priority.	persons refuse to vaccinate their children?		
1.	Do you consider this as a priority?		
2.	\Box Do you consider this as a priority?		
3.	\Box Do you consider this as a priority?		

How to use (and how not to use) survey questions to assess vaccine hesitancy

When countries select questions from these tables for general surveys to monitor hesitancy, several points must be considered 1) refusal is not the same as hesitancy i.e. counting only refusers will not capture hesitancy, 2) causes of hesitancy may be missed, as not all determinants in the Matrix of Determinants of Vaccine Hesitancy are covered by these questions (see below) 3) the overall importance of any one determinant will not necessarily be obvious from the answers, as it may simply be the current one that comes to respondent's mind 4) question sequencing matters. Leading questions may drive answers in a particular direction and make one factor seem more important. The context can also alter the relevance of specific questions and/or may influence the answers. In conclusion, when conducting vaccine hesitancy surveys, care must be taken in question selection and in interpretation of the answers.

Selecting survey questions to assess the underlying determinants of vaccine hesitancy

The Working Group developed examples of questions that relate to the factors in the Working Group Determinants of Vaccine Hesitancy Matrix (see Appendix 5.3). As with the above questions, these need to be used with great caution, as they may generate concerns that had not been prevalent prior to asking the question. The general open-ended questions seeking determinants noted above (Table 4) maybe a more positive approach, albeit requiring more skills as well as time to interpret the results.

Of importance, all of the survey questions, whether from the general survey or from the determinant examples, need to be pilot tested and validated in all settings and then refined.

Section 5C: Diagnosis of Determinants of Vaccine Hesitancy in Specific Subgroups.

As reviewed in Section 4, a multitude of factors can potentially influence parents'/guardians' decision(s) to seek out/accept immunization for themselves or their child. These factors vary with the population subgroup, context, setting, time, and specific vaccine. To address vaccine hesitancy effectively, interventions must target the specific factors in the subgroup of the population that are leading to vaccine hesitancy at that time and in that context. Therefore, beyond assessing if vaccine hesitancy is present in a country, the population immunization uptake data need to be analyzed to detect subgroups with lower than expected coverage rates, given available vaccine services. These subgroups may be linked by geography, culture, socioeconomic and/or other factors. Determination of the factors leading to this hesitancy must be done with care, so that the most appropriate intervention options can be selected. Simply applying a questionnaire using items selected from the Matrix of Determinants of Vaccine Hesitancy Questions (Appendix A5.3) is not adequate and will likley not yield correct diagnosis. Outright refusers of vaccines must be differentiated from the vaccine hesitant. Effective interventions must then be tailored to address the specific factors affecting the subgroup populations' behavioural decisions. Interventions will differ by subgroup, context, setting, vaccine, time, and resources.

In 2011, because of growing concerns about vaccine hesitancy, the European Technical Advisory Group of Experts on Immunization (ETAGE) suggested that WHO EUR develop tools to help countries better address this complex problem. After extensive consultation, EUR developed an evidence- and theory- based behavioural insight framework, the Guide to Tailoring Immunization Programmes (TIP) in 2013¹⁶. Much of the underpinning of TIP flows from the PSI Delta Marketing Process 7 Steps (see Appendix A5.4 Table A5.4.1), which has proven successful in achieving behavioural change in many low income countries (e.g. in Kenya-in HIV, maternal child health and other programs¹⁷).

TIP was developed "to provide proven methods and tools that can help national immunization programs design targeted strategies that lead to increased uptake of infant and child vaccination, thereby increasing the immunization coverage rates and curbing the risks of vaccine preventable diseases in the region".

TIP provides tools to help:

1) identify and prioritize vaccine hesitant populations and subgroups,

2) diagnose the demand and supply -side barriers to vaccination in these populations

3) **design evidence–informed responses** to vaccine hesitancy appropriate to the setting, context and hesitant population.

¹⁶ http://www.euro.who.int/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf, accessed 16.09.2014

¹⁷ http://www.psikenya.org/index.php?id=44, accessed 16.09.2014

TIP is not a communication tool but rather a diagnostic guide to define and diagnose behaviourally related concerns such as vaccine hesitancy and then outline appropriate interventions, implement them, and then test and evaluate the outcomes.

In WHO EUR, TIP has now been successfully applied in Bulgaria, Sweden, and the United Kingdom to diagnose and develop targeted interventions for subgroups with lower than expected vaccine uptake. In Bulgaria, TIP diagnostics revealed that for the Roma population, continuing the default intervention to increase vaccine program information and awareness messages was not likely to improve uptake in this subgroup. Neither lack of knowledge and awareness about vaccines nor lack of confidence in the vaccines was the cause of the hesitancy. The major barrier was access to an immunization program that was welcoming to Roma, as the quality of the health worker–caregiver encounter was found to be the most significant determinant of vaccine uptake. These diagnostic findings were used to tailor and target programs designed to address the main cause of Roma vaccine hesitancy.

In Sweden, application of the TIP diagnostic tool to: a) Somali immigrants, b) anthroposophic believers and c) unregistered migrant communities helped Sweden better prioritise the immunization program needs of each community by providing better insight into their preferences and requirements¹⁸. The United Kingdom had launched a TIP project to address vaccine hesitancy in the Orthodox Jewish communities in Greater London.

Subgroup segmentation of those who are vaccine hesitant can be seen in the Bulgarian example (e.g. the late child, the mobile child, the invisible child, the wary caregiver, the poor child) and the Swedish example (e.g. group conformers, attentive delayers, convenience seekers, promoters of natural immunity). Of note, these subgroups cut across many common profiles used to describe populations, such as socioeconomic status, ethnicity, and religion. In both countries, application of TIP led to customized solutions that specifically addressed the hesitancy problem with available resources. In some instances (a combination of) policy, legal, and communications changes may be needed, once the specific hesitancy problems are identified.

The United Kingdom, Sweden and The Netherlands are tailoring the TIP framework to address intransigence among care providers in dealing with antimicrobial resistance (TAP) i.e. more prudent use of antibiotics. This highlights how the principles in TIP can be applied to other communicable and non-communicable disease areas, where behavioural change is needed to improve outcomes.

More countries in Europe have expressed interest in using TIP in 2014. The influenza team at WHO EUR has begun to adapt the same diagnostic framework for targeting health workers to drive demand for influenza vaccine (TIP-FLU). A case study is underway in Montenegro.

Beyond EUR, use of TIP is being explored in Manitoba, Canada as a means of tailoring their immunization program to increase vaccine uptake among its aboriginal population. Efforts are underway to adapt TIP for LIC settings in collaboration with partners in South Africa.

¹⁸ <u>http://www.fhi.no/dokumenter/0ce868ba30.pdf</u>, accessed 16.09.2014
A major issue constraining wider rollout of TIP is that it requires knowledgeable facilitators with sophisticated expertise. To address this gap, a TIP consultant training program was held in June 2014 and more are planned. In parallel, with financing from the US Centers for Disease Control and Prevention (CDC), a practical TIP field guide for national immunization managers is being developed as a companion to the current 2013 TIP Guide. This more user-friendly document will support the use of TIP in settings where personnel and financial resources are scarce. The 2013 TIP Guide is also being updated, with new examples included, and a more user-friendly step-by-step approach to implementation incorporated.

The Vaccine Hesitancy Working Group has closely followed the development, implementation, use and evolution of the TIP Guide and Program. The Working Group noted that TIP does not support the use of one or more specific intervention strategies, but segmentation of the population to determine the subgroup(s) at risk, the diagnosis of the relevant barriers and enablers of vaccine uptake in the subgroup(s) and development of an intervention tailored to the findings, context and available resources for each subgroup. The Working Group agreed that the principles upon which TIP is based are applicable to all WHO regions. IVIR-AC presenters from Africa, India and Pakistan highlighted the growing importance of and need for community-directed research to better understand hesitancy factors. TIP might be a valuable tool for diagnosing the determinants of vaccine hesitancy in subgroups in these settings, though this will require adaptation.

Given the demand for and demonstrated usefulness of TIP in the WHO EUR region, following the December 2013 meeting, the Working Group was tasked with developing recommendations on how TIP could be adapted for use in a more global context. The Working Group proposed that four major areas be addressed in order to move TIP to a global level:

- 1. Rework and simplify the document by region or by level of income (high, middle, lower income countries) to better fit end users' needs- This is being addressed in part by the development of the more practical immunization manager field guide.
- 2. Develop resources /expertise/training to support implementation of TIP in WHO Regions and countries. A cadre of TIP facilitators is needed. The training program held in June 2014 by WHO EUR is a beginning step to addressing this gap.
- 3. Ensure each WHO region has local expertise and tool kits adapted to its region to support TIPSfacilitator training which may need to be tailored to fit high, middle and low income settings in different regions. Experience is needed to determine how training can best be adapted to local needs.
- 4. Develop a means of sharing the lessons learned from TIPS interventions and outcomes, both successes and failures, across regions and globally.

WHO HQ has received funding from the US CDC to expand the use of TIP globally. In collaboration with experts on TIP from WHO EUR and UNICEF, one of the first steps was to look at application of TIP in South Africa. In order to magnify the potential for success of field-testing of TIP there, links

were made to social-behavioural change programs that exist at several universities in South Africa. The pilot test of the TIP framework in South Africa in 2014 was proposed to cover two aspects: 1) application of the TIP framework assessing any shortcomings of the methods in this setting and 2) application of the tool to see if a meaningful public health impact e.g. higher vaccine acceptance, less vaccine preventable diseases.

The Working Group noted that the success of TIP underlines how application of research evidence from behavioural economics, the medical humanities, psychology, and neuroscience can help decision-makers understand vaccine acceptance decisions. These insights can better equip decision-makers and program managers in tackling vaccine hesitancy. These same principles also appear applicable in addressing communicable and non-communicable diseases in which patient behavioural choices markedly influence outcomes. Behavioural insight methods also have application in outbreak and emergency settings where a rapid and accurate understanding of the populations affected is essential to appropriate planning and response strategy.

Given this breadth of potential for benefit, the integrated knowledge and skills of sociologists, behavioural psychologists, anthropologists, experts in social marketing and communication as well as specific disease experts need to come together to be integrated into core behaviour insights groups at WHO headquarters and at the regional level. Insights can be initially applied to tackling vaccine hesitancy and driving equitable demand for vaccine(s) and then applied to other communicable and non- communicable disease areas where behavioural decisions markedly influence outcomes.

The Working Group also noted that EUR experiences in addressing vaccine hesitancy with this tool need to be evaluated through accumulation and sharing of lessons learned and development of best practices for application of TIP to different subgroups, contexts, vaccines and settings. TIP application to other areas also needs to be evaluated. The Working Group was informed that UNICEF is working with AFRO on a communication document at the request of the WHO African Task Force on Immunization (Regional TAG). Growing immunization communication strengths in AFRO, as recommended by the Independent Monitoring Board for the GPEI, will likely work synergistically with potential TIP- determined interventions.

Section 6: Strategies to address Vaccine Hesitancy; Research gaps and Landscape Analysis

Deliverables

- Identify existing activities and strategies that have had or could have a positive impact including looking at successful strategies that have worked and 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;
- Perform a landscape analysis of who/what organizations are working on this issue in various settings/countries
- Outline the specific role of WHO in addressing vaccine hesitancy;
- Identify the specific role of regional and country advisory committees.

To address these deliverables, the Working Group undertook a) a systematic review of strategies to address vaccine hesitancy, b) a review of published reviews on strategies for addressing vaccine hesitancy, c) a review of industry and organizational approaches to shaping behaviours using social marketing principles and further discussion of communication in relationship to social marketing, d) definition of research gaps in vaccine hesitancy and e) a landscape analysis of major actors in vaccine hesitancy:

Strategies to address Vaccine Hesitancy

The Working Group determined that while vaccine hesitancy is an important problem that needs to be addressed to help increase vaccine acceptance within a population, overall immunization uptake rates need to be improved using known evidence-based strategies, which may or may not also address hesitancy. The benefits of immunization can be further optimized if, concurrent with evidence-based uptake strategies, vaccine hesitancy factors are determined and specifically addressed.

With respect to strategies, the Working Group concluded that:

1. The extensive systematic review of peer reviewed and gray literature, and the review of existing reviews did not identify strategies that specifically overcame hesitancy in any populations.

2. The systematic review of both peer reviewed and gray literature, and the review of existing reviews did identify intervention strategies that improved vaccine uptake. Most studies were observational in design, yielding a low quality of evidence. Nevertheless, increases in vaccine uptake were observed.

3. With respect to interventions to increase vaccine uptake, no single strategy or combination of strategies has been applied in all countries (HIC, MIC, LIC) or all contexts with a positive impact. This finding reflected the diversity of drivers related to vaccine hesitancy and reinforced the importance of understanding and addressing local context-specific issues.

4. For maintaining and improving vaccine uptake, multi-component strategies appeared to be more effective than single component strategies.

5. Interventions with the largest positive effects on vaccine uptake are those that (not in order of importance): a) directly target unvaccinated or under-vaccinated populations; b) aim to increase knowledge and awareness about vaccines and vaccination which have proven to be particularly useful in practice; c) improve convenience and access to vaccination; d) target specific populations such as the local community and HCW; e) mandate vaccinations or impose some type of sanction for non-vaccination; f) employ reminder and follow-up; and g) engage religious or other influential leaders to promote vaccination in the community.

6. Based upon the evidence, integrated, multi-component strategies effective for improving vaccine uptake should be adapted to the context and specific determinants, promoted and evaluated in all immunization programs. Lessons learned about impact on uptake in different settings should be shared.

7. With respect to increasing uptake, the paucity of published negative studies identified by the systematic review precluded identification of the strategies that do not work or might work only in a specific setting.

8. Using GRADE to assess the quality of the uptake interventions, the few effective vaccine uptake strategies included social mobilisation, mass media, communication tool-based training for health care worker, non-financial incentives, and reminder-recall activities. However, evidence is not available for all settings.

9. As neither hesitancy, nor the major factors underlying the hesitancy were assessed prior to or after the uptake intervention, the actual impact of these uptake interventions on hesitancy is unknown. However, some of these uptake interventions might have addressed hesitancy related to specific factors such as a lack of knowledge, cultural norms or complacency if these were present.

10. None of the effective vaccine uptake interventions were seen as innovative or promising for global application to address hesitancy in different contexts.

11. The early success of the Tailoring Immunization Programmes (TIP)(Section 5) recently developed by WHO EUR, built on social marketing principles and behavioural theories suggests that this is a potentially useful strategy to adapt and evaluate in LMIC.

12. Utilizing TIP, hesitancy can be addressed by identifying the target population, determining the major factors underlying their hesitancy; tailoring the intervention strategy to address these factors

and evaluating the outcome. Doing this concurrently with implementation of uptake intervention strategies might further increase overall vaccine uptake rates.

13. Based upon experience from UNICEF, integration of immunization with other health and nonhealth services may help address complacency and convenience vaccine hesitancy issues in some settings.

14. The impact of pain mitigation with immunization on vaccine hesitancy was not included in the systematic review but evidence-based guidelines for addressing pain are available.

15. Review of industry and other organizations' approaches to changing behaviour suggests that social marketing techniques may be useful in changing vaccine hesitancy. The WHO –EUR Tailoring Immunization Programmes to address hesitancy is based upon social marketing principles.

16. Communication can not only improve knowledge but also influence policy, the environment and realize behavioural changes. Communications is a key component of strategies to address vaccine hesitancy, but communication alone will not resolve every vaccine hesitancy issue. Similarly, correcting poor communication that is contributing to vaccine hesitancy will not necessarily correct vaccine hesitancy.

17. Ensuring education and knowledge about vaccines in younger individuals (children, adolescents, young adults) may provide a good opportunity to shape future vaccine acceptance behaviour of parents and adults and minimize the development of hesitancy although evidence of the success of such an approach is needed.

18. Based on evidence from the GPEI, discussion of and efforts to address vaccine hesitancy in themselves do not lead to increased vaccine hesitancy.

19. Further collaboration between UNICEF and WHO on addressing vaccine hesitancy would be beneficial. As was the case when vaccine safety concerns gained prominence starting in the 1980s until today, countries need to include a capacity that measures and addresses with vaccine hesitancy. WHO HQ and regional expertise to address hesitancy would be a helpful resource for countries.

Vaccine Hesitancy Gaps and Needs: Research Opportunities

The Working Group determined that

1. The field is young, and as such, there are many gaps in knowledge, diagnosis of the determinants of vaccine hesitancy and effective strategies to address hesitancy in different settings. To accelerate the maturation of the field, a research community should be fostered to share ideas and best practices

2. Research on vaccine hesitancy and the most effective strategies for correction is needed at the national, sub-national and subgroup level in HIC, MIC as well as LIC.

3. Research questions are likely to evolve as new insights into the complex behavioural phenomenon of vaccine hesitancy become available

4. With the evolution of validated, standardized tools and methods, suggested research foci include:

- a. Prevalence of vaccine hesitancy in different countries, settings and contexts
- b. Assessments of determinants of vaccine hesitancy see Appendix 5.3- in different contexts
- c. Understanding vaccine decision-making
- d. Designing and piloting of new strategies to address vaccine hesitancy in different contexts, settings, and vaccines including adaptation and evaluation (such as the TIP tool) and the application of individual approaches to diagnosing and responding to vaccine hesitancy to communities.
- e. Determinants of recrudescence of vaccine hesitancy and appropriate early interventions

Vaccine Hesitancy Evidence, Policy and Programs

The Working Group determined that

1. As vaccine hesitancy is a complex behavioural phenomenon, and no single best practice intervention to address hesitancy in all its contexts has been found, more nuanced, locally tailored and multicomponent approaches are required.

2. Evidence- informed policy and programs to address hesitancy need to focus on capacity building for detection of hesitancy, diagnosis of the cause(s) in the subpopulation, then development of tailored strategy to fit, implementation and evaluation of impact on vaccine uptake and then sharing of lessons learned.

3. Immunization programs need to regularly determine if and where pockets of vaccine hesitancy exist in their country as part of good program management.

4. WHO EUR TIP offers a model for population segmentation, diagnosis of underlying causes of vaccine hesitancy in hesitant subgroups, and tailoring of interventions to address the underlying factors.

5. Given that immunization programs should have established close links with civil society organizations, these can be helpful in mobilizing support for immunization, reinforcing that immunizations are a social norm, raising demand for vaccines, and assisting in addressing vaccine hesitancy, depending on the underlying hesitancy factors

Need for Tools and Opportunities to Share Vaccine Hesitancy Lessons Learned

The Working Group identified the need:

1. To apply the 2013 revised JRF Indicators (Section 5) to facilitate monitoring of vaccine hesitancy at country, regional and global levels; determination of similar and divergent vaccine hesitancy issues and successful interventions across regions and globally.

2. For validated, standardized and improved tools to

- a. document vaccine hesitancy within a country- segmentation of the population (application of TIP modified to fit different settings (Section 5))
- b. diagnosis factors influencing vaccine hesitancy in specific subgroups (application of TIP adapted to fit different settings (Section 5))
- c. intervene effectively to address vaccine hesitancy and evaluate the impact of programs such as TIP in different settings, in particular in LIC

3. To document best evidence-based practices to diagnose and address vaccine hesitancy in different contexts.

4. To establish an interdisciplinary community/network of researchers, health care workers, and public health professionals to, share experience and evidence about best practices for addressing vaccine hesitancy in different settings and contexts.

Landscape Analysis of organizations working on vaccine hesitancy

The Working Group determined that

1. A number of advisory committees, researchers and organizations have started to study and address the issue of vaccine hesitancy, including defining the problem, gathering information on its determinants and expressions, and suggesting potential intervention strategies to address vaccine hesitancy and mitigate its negative impacts on vaccine uptake. Multiple revisions of the landscape indicate a growth in the field, even over the last two years.

2. Inclusion of organizations addressing supply side criteria as well as hesitancy/demand side criteria would be useful to provide a broad oversight of the work being done. Most of the vaccine-related work indicated in the landscape analysis is on supply side criteria, rather than hesitancy /demand-side criteria.

3. WHO should encourage collaboration among those identified in the landscape of organisations doing work on vaccine hesitancy. Opportunities are needed for sharing of findings and lesson learned on vaccine hesitancy across and amongst these organizations and to others.

4. The landscape analysis of organisations working on vaccine hesitancy found few global vaccine reporting or surveillance systems currently measuring hesitancy/ demand-side indicators, such as vaccine hesitancy. This is not surprising given the acknowledgement of the newness of the issue– and its serious impacts on vaccine uptake and public health outcomes. There are a number of current

efforts to pilot survey approaches, as well as media and social media monitoring to detect emerging vaccine hesitancy.

5. The landscape of organizations could be used as a resource to facilitate collaboration among researchers and key stakeholders working on vaccine hesitancy.

Section 6A: Intervention Strategies to address Vaccine Hesitancy:

6A.1 Reviews of Intervention Strategies to address Vaccine Hesitancy Requested Systematic Review

The Working Group commissioned a systematic review of intervention strategies to address vaccine hesitancy. Appendix A6A.1 provides the Executive Summary of the commissioned review. A very brief overview of the findings follows:

The review of strategies he published and gray literature form January 2007 to October 2013 had the following specific objectives:

1) Identify and describe the findings of published strategies related to vaccine hesitancy and hesitancy in the use of other health technologies (i.e. reproductive health technologies chosen).

2) Map all evaluated strategies to the SAGE Working Group Matrix of Determinants of Vaccine Hesitancy and identify key characteristics.

3) Assess relevant evaluated strategies using Grading of Recommendations Assessment, Development and Evaluation (GRADE); relevance was informed by the Population, Intervention, Comparison, outcome (PICO) questions defined a priori by the Working Group and grouped by one of four themes, including: i) Multi-component, ii) Dialogue-based, including dialogue with religious leaders, iii) Reminder/recall-based or iv) Incentive-based.

4) Synthesize findings in a manner that informs the design of future interventions and further research.

A major issue that emerged from this analysis was that few studies defined the degree of hesitancy in the population or determined the major factors underlying hesitancy in the study population. Only five studies used the terms 'vaccine hesitant/hesitancy'. Most studies examined the intervention(s) impact on vaccine uptake or acceptance, not on hesitancy. These studies were retained because issues noted for study matched one or more of the determinants in the Working Group Determinants of Vaccine Hesitancy Matrix. However, the degree of hesitancy in the study population attributable to the specific determinant(s) studied is unknown. Another problem in the review was that interventions that failed in the field have received little attention in the published or grey literature; hence failure of an intervention in one population was likely to not be reported, though success would have been. Hence, the effectiveness of specific interventions in addressing different determinants of vaccine hesitancy in different contexts is unclear.

Thus, despite extensive literature searches from January 2007 to October 2013, only 14% (166/1149) of the peer-reviewed studies and 25% (15/59) of the grey literature evaluated interventions relating to

impact on vaccine uptake. The bulk of the retrieved literature originated from AMR and EUR. Across all regions and literature, the majority of interventions were multi-component in nature, followed by dialogue-based approaches (except EMR, where only multi-component interventions were found). Reminder-recall interventions featured only in higher-income regions (AMR, EUR, WPR), and incentives appeared only in AMR, AFR and SEAR.

Bearing in mind the critical caveats noted above, multi- component interventions were found to be more effective than single component interventions in increasing vaccine uptake in the populations studied. Targeting of populations was also shown to be helpful; underlining the importance of matching the intervention to the cause of poor vaccine acceptance in the population.

Utilizing the GRADE approach to assess quality yielded evidence of moderate confidence in the impact on uptake of social mobilisation, mass media, communication tool-based training for health care worker, non-financial incentives, and reminder-recall activities. However, all studies had weaknesses. Furthermore, as noted above the populations were not well-defined with respect to the presence of either hesitancy or the major determinants underlying hesitancy, making adoption of these to address hesitancy problematic. It is likely however, that some of these uptake strategies might be effective in addressing complacency and convenience hesitancy issues.

A review of successful interventions in reproductive health showed some important parallels. Specifically, dialogue-based interventions, particularly those incorporating a focus on community engagement/social mobilisation and the improvement of health care worker communication, were most effective in improving uptake. Similarly, single-component interventions did not work as well as those that were multi-component. Also, passive interventions (e.g., posters, radio announcements, websites and media releases) that did not have an additional engagement component(s) were less effective. However, as was found in the vaccine hesitancy strategy systematic review, the specific factors underlying poor reproductive health intervention uptake were not well defined in the study populations, making interpretation of effectiveness with different determinants difficult. The Working Group also noted that given that reproductive health decisions are a behavioural phenomenon like vaccine decisions, adaptation of the WHO EUR TIP to address hesitancy surrounding the acceptance of reproductive health intervention of the population to find the reproductive health hesitant subgroups, diagnosis of the major causes of hesitancy in these subgroups and then tailoring the intervention to address the causes) might lead to further improvements in uptake, as has been seen with vaccine hesitancy (See Section 5).

The review found evidence that mandatory immunization requirements can increase vaccine acceptance in some circumstances; however, the Working Group noted that these strategies may be seen as coercive and intrusive and can limit trust. Evidence from the United States indicates that mandating influenza vaccine for health care workers can substantially increase uptake compared to voluntary programs where education, incentives, declination were used. However, in Europe, mandatory healthcare worker immunization requirements vary widely from country to country

suggesting limited acceptance of this type of policy at this time. Mandatory immunization for school admittance might be helpful in some HIC and MIC but would add yet another barrier to access to primary education in LIC; further, mandatory immunization might trigger unintended negative consequences. Thus, mandating immunization as a strategy to address vaccine hesitancy must be approached with great care and caution. The impact of potential negative consequences (e.g. distrust in the immunization program) may outweigh potential benefits such as the increase in vaccination coverage in some settings.

Despite the large body of literature on the many determinants of vaccine hesitancy, most interventions to improve uptake were directed at individual issues such as vaccine/vaccination specific concerns, knowledge gaps, mode of delivery, and role of healthcare professionals; rather than community and subgroup wide concerns. In addition, little attention has been paid to intermediate outcomes such as changes in knowledge, social norms, attitudes and awareness in communities in response to these strategies. Such outcomes might indicate important shifts along the vaccine hesitancy continuum, either away from or towards acceptance, even if they do not necessarily lead to a change in vaccine acceptance. Appreciating where individuals and communities lie on the continuum and what defines this could offer insights to inform intervention design.

Review of Published Systematic Reviews

The Working Group summarized the published reviews on strategies to increase vaccine uptake or vaccine acceptance published between January 2006 and May 2014. Eleven literature reviews or metaanalysis on strategies to increase vaccine uptake or vaccine acceptance in the public or among health care providers were included (see Appendix A6.2). Only two of these reviews directly targeted strategies addressing vaccine hesitancy (defined as voluntary refusal or delay of recommended childhood vaccines while vaccination services are available). In addition, in the United States, the Community Guide recommendations were reviewed, as these regularly include evidence-based recommendations on interventions intended to improve routine delivery of universally recommended vaccinations. The findings of the review of reviews are summarized in Tables in Appendix A6.2.

In brief, this review also found no strong evidence to recommend any specific intervention to address vaccine hesitancy or refusal. The reviewed studies included interventions of diverse content and approaches implemented in different settings and targeting various populations. The number of interventions assessed that were similar enough to allow them to be grouped together for meta-analysis was insufficient to demonstrate effectiveness using recognized validation criteria¹⁹. In addition, many of the reviewed studies were conducted in the United States with few from LMIC, further limiting global generalization. The reviewed studies that met quality criteria were mostly single-component interventions that are less challenging to evaluate than multi-component interventions, or interventions

¹⁹ www.cochrane-handbook.org, accessed 16.09.2014

aiming to change determinants that are difficult to measure (e.g. social norms). Finally, few studies included in the reviews used vaccine uptake or on-time vaccination as an outcome, and even fewer studies directly targeted vaccine hesitant patients.

While acknowledging these caveats, the findings showed that reminders and recall for patients and health care providers help improve vaccine uptake among various groups and in different settings, but there is limited evidence in support of their use to address vaccine hesitancy. There is mixed evidence on the effectiveness of face-to-face communication interventions, health care providers' training interventions, community-based interventions and interventions using mass media. While many communication tools aimed at improving health care provider discussions with vaccine-hesitant parents have been published, few have been evaluated. Whereas communication frameworks often suggest discussing vaccines in a participatory and open manner, a 2013 study by Opel, et al.²⁰ found that more directive, presumptive discussion styles by healthcare providers were more effective in improving vaccine acceptance in hesitant middle to upper class parents/caregivers studied in Seattle, USA. Interventions using mass media, including the Internet, are appealing but challenging to evaluate and not well-suited to the usual experimental designs. A recent study by Nyhan et al, 2014²¹ showed that pro- immunization messaging has differing impacts, depending on the level of vaccine hesitancy among those targeted. Among those who are more strongly negative, and set in their views against vaccines, these messages may have a backfire effect. However, Nyhan's study also showed that provaccine messages reinforce pro-vaccine attitudes. Given that the majority of parents accept vaccines, pro-vaccine messages may be needed to reinforce and support positive sentiment and help prevent emerging hesitancy from expanding.

The value of population segmentation and diagnosis of the determinants of hesitancy noted in the TIP (Section 5) approach, as well as in the Working Group Matrix of vaccine determinants, became even more evident to the Working Group following this systematic review and review of reviews. The Working Group also noted that both the systematic review and the review of reviews emphasized that vaccine hesitancy is a complex and dynamic behavioural phenomenon. Thus it is not surprising that multicomponent rather than single component strategies were found to be more successful, and that no one best strategy was found for any setting.

Future strategies need to address the complexities of vaccine hesitancy in their design and evaluation taking into account the following: 1) target subgroups who are hesitant and understand their underlying hesitancy drivers; 2) focus on meaningful engagement (i.e. dialogue-based, social mobilisation) that supports realistic action; 3) ensure the intervention(s) address(es) the identified major hesitancy determinants, fits the context, setting and resources; and 4) evaluate the intervention outcomes on hesitancy and on vaccine acceptance and share the lessons learned.

²⁰ Opel at al. The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits. Paediatrics 2013; 132:6 1037-1046

²¹ Nyhan et al. Effective messages in vaccine promotion: a randomized trial. Paediatrics. 2014 Apr;133(4):e835-42

6A.2 Other Strategies

Pain Mitigation

No evidence on mitigation of immunization pain was retrieved and not addressed in the systematic reviews, yet injection pain has been shown to cause distress for recipients, parents, adults and those giving the injection. Fear of injection can lead to hesitancy. Evidence based guidelines on pain mitigation with immunization have been published²². While pharmacological prevention with topical anaesthetics is helpful, it adds expense to immunization. However, other effective strategies for amelioration of pain such as physical intervention with proper holding, needle injection techniques etc, and psychological interventions such as distraction etc, require only training and could be readily applied more widely. Early research in HIC has shown that parents are more comfortable with infant immunization when pain is controlled²³, but this intervention has not been specifically tested on those in whom vaccine hesitancy is related to fear of pain.

Intervention Strategies with TIP

The WHO EUR TIP is an approach to identify underlying vaccine hesitancy factors and tailor strategies to address hesitancy based on the context and the resources available (Section 5). Preliminary results suggest that this can be very effective in addressing hesitancy but more evaluation is needed to determine what strategies are most effective in addressing different determinant(s) of hesitancy in different settings. The approach should be adapted and evaluated in a wider range of settings including those in LIC (see Section 5)

Strategies used in Mass Vaccination Campaigns

As noted in Section 3, mass vaccination campaigns can provoke hesitancy. While neither the systematic review of strategies nor the review of reviews identified research which explicitly looked at hesitancy in the context of mass campaigns, the Working Group did note that *successful* mass campaigns, such as for polio elimination in India (although the reaction to the mass polio campaign approach has also provoked distrust in some countries), polio virus containment in Israel in 2013, Meningococcal A campaigns in several meningitis belt countries in Africa and Meningococcal C outbreak control campaigns in HIC, had a number of common features. In each case, the vaccine preventable disease was well known and feared. Cases were well publicized. Leaders from all levels were actively involved. Communities were directly involved in helping with the campaigns and access to vaccine was made as easy as possible. Social norms of acceptance were publicized. All of these

²² Taddio A. et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline (summary). CMAJ. 2010 Dec 14;182(18):1989-95

²³ Taddio et al Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations: a cluster randomized trial. Pain 2014;155(7):1288-92

appeared to increase vaccine acceptance as although hesitancy was not measured, their impact on it is unknown. Of note, these strategies fit with social marketing concepts discussed below. More evaluation of successful mass campaigns is needed to determine if there are particular hesitancy factors that are more common in mass campaigns in particular settings and what strategies are most effective in addressing these.

6A.3 Strategies to Address Vaccine Hesitancy: Industry and Organizational Approaches to Shaping Behaviour: Social Marketing and Communication

Beyond the systematic review and review of reviews of strategies, the Working Group explored private-sector approaches to shaping behaviour, as well as strategies used by other organizations to change behaviour. The Working Group heard from the International Food and Beverage Alliance (IFBA) about marketing strategies used by that industry. The IFBA was established in 2008 when the major food and non-alcoholic beverage manufacturers committed to supporting WHO's 2004 Global Strategy on Diet, Physical Activity and Health. The IFBA representatives noted the sophistication, from a marketing perspective, of the anti-vaccination movement (e.g. branding, focusing on emotions - fear of vaccines - rather than facts). Key industry messages to the Working Group included the following (points particularly relevant to vaccine hesitancy are in italics):

- All that really matters is the power of the story.
- Consumers care about benefits, not supporting facts.
- *Brand* = *product* + *compelling story*.
- *Reason leads to conclusions, while emotion leads to action (i.e. change comes from feelings, not facts).*
- It is important to win the hearts, minds, and now, voice. Due to social media, consumers have a mouth piece and a large portion of media consumption is media generated by other consumers.
- The rise of social media has benefits and risks. You can share information on a massive scale at zero cost, but there is less control.
- Consumers believe more in messages from other consumers than from big institutions.
- It is important to find the intersection of brand topics (what the brand wants to talk about) and audience interests (what existing and desired audiences care about).
- Consumer's rationale for decisions may not reflect the true motivation (e.g. give fact-based reasons, but emotional reasons may have in fact driven the behavior).
- It is impossible to please all consumers, and some will not like you.
- *One big idea needs to drive the entire communications strategy.* Only one or two messages can be communicated the rest must be sacrificed.
- Communication is increasingly about dialogue back and forth in the context of social media.
- A communication brief includes: competitive content landscape, target consumer, brand opportunity, communication task, core insight, core essence, functional benefit, emotional benefit, meaningful product truth, brand personality, obtainable brand proposition, key performance indicators. *Effective communication strategies are not simple*.

Some of the messages that particularly resonated with the Working Group included focusing on the benefits of immunization and drawing on the emotional values around child health. Trying to focus on one or two key messages is challenging for a technical organization like WHO and/or country immunization programs, but it is important that pro-vaccine initiatives start driving the conversation, as conversation and dialogue are the new frontier of communication. The Working Group concluded that positive messaging (proactive) was the preferred approach, as opposed to combative messaging (reactive), a currently common strategy. World Immunization Week, in the scope of WHO, is an opportunity to build positive public dialogue around.

Areas of product marketing that are more challenging to apply to vaccination include a) the cost of large marketing campaigns, b) a high proportion of people may have to accept the message for population benefit (herd immunity), c) using the social media approach in areas where not everyone has access, d) the influence of health care workers on vaccine decision making is large, and e) the benefit from vaccines lies in the prevention of a bad event as opposed to a good event happening. In addition, because vaccination programs are about health rather than profit, there are ethical issues such as beneficence and justice. Rather than product competitors, vaccination programs are struggling with the anti-vaccine movement, political groups like the Taliban, and social/cultural norms within certain communities. Furthermore, if lack of trust underlies vaccine hesitancy, it may be vaccine-related or broader distrust in health providers, health system or government and/or politics. Given that trust is so important, immunization communication campaigns done by or in collaboration with a company, a distrusted government, or with substantial finances from industry may cause more mistrust. Community engagement and social mobilization are important components for garnering trust. Where/who the messages come from is important when trust is a driver of hesitancy. As the role of social media in vaccine decision-making is poorly understood, the content of social media needs to be better monitored with respect to vaccine attitudes and the influence of social networks, both for adults and children. Social media interventions need to be embarked on with some caution because of these complexities. Mass communication campaigns may be more useful building or maintaining the provaccination social norms (see Nyhan et al discussed above), while targeted communication interventions might be more effective in addressing some aspects of vaccine hesitancy (segmentation).

Discussion also focused on the role of childhood beliefs about vaccination. Historically, children have not been systematically educated in schools about vaccines, resulting in some in the adult population (i.e. parents and adults) who do not appreciate their benefits to health and societal value for their children and for themselves. While opportunities to learn about vaccines outside of schools exist (e.g. from media, pamphlets, from health care professionals) these routes may miss many in the population. In contrast, older generations understood the value of vaccines because they personally experienced and/or saw the disease impact as children and therefore as adults did not need to be taught about this in school. Now most vaccine preventable diseases have disappeared as a result of high vaccine uptake negating the personal experience route for education. Ensuring education and knowledge about vaccines in younger individuals (children, adolescents, young adults) possibly through school based programs may be a good opportunity to shape future vaccine acceptance behaviour of parents and

adults and minimize the potential for development of hesitancy although more evidence of this is needed possibly from areas like environmental activism, tobacco, exercise behaviour change initiatives. Many children today are highly engaged in social media and peer-group provision of information is very influential, so ensuring education and knowledge about vaccines in younger individuals may be a good opportunity to further shape future vaccine beliefs and behaviours.

The Working Group also reviewed social marketing strategies of several organizations that have successfully translated profit-driven marketing approaches into positive public health impact e.g. marketing of reproductive health services, bed nets, oral rehydration solution, and circumcision. Many of the principles used by these organizations underpin the WHO EUR 2013 TIP discussed in Section 5 wich has shown success in addressing hesitancy in different settings in that region. The UNICEF strategies used in the GPEI, such as programs to reach the hard to reach to change behaviours were also examined and need to be considered more closely to determine how they might be applied to other immunization issues beyond polio. UNICEF and others have found that integration of health prevention and intervention services with other needed and desired health and non-health related initiatives both for individuals and for communities has met with good success in some LIC settings. At the ground level, front line health workers, even with limited training, can be taught opportunistically to include immunization in a variety of health and non-health services. This approach may help address some hesitancy factors. Adaption into HMIC settings needs to be explored.

The Working Group further discussed broader communication and social mobilization strategies in terms of their potential application in addressing vaccine hesitancy. The point was strongly made, and reinforced by regional WHO offices, that many countries lack robust immunization communications strategies, and even fewer have specific strategies in place to address vaccine hesitancy. The platforms for messages need to be considered in terms of who is being targeted by media campaigns, insertion in soap operas, worksites etc. But both the messaging and the tools must be based on best current practise and the impact measured in terms of reach and impact on vaccine knowledge and vaccine uptake behaviours. The study of Nyhan et al., referred to earlier, suggests messages tailoring to fit the target audiences is key and reinforced the need to evaluate such strategies to ensure that they have the intended effect and impact. More resources need to be invested in vaccine communication. The Working Group concluded that immunization program every country should have the capacity and financial resources to deal with vaccine risk communication especially in light of the growing number of new vaccines and combinations of vaccines becoming available. Given that many countries have limited resources and capacity to expand existing efforts to monitor emerging hesitancy and develop appropriate strategies, support from regional as well as international partners is needed. For program efficiency, integrating these communication activities with other health promotion areas (e.g. immunization and childcare) may be desirable.

The Working Group reviewed the current communication focus of a) WHO and UNICEF on vaccine hesitancy; b) WHO on safety activities, such as the vaccine safety e-learning module and vaccine safety communications and c) UNICEF on Communications for Development (C4D). The Working Group noted that further collaboration between UNICEF and WHO on vaccine hesitancy interventions and on

communications is needed. The Working Group emphasized that dealing with vaccine hesitancy requires more than communications, and may require legislative, policy, programmatic and educational interventions. As was the case when vaccine safety gained prominence in the 1980s, countries need to build their capacity to monitor and address vaccine hesitancy in a timely manner. The Working Group concluded that every WHO regional office should have a staff member with the relevant expertise and experience needed to diagnose and address vaccine hesitancy to support countries in the region.

One concern raised by some members of the immunization community is the worry that public discussion of hesitancy "legitimizes" it and will make the situation worse i.e. a self-fulfilling prophecy. In addressing this concern, the Working Group noted the importance of reinforcing that immunization is the social norm and also reviewed data from UNICEF and the GPEI on community and individual concerns raised about polio immunization in Nigeria and India. Noteworthy findings were that only 1.2% of children in the polio endemic countries were not vaccinated due to refusal, and the refusal rates were highest where insecurity and social strife were highest. Many of the unvaccinated were children who had been missed i.e. not at home when called rather than having refused the vaccine (although in some settings this was interpreted as a "silent refusal". When organized resistance to polio immunization was present, it was typically based on political opposition to the government or an outside group seen to be supporting immunization and the resistance usually had a dynamic leader at the centre of the movement. Grievances were often linked to lack of other services and amenities (i.e. immunization provided a bargaining chip to leverage access to other services or demanding political actions of government or international players such as "stopping the drones"). Addressing vaccine hesitancy, especially through building the trust of the local leaders can lead to increases in vaccine acceptance in communities and prevent vaccine hesitancy. Thus, the evidence from GPEI does not support the hypothesis that discussing/addressing hesitancy makes the situation worse. Instead, determining the specific factors underlying hesitancy in a subgroup and addressing these factors specifically is key and can help mitigate hesitancy.

Section 6B: Vaccine Hesitancy Gaps and Needs: Research Opportunities

The Working Group noted the complexity of vaccine hesitancy and the many gaps in current knowledge and best practices. Given that hesitancy is context, time, place and vaccine specific, there is need for research in HIC, MIC and LIC in all regions to understand the scope, scale and reasons underlying vaccine hesitancy to inform appropriate responses.

One of the major problems identified in the systematic review of intervention strategies (See Section 6A.1) was the lack of data on vaccine hesitancy levels in the populations where the interventions were tested. A second challenge was the lack of validated and standardized tools to assess and measure vaccine hesitancy rates and underlying hesitancy determinants across settings and between groups, and monitoring trends over time. The survey instruments developed and validated in the United States (See Section 5) but may not be applicable in other HIC or in MIC or LIC. A list of general hesitancy survey questions has been developed by the Working Group (See Section 5) these need to be validated across HMLIC as well as tested in different health care systems, socio-cultural contexts, and vaccine programs, and at the national, sub-national and in some instances the local subgroup level. Special attention also

needs to be paid to differences and similarities between routine delivery of immunization programs and mass campaigns in different settings and contexts.

A third challenge concerns interventions. As noted in the systematic review and review of reviews, most studies did not define hesitancy in the study population and only measured change in vaccine uptake, without determining if the intervention changed hesitancy. Given the paucity of information, if strategies to address vaccine hesitancy are implemented, not only must the population be fully described, but there also must be rigorous evaluation of the impact of the intervention(s) and its (their) components on vaccine hesitancy as well as on vaccine acceptance.

Based upon these three gaps, the following research priorities areas are suggested:

1. Prevalence of vaccine hesitancy: some examples of proposed research questions

- To what extent does vaccine hesitancy exist among vaccinated individuals? What are the most effective ways to identify these vaccine-hesitant individuals? What are their needs?
- In settings where vaccine and vaccination services are otherwise available, at what threshold is "vaccine demand" low enough to suggest that vaccine hesitancy is a problem in a population or sub-group?
- How does vaccine hesitancy among health care professionals impact vaccine acceptance in their patients? What is the level of vaccine hesitancy among health care professionals? What are the most effective ways to assess vaccine hesitancy among health care professionals who are involved in vaccine delivery?
- What is the impact of vaccine hesitancy on vaccine uptake? What is the level of hesitancy that could lead to significant vaccine delays or refusal?
- What is the best proxy marker of vaccine hesitancy in the population? In a subgroup?
- Given that vaccine hesitancy varies across time, place, program (routine vs. mass campaign) and vaccine and is not uniform across a population or subgroup, how best can vaccine hesitancy be quantified and described in a country?

These questions should be answered in a consensus-building approach between researchers, public health and medical/health communities using a common understanding of vaccine hesitancy and its scope (See Section 3).

2. Determinants of vaccine hesitancy: some examples of proposed research questions

- What are the causes of vaccine hesitancy at the individual level (convenience? complacency? confidence?) in different contexts and settings in HIC, MIC and LIC?
 - When and how are parental beliefs and attitudes toward vaccines formed?
 - What is the impact of interactions with health care providers on vaccine hesitancy? Does it differ by the type of health care professional (e.g. physicians, nurses, complementary

or alternative medicine practitioners, traditional health providers with limited to no professional training) and/or by their work context?

- What are the main drivers of vaccine hesitancy among health care workers and do these drivers differ from those in the communities they serve?
- To what extent does vaccine hesitancy result from broader socio-cultural and structural influences?
 - To what extent does vaccine hesitancy result from the way that vaccination services are delivered (e.g. mass vaccination campaigns vs. routine programs)?
 - To what extent does vaccine hesitancy result from negative influences of communication and the media environment (e.g. anti-vaccination messaging and the Internet)?
 - To what extent does vaccine hesitancy result from the influence of social networks?
 - To what extent does vaccine hesitancy result from religious beliefs?
 - Does early (school age) education about vaccines change hesitancy perceptions with age? Does this change hesitancy among parents i.e. perhaps learn from their children?

In addition to measuring the prevalence of vaccine hesitancy at the national / sub-national level, more in-depth research should be undertaken to gain a better understanding of the context-specific underlying causes of hesitancy. As shown by the Working Group Determinants of Vaccine Hesitancy Matrix (See Section 3), there are many potential influences on vaccine hesitancy that need to be assessed. In addition to identifying determinants of vaccine hesitancy among sub-groups or populations, it is important to understand *how* and *why* these factors link to vaccine hesitancy.

3. Strategies to address vaccine hesitancy: some examples of proposed research questions

- What is the impact of strategies on vaccine hesitancy using social networks (e.g. peer-to-peer communication stressing fully vaccinated community, use of social media by HCW or vaccine "champion" parents to talk with vaccine-hesitant parents)?
- The emergence of Web 2.0 means that concerns about vaccination information online must expand beyond simply the possibility that people might access information of varying quality. How do people use the current Web? How does such usage influence decision-making processes? What are the implications for communication strategies about vaccination?
- The use of religious and local leaders and prominent citizens in interventions to increase vaccine uptake or reduce vaccine refusal is often recommended, especially in LMIC. What are the best practices? Might there be unintended consequences of such approaches?
- How can communities best be mobilized in support of vaccination i.e. set social norms as provaccination?
- Many communication tools are available for health care providers to discuss with vaccinehesitant patients. How effective are these and in what settings? What are the best ways to improve communications with patients in HIC, MIC, and LIC?

- How best can a population be segmented into those who are vaccine hesitant and those who are not? How can the determinants be most efficiently diagnosed in order to apply the most appropriate interventions to the designated subgroup? i.e. optimization of TIP
- What communication and social change strategies that have been shown to be effective in changing behaviour in other settings work for vaccine hesitancy?

As vaccine hesitancy is context-, time-, place- and vaccine-specific, research needs to be expanded to capture factors not only at the individual level but also at the community level, the contextual level (politics and policies, communication and media, social norms, influential leaders, etc.) and the organizational level (vaccine and vaccination specifics issues, mode of delivery, etc.) Furthermore, as immunization program managers play a key role in driving vaccine-related policies and activities, their and their staffs' capacities to assess and address vaccine hesitancy in the populations they serve need to be improved. WHO and UNICEF regional offices need a designated vaccine hesitancy person/program with the appropriate skills, expertise and knowledge to address hesitancy. Cross-linkages between programs should be strengthened as vaccine hesitancy is an over arching concept which spans across various immunization-related fields. An integrated approach is needed to ensure consideration of vaccine hesitancy within different work streams. WHO should support development and validation of tools to support immunization program managers in identifying the causes of vaccine hesitancy, in measuring and monitoring vaccine hesitancy, and in responding effectively to the diagnosed drivers of hesitancy in the populations and subpopulations they serve.

In summary, vaccine hesitancy research is needed in all WHO regions in three areas- 1) prevalence of vaccine hesitancy, 2) determinants of hesitancy and 3) interventions to address vaccine hesitancy in HIC, MIC and LIC, as well as within sub groups. Research questions are likely to evolve as new insights into the complex phenomenon of vaccine hesitancy become available.

Section 6C: Vaccine Hesitancy Evidence, Policy, and Programs

While the need for evidence-informed guidance on policies that have an impact on health system performance is widely accepted²⁴, moving evidence into policy and program changes can be challenging. Several articles in 2012^{24,25,26} provide models for moving knowledge into policy, programs and practice change in LMIC. The process works relatively well for knowledge translation when evidence is straight forward, the conclusions clear, and the problem well-defined and linear, such as with a drug treatment for a specific disease. However, the more complex the problem the less easy it is to conduct a quality systematic review and use GRADE to assess the quality of the retrieved evidence as was shown in the systematic review of intervention strategies, where comparable studies were few. Furthermore, moving research into practice, even with systematic review of the evidence can be fraught with difficulty. For example, despite overwhelming evidence from systematic reviews, evidence-based

²⁴ Bosch-Capblanch et al. Guidance for Evidence-Informed Policies about Health Systems: Rationale for and Challenges of Guidance Development Plos Medicine 2012;9(3): e1001185

²⁵ Lavis et al. Guidance for evidence-informed policies about health systems: linking guidance development to policy development. PloS Med. 2012;9(3):e1001186

²⁶ Lewin et al. Guidance for evidence-informed policies about health systems: assessing how much confidence to place in the research evidence. Plos Medicine 2012;9: e1001187

guidelines, education programs and public engagement, there are still many patients with undiagnosed and/or mistreated or undertreated hypertension in HIC.

Vaccine hesitancy is a complex behavioural phenomenon, not a "simple" problem, and the evidence does not lead to a single best practice intervention to address hesitancy in all contexts. At this point, the TIP model appears to have promise in guiding the tailoring of interventions to address underlying hesitancy determinants. In general, there is need to focus on capacity building for detection of hesitancy, diagnosis of the cause(s) in the subpopulation, development of tailored strategies, and implementation and evaluation of the impact on vaccine uptake, followed by sharing of lessons learned.

Regional Technical Immunization Advisory Groups (RTAG) as well as National Immunization Technical Advisory Committees (NITAG) need to assess whether issues of vaccine hesitancy are present in their region and country and how these may impact on policy recommendations. The Working Group did not consider a prescriptive approach on the role of either regional or country advisory committees as beneficial given the variations across regions and countries.

Section 6D: Roles and Need for Tools and Opportunities to Share Vaccine Hesitancy Experience and Knowledge

The Working Group has suggested roles for WHO, partenrs and member states in addressing vaccine hesitancy in Section 8 – Recommendations.

While vaccine hesitancy has existed ever since vaccines and vaccination programs began, recent acknowlegement that it can influence the impact of vaccination programs has highlighted the need to understand and address it more systematically. Vaccine hesitancy is a complex behavioural phenomenon.

The Working Group identified the need to use the 2013 revised JRF Indicators (Section 5) to facilitate monitoring of vaccine hesitancy at the country, regional and global levels; determination of similar and divergent vaccine hesitancy issues and intervention successes across regions and globally. There is also a need for validated tools to document vaccine hesitancy within a country- segmentation of the population (e.g application of TIP modified to fit different settings suggested (Section 5)); to diagnose factors influencing vaccine hesitancy in specific subgroups and then to intervene effectively to address vaccine hesitancy and evaluate the impact of approaches in different settings. Best evidence-based practices to diagnosis and address vaccine hesitancy in different contexts need to be documented and lessons learned shared. Currently, beyond publication in academic journals, there are no regular opportunities and systems for sharing lessons learned about vaccine hesitancy in different settings.

Section 6E: Vaccine Hesitancy Landscape Analysis- List of key players working on the issue of Vaccine Hesitancy

Within the Terms of Reference for the SAGE Working Group on Vaccine Hesitancy⁴, one deliverable was to perform a landscape analysis of who/ what organizations are working on vaccine hesitancy in various settings/countries.

The working group developed the following objectives for conducting the landscape of analysis:

- a) Identify organizations working on the issue of vaccine hesitancy in various settings/countries.
- b) Identify those working on the issue of vaccine hesitancy to identify potential partners, donors and collaborators in the field.
- c) Identify the regions where work is being done on vaccine hesitancy and what kind of work is being done in each area. Have those identified state what work their organization is doing to address vaccine hesitancy.

The landscape analysis of organisations working on vaccine hesitancy (Appendix A6C.1) attempted to take a relatively broad view of vaccine hesitancy by including some of the most active specialized vaccine-hesitancy actors in the field, with examples from many different types of organizations at many different levels with the aim of developing a more comprehensive list over time as stakeholders, organizations, institutes and communities respond with suggested additions.

Five categories and four sub-categories of actors were determined to represent the groups working on vaccine hesitancy, including Governments (national and regional), Non-for-profit, Donors, Researchand Multinational Organizations. One further category was included to represent any actor that did not fit in the above categories but was still producing important work related to vaccine hesitancy. Industry was initially not included as its own category in this framework. While the vaccine industry has a major stake in vaccine hesitancy, is keen to combat hesitancy and therefore conducts work on the issue, it was seen as not beneficial to analyze each member of the vaccine industry individually. Instead, the vaccine industry was included as one entity in the 'other' category, so their work and interests as a group could be presented in the landscape analysis.

Seven areas of work and/or interest being carried out by actors working on the issue of vaccine hesitancy were identified, including research, policy recommendation, intervention, education and promotion, collaboration, goal setting and social mobilization. Inclusion/exclusion criteria were outlined by the Working Group. Inclusion criteria included working in at least two of seven areas of interest, specific examples of activities related to vaccine hesitancy. Exclusion criteria included actors promoting vaccine hesitancy or who are part of the anti-vaccination lobby, actors that have not worked on vaccine hesitancy in the last five years.

Two search strategies were used: 1) systematic review of the literature conducted in English and Mandarin over a range of databases and search engines and 2) snowballing technique to obtain unpublished information through personal communication with Working Group members and players identified through the initial literature search, as well as WHO partners familiar with regional/local circumstances to identify organizations relevant to the landscape analysis.(See Report Appendix 6C.1)

Categories		Key Actors	Areas of Work/Interest 1)	Actions 2)	Region	Collaborators and Affiliates
Gov	National					
	Regional					
Not-for-profit						
Doners						
Research	Individual					
	Organisations					
Multinationals						
Other						

The following framework was developed for listing organizations/key players.

Including research, policy recommendations, intervention, education/promotion, collaboration, goal setting and social mobilisation.
Examples current activities related to the issue of vaccine hesitancy the actor is engaged in.

In brief, the landscape analysis found that a number of advisory committees and organizations have started to address vaccine hesitancy, defining the problem, gathering information on hesitancy and suggesting potential intervention strategies. However, although organisations are starting to view vaccine hesitancy as an important topic, many simply discuss and highlight the issue, without making meaningful contributions (e.g. research, interventions, recommendation). Furthermore, the landscape analysis did not find many global vaccine reporting or surveillance systems currently measuring vaccine hesitancy, although there are a number of groups who are trialling different approaches to measurement.

A wide variety of groups were found, focusing on the promotion of vaccines and therefore addressing vaccine hesitancy in the population. In the future, an organization will need to be responsible for updating the data in the Landscape Analysis.

In summary, there is a growing list of researchers and organizations documenting and/ or studying vaccine hesitancy that are an important resource for addressing the growing needs to measure and address vaccine hesitancy.

Section 6F: Moving Forward

While vaccine hesitancy is complex and context specific varying across time, place and vaccines, with a myriad of potential underlying determinants, the Working Group emphasized that there are a number of clear paths forward. While more research is needed there are current best practices for addressing hesitancy to follow now.

As part of best practice, immunization programs need to monitor their populations to detect pockets where vaccine up take rates are lower than would be expected with the services available. Often there are clusters of the vaccine hesitant within segment(s) of the population even when overall coverage is high. The WHO EUR TIP model provides an effective strategy to address hesitancy by segmentation of the population into subgroups with higher hesitancy levels, diagnosis of the major underlying factors, then tailoring the intervention to address these factors followed by evaluation of outcomes. Steps are

already underway to adapt TIP for use in LICs and to make the program more user friendly for immunization program managers to use with help from experts with appropriate back grounds.

The systematic review and the review of review of intervention strategies highlighted a number of effective strategies for improving vaccine uptake albeit not all necessarily related to hesitancy. While more work is needed, immunization programs need to incorporate the ones that fit their setting and resources into their program in order to support vaccine uptake. Given that immunization programs should have established close links with civil society organization, these can be helpful in mobilizing support for immunization, raising demand for vaccines and assisting in addressing vaccine hesitancy depending on the underlying hesitancy factors. Social mobilization, possibly through civil organization support, and a quality vaccine communication plan and program are important components for all immunization programs in dealing with hesitancy.

Effectively addressing vaccine hesitancy in addition to these general actions to support vaccine acceptance is part of good housekeeping for a quality immunization program. All immunization programs need to incorporate a plan to measure and address vaccine hesitancy into their country's immunization program. The compendium of vaccine hesitancy survey questions may help inform these surveys and facilitate inter- country comparisons. Sharing of immunization program country findings on hesitancy can lead to improved understanding of vaccine hesitancy and development of best intervention practices according to different major underlying factors in different contexts.

The working group acknowledged the importance of recognizing that addressing the needed behaviour change to overcome vaccine hesitancy is similar to the needed behaviour change required to address other complex communicable and non- communicable problems such as poor population compliance with the diagnosis and management of a chronic disease such as hypertension, diabetes, sexually transmitted infections etc.

As integration of health prevention and intervention services with other needed and wanted health and non-health related initiatives both for individuals and for communities has met with good success in some LIC settings, this strategy can be applied at the ground level. Front line health workers, even with limited training, can be taught opportunistically include immunization into variety of health and non-health services. This may help address some complacency and convenience hesitancy factors and minimize missed opportunities.

The Working Group concluded that the field of vaccine hesitancy is still evolving with a multitude of research activities being conducted by various groups and stakeholders. This will need ongoing evaluation, validation of the tools developed by the Working Group and assessment of future and current research and strategies beyond the realm of the Working Group.

Despite the lack of standardized, validated tools, immunization programs should move forward by implementing strategies to increase vaccination uptake.

Section 7: Recommendations

Vaccines have saved countless lives. However, to optimize control of vaccine preventable diseases, high immunization coverage rates must be achieved. While hesitancy to accept immunization has occurred since vaccines were first introduced, in the past decade hesitancy has been increasingly recognized as a problem that needs attention if high uptake rates are to be achieved and maintained.

The Working Group defined vaccine hesitancy:

Vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccine services. Vaccine hesitancy is complex and context specific varying across time, place and vaccines. It includes factors such as complacency, convenience and confidence.

Following a 2.5 year review of vaccine hesitancy the SAGE Working Group on Vaccine Hesitancy makes the following recommendations:

1. General recommendations

Following conclusions should be acknowledged and disseminated widely:

- a) Vaccine hesitancy is a complex and rapidly changing global problem that requires ongoing monitoring.
- b) There are many determinants of vaccine hesitancy that are laid out in the Matrix developed by the Working Group.
- c) Concerns about vaccine safety can be linked to vaccine hesitancy, but safety concerns are only one factor that may drive hesitancy.
- d) Addressing vaccine hesitancy within a country and/or subgroup requires an understanding of the magnitude and setting of the problem, diagnosis of the root causes, tailored evidence-based strategies to address the causes, monitoring and evaluation to determine the impact of the intervention and whether vaccine acceptance has improved, and ongoing monitoring for possible recurrence of the problem.
- e) There is no single intervention strategy that addresses all instances of vaccine hesitancy.
- f) In low vaccine uptake situations where lack of access to available services is the major factor, vaccine hesitancy can be present but it should not be the priority of immunization programs to address; improving services and access is the priority.

2. Specific recommendations

To WHO:

- a) Develop core capabilities at headquarters and regional level for gaining behavioural insights that can be applied in an integrated fashion to many communicable and non-communicable diseases, including to hesitancy. This will require the integrated skills and knowledge of sociologists, behavioural psychologists, anthropologists, experts in social marketing and communication as well as specific disease experts. Efficiency and effectiveness of programs could be optimized, as this recognizes that addressing the needed behaviour change to overcome vaccine hesitancy is similar to the needed behaviour change required to address other complex communicable and non- communicable problems such as poor population compliance with the diagnosis and management of chronic diseases such as hypertension, diabetes, sexually transmitted infections etc.
- b) Engage partners, including civil society organizations, at the global, regional and country levels, to mobilize in support of immunization, its benefits to individuals and for communities.
- c) Cross-linkages between programs should be strengthened as vaccine hesitancy is an overarching concept which spans across various immunization-related fields. An integrated approach is needed to ensure consideration of vaccine hesitancy within different work streams. The landscape of organisations active in the field of vaccine hesitancy needs to be maintained and updated as a resource to facilitate collaboration and facilitate the establishment of global networks of researchers and stakeholders working on vaccine hesitancy.
- d) If beyond their scope, WHO should identify the suitable partners to take on the planning and implementation for vaccine hesitancy related work.

To UNICEF:

a) Given their vast experience in the field of polio with expertise in civil society organization, in communications and in behavioural change, UNICEF should continue their work with member states and ensure competencies in the field of vaccine hesitancy. Although much attention is given to the experiences from LIC, the lessons learned that apply to vaccine hesitancy need to be shared with HIC and MIC. This applies in particular to the findings obtained from addressing issues around polio vaccination.

To WHO and UNICEF:

- a) Create an organizational structure to address and coordinate vaccine hesitancy and demand issues at HQ level:
 - 1. Vaccine hesitancy work is not done in isolation but is intertwined, hence should be taken into consideration by all departments working in the field of immunization and beyond.
 - 2. Regular synthesis, digestion and sharing of vaccine hesitancy monitoring, intervention, prevention, training and research findings globally and regionally should be ensured.
 - 3. Regular updating and dissemination of best practices in management of and training for addressing vaccine hesitancy in HIC, MIC and LIC should be facilitated.
 - 4. One of potentially other useful tools is the WHO EUR TIP model which should be adapted for global use. Necessary support for training the trainers should be provided. Countries should be supported in using TIP and sharing their lessons learned as its effectiveness needs to be monitored, in particular LIC and MIC.
 - 5. The pilot testing and validation of the sample survey questions linked to the Matrix of determinants in various contexts needs to be undertaken and coordinated jointly.
- b) Consider the implementation of one or both of the proposed indicators into the regional JRFs
 - 1. The proposed etiological indicator will allow the monitoring of the three major concerns of immunization managers in regard to vaccine hesitancy by year and their potential shift over time.
 - 2. The proposed process JRF indicator determines if regular assessment for vaccine hesitancy is taking place. Use of country vaccine hesitancy survey findings will in the future lead to improvement of the data reported on in the annual JRF. Beyond assessment of process, the indicator serves as a reminder of good program practices and an advocacy tool.
 - 3. The data deriving from the indicators will be assessed by the GVAP Working Group. These analyses may lead to further refinement of the indicators.

To WHO, UNICEF, other international organisations and partners:

- a) Build regional capacity to support country progress on vaccine hesitancy.
- b) Ensure opportunities for community input into vaccine hesitancy strategies for prevention, diagnosis, intervention and monitoring to ensure that they resonate with communities.

- c) As steps are taken to improve vaccine program communications in LMIC, ensure that these also facilitate an understanding of vaccine hesitancy and the role communication may or may not play in driving and addressing hesitancy.
- d) Create and /or facilitate opportunities for sharing lessons learned about vaccine hesitancy on a regular basis.
- e) Work together to develop, validate and/or promote the use of tools to address vaccine hesitancy in different setting in HIC, MIC and LIC, including tools on monitoring, diagnosis, intervention, evaluation of impact, cost and community acceptability.
- f) As integration of health prevention and intervention services with other needed and wanted health and non-health related initiatives both for individuals and for communities has met with good success and needs to be applied more widely, immunization needs to be included. This can help address some complacency and convenience hesitancy factors.
- g) Encourage and support research on vaccine hesitancy:
 - i. Research on prevalence, determinants, effective intervention strategies, prevention, recrudescence and early intervention especially in LMIC but also in HIC.
 - ii. Expand research to capture factors not only at the individual level, but also at the community, contextual (politics and policies, communication and media, social norms, influential leaders, civil society organizations etc.), and organizational levels (vaccine and vaccination specifics issues, mode of delivery, etc) in HIC, MIC and LIC settings.

To regional and country immunization advisory committees:

- a) Give consideration to vaccine hesitancy issues in their region or country.
- b) Assist with dissemination of the deliverables developed by the Working Group.

To member states:

a) Incorporate a plan to measure and address vaccine hesitancy into their country's immunization program as part of good program practices; the compendium of vaccine hesitancy survey questions may help; use of questions from the compendium facilitates inter-country comparisons, though the survey questions still remain to be validated throughout different settings.

- b) Within the immunization program and beyond, undertake education and training of health care workers to empower these to address vaccine hesitancy issue in patients and parents.
- c) Given their impact on the patient, vaccine hesitant behaviours within HCWs should be addressed.
- d) Ensure education on vaccination and immunization in general, and addressing vaccine hesitant patients in particular, by inclusion relevant training into academic curricula of nursing, medical and other health care professional students.
- e) Ensuring education and knowledge about vaccines in younger individuals provides a good opportunity to further shape future vaccine beliefs and behaviour.
- f) As part of good immunization program practice, civil society organizations need to be involved in supporting vaccine programs, in enhancing demand for vaccine and in helping to address vaccine hesitancy depending upon the underlying factors.
- g) Regularly share country information, research and lessons-learned on vaccine hesitancy among member states. Practices and interventions, ideally evidence-informed, need to be documented, evaluated and shared.
- h) The systematic review and the review of review of intervention strategies highlighted a number of effective strategies for improving vaccine uptake albeit not all necessarily related to hesitancy. While more work is needed, immunization programs need to incorporate the ones that fit their setting and resources into their program in order to maintain or increase vaccination uptake.