



COMMENTARY



## Maternal immunization country readiness: a checklist approach

Michelle L. Giles<sup>a</sup>, Elizabeth M. Mason<sup>b</sup>, Philipp Lambach<sup>c</sup>, and Carsten Mantel<sup>d</sup>

<sup>a</sup>Department of Obstetrics and Gynecology, Monash University, Melbourne, Australia; <sup>b</sup>Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK; <sup>c</sup>Department of Immunization, Vaccines and Biologicals (IVB), World Health Organization, Geneva, Switzerland; <sup>d</sup>MMGH Consulting, Zurich, Switzerland

### ABSTRACT

Prior to the addition of a maternal vaccine onto the National Immunization Programme, it is important for a country to evaluate their capacity and readiness. This checklist has been developed that is deliberately not restricted to any particular vaccine so it can be applied by national-level stakeholders during the decision-making stage for the introduction of any additional or new maternal vaccine. It is suggested that a team consisting of representatives from the Ministry of Health, including the National Immunization Programme (NIP) and Maternal, Newborn and Child Health (MNCH) programs complete and review the checklist together. This checklist enables countries to assess their capacity, strengths and weaknesses and identify a list of priorities to allow for smooth implementation of maternal vaccines.

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### Background

Vaccination of pregnant women has the potential to protect not only mothers from vaccine-preventable diseases (VPDs) but also their vulnerable infants, through the transfer of pathogen-specific IgG antibodies via the placenta. The World Health Organization (WHO) Strategic Advisory Group for Experts (SAGE) on Immunization recommends routine vaccination of pregnant women against tetanus and seasonal influenza.<sup>1,2</sup> In 2014, the Global Advisory Committee for Vaccine Safety (GACVS) of the WHO confirmed the reassuring safety profile of maternal immunization with inactivated seasonal and pandemic influenza, meningococcal polysaccharide and conjugate vaccines, tetanus toxoid containing vaccine (TTCV) and pertussis combination vaccines for both the mother and the infant.<sup>3</sup> Maternal tetanus vaccination programs and other initiatives such as clean birth and clean cord care practices have led to an estimated 96% reduction in neonatal mortality from tetanus.<sup>4</sup> Successful maternal vaccination not only against tetanus but also against influenza and pertussis has led to the development of 'purpose-built' vaccines targeting pregnant women, such as those against Group B Streptococcus (GBS) and Respiratory Syncytial Virus (RSV). While vaccine development seems technically feasible and several candidates are in or about to enter clinical development, implementation issues remain critical to vaccine decision-making and to further inform the Research and Development community, as these may affect policy making and vaccination coverage if not identified and addressed early on.

The implementation of maternal vaccines has highlighted some important challenges with relatively small numbers of low- and middle-income countries introducing any additional maternal vaccine beyond TTCV to date. In 2014, a global review of national influenza policies reported that 115/194 countries

(59%) had a national influenza policy, and of these, only 42% included pregnant women.<sup>5</sup> Of the 115 countries with a national influenza policy, only one was a low-income country and 19 were lower-middle-income countries.<sup>5</sup> Other authors have speculated on the factors contributing to the underuse of influenza vaccine including the need for yearly vaccination, a lack of infrastructure in low-income countries to provide services to all eligible persons and weak systems to evaluate, procure, regulate, store, distribute, and administer vaccines.<sup>6</sup> With the new maternal vaccine candidates on the horizon, it is important to identify the key elements required for successful introduction. With this in mind, PATH and WHO have brought together a diverse group of key stakeholders, the Advancing Maternal Immunization (AMI) collaboration, to identify gaps and develop a roadmap outlining the priority next steps for advancing maternal immunization.<sup>7</sup> At the same time, WHO and the London School of Hygiene and Tropical Medicine initiated a project to develop a value proposition for GBS vaccines, considering both high and low-resource segments of the market. This project assesses the preventable burden of disease, estimates expected costs and gains from vaccinating pregnant women, and considers feasibility and operational aspects. Even though these projects are specific for RSV and GBS vaccines, many of the principles may apply to the introduction of other maternal vaccines such as increasing stakeholder awareness of disease burden and supporting coordination between immunization and Maternal, Newborn and Child Health (MNCH) programs to ensure operations and logistics are in place to optimally deliver vaccines to pregnant women.<sup>7</sup> In addition to vaccines against RSV and GBS, other potential new maternal vaccines in the next 10 years include those against cytomegalovirus, universal influenza, and monovalent pertussis.



**CONTACT** M. L. Giles  [michelle.giles@monash.edu](mailto:michelle.giles@monash.edu)  Department of Obstetrics and Gynecology, Monash University, 246 Clayton Road, Clayton 3168, Australia  
Philipp Lambach is a staff member of the World Health Organization. The views expressed in this publication are those of the authors and not necessarily those of the World Health Organization.

Table 1. Maternal immunization readiness checklist.

Question	Indicator	Definition	Rationale	Yes but needs strengthening prior to introduction	
				Yes	No
Is there an existing national policy on maternal tetanus immunization?	Policy	N/A	An existing policy on maternal tetanus immunization provides the foundation upon which new maternal vaccines can be integrated	Yes	No
Is there a national policy on number and content of ANC visits?	Policy	N/A	A policy on the number and content of ANC visits helps to adapt messaging from HWs to ensure that pregnant women attend the minimum recommended number of visits at the recommended times during pregnancy to conduct appropriate tests and interventions	Yes	No
Is there a functioning NITAG?	Governance	The minimal set of indicators agreed to by WHO to allow for monitoring of functionality at a global level: legislative or administrative basis for the advisory group; written terms of reference; at least five different areas of expertise among members; at least one meeting per year; circulation of the agenda and background documents at least one week prior to meetings; mandatory disclosure of any conflict of interest	A functional NITAG is a formally constituted national technical advisory body, responsible for providing independent, evidence-informed advice to health authorities. The main role of NITAGs is to collect, review, assess and organize scientific evidence on vaccine-related topics in the form of recommendations to national health authorities, that take into account the local epidemiologic and social context which is essential when considering introduction of an additional or new maternal vaccine	Yes	No
If there is a NITAG, is there a MNCH expert on the NITAG?	Governance	N/A	When considering maternal vaccination, particularly if implementation is to be via ANC services, then consultation with experts on maternal and newborn health and ANC service delivery is essential to ensure factors unique to the antenatal context are considered and addressed to minimize barriers and maximize smooth introduction	Yes	No
If there is no MNCH expert on the NITAG is there engagement with the relevant expert group(s)?	Governance	Examples may include MNCH, Professional Obstetric or Pediatric organizations	See above	Yes	No
Do you give any maternal vaccines in addition to TT/Td (e.g. Influenza, Pertussis, Yellow Fever, Meningococcal A)?	Recent experience introducing additional maternal vaccines	N/A	Experience in introducing an additional maternal vaccine to existing maternal tetanus programs may mean that relevant mechanisms, e.g., committees, HW training, communication strategies etc in the ANC setting have been developed and strengthened	Yes	No
Have you introduced any new vaccine(s) in the NIP in the previous 5 years?	Recent experience introducing new vaccines	N/A	Recent experience introducing a new vaccine may mean that relevant mechanisms, e.g., committees, HW training programs, communication strategies etc. have been developed and strengthened in the NIP in addition to strengthening surveillance systems and monitoring and evaluation processes	Yes	No
Is the NIP able to mobilize and use sufficient resources for the existing program and its expansion without threatening financial sustainability of domestic funding?	Financing	N/A	Short and long-term funding needs to be clearly defined prior to the introduction of a new maternal vaccine to ensure readiness for implementation	Yes	No
Is the PAB >90%?	Existing Tetanus Program	Proportion of babies protected from tetanus at birth	PAB can be used to estimate performance of the existing maternal tetanus immunization program.	Yes	No
Does TT2+ coverage meet targets defined in the National Policy or WHO-recommended coverage targets?	Existing Tetanus Program	Proportion of pregnant women receiving at least two doses of Tetanus toxoid containing vaccine	TT2+ coverage can be used to estimate performance of the existing maternal tetanus immunization program.	Yes	No
Does DTP3 coverage meet targets (per age group) defined in the National Immunization Policy?	Existing Immunization Program	Third dose diphtheria-tetanus-pertussis immunization in children	Defined targets for routine vaccines (as stated in local policies and guidelines) and experience in reaching hard-to-reach areas or communities based on coverage targets are strong attributes when considering introduction of new maternal vaccines.	Yes	No

(Continued)

Table 1. (Continued).

Question	Indicator	Definition	Rationale	Yes but needs strengthening prior to introduction	
				Yes	No
Does ANC4+ coverage meet targets as defined in the national antenatal care policy or internationally recommended coverage targets?	Existing Antenatal Care	Number of women having at least 4 ANC attendances, over all pregnant women.	Attending the minimum number of recommended antenatal contacts is important to maximize the opportunities for vaccination during pregnancy. As the number of recommended maternal vaccines increases and/or new vaccines come with specific recommendations for administration according to gestational window, the need for multiple ANC contacts across a number of trimesters becomes increasingly important.		
Is a system in place to record the proportion of women who have at least one ANC visit in the 3 <sup>rd</sup> trimester?	Existing Antenatal Care	At least one ANC visit taking place after 28 weeks gestation.	New maternal vaccines may be recommended within a short vaccination time window during pregnancy therefore having a system in place to record when women are attending for ANC visits is beneficial		
Is a system in place to record the proportion of women who have at least one ANC visit in the 2 <sup>nd</sup> trimester?	Existing Antenatal Care	At least one ANC visit taking place between 14 and 27 weeks gestation.	Having a system in place to document/record when women are attending ANC services is beneficial particularly if future vaccines are to be provided through ANC, and especially if recommended for specific gestational age windows.		
Is a system in place to record ANC quality?	Existing Antenatal Care	No agreed definition	Although no agreed definition is yet established, consideration of not just the number of ANC visits but whether practitioners with good clinical and interpersonal skills are providing individualized, person-centered care at every antenatal contact, implementing evidence-based effective practices in a timely manner, and providing information and psycho-social and emotional support. If quality of ANC is poor and women's experience is negative then evidence suggests that women will not attend ANC irrespective of the number of recommended visits.		
Are there any ANC fees currently incurred by pregnant women?	Existing Antenatal Care	ANC fees may be for examination, appointments, ultrasound, laboratory tests etc.	Fees may be a disincentive to ANC attendance; therefore they are an important factor to consider.		
Are program coordination, roles and responsibilities by NIP and ANC/MNCH clearly defined and understood?	Program co-ordination	Both NIP and ANC share joint responsibility for maternal immunization (although this may vary depending on local contexts).	Having clearly defined roles and responsibilities, as well as communication pathways between NIP and ANC are important to ensure functional integration of maternal immunization into the broader immunization program		
Is a program in place for HW education and training in relation to maternal immunization?	Delivery platform	N/A	An adequately trained workforce (quality of staff) is important in the context of maternal immunization to be able to communicate with pregnant women, answer questions, safely administer vaccines and have the knowledge and experience to address any adverse events.		
Is there an adequate number of HWs to deliver new maternal vaccines without compromising delivery of existing components of antenatal care?	Delivery platform	The actual number will depend on the level of service provision and can be defined by the country.	Adequate human resource capacity (number of staff) needs to be available to ensure demand is met and administration and delivery of the immunization program occurs safely		
Is the vaccine procurement system robust and able to forecast demand for all existing and new vaccines?	Vaccine delivery system	N/A	A plan for procurement including national licensure processes, estimated target population size, forecasting the number of doses and injection supplies required per year is needed to ensure adequate and sustained vaccine supply.		
Is the cold chain capacity adequate for existing vaccines and for the addition of a new vaccine?	Vaccine delivery system	N/A	Existing cold chain must demonstrate adequate capacity and performance to absorb the introduction of a new vaccine. This includes adequate cold storage space or plans to expand to meet future needs. Reliable storage and cold chain is vital to the quality and goals of the immunization program.		

(Continued)

Table 1. (Continued).

Question	Indicator	Definition	Rationale	Yes but needs strengthening prior to introduction	No
Is surveillance for maternal mortality and VPDs in place?	Surveillance	This system should track all maternal deaths in real time, help understand the contributing factors and stimulate and guide actions to prevent further deaths. The Maternal Death Surveillance and Response is a model of such a system.	A surveillance system to monitor maternal mortality and disease, (specifically related to maternal vaccines such as puerperal sepsis due to GBS, tetanus, influenza, pertussis, RSV) and epidemiological changes in disease burden can assist in assessing performance of the NIP and ANC and in identifying weaknesses or gaps.		
Is surveillance for neonatal mortality and VPDs in place?	Surveillance	This system should capture the number of deaths and causes, and also have the capacity to identify specific cases for analysis with a view of response or action to be taken.	A surveillance system to monitor neonatal mortality and disease, (specifically related to maternal vaccines such as tetanus, influenza, pertussis, RSV, GBS) and epidemiological changes in disease burden can assist in assessing performance of the NIP and ANC and in identifying weaknesses or gaps.		
Is stillbirth surveillance in place?	Surveillance	WHO definition for stillbirth: 1000 g or 28 weeks and above. Many countries use 500 g and 24 weeks and above.	A surveillance system to monitor stillbirths, which may include timing, weight and cause and epidemiological changes in disease burden can be used to assist in assessing performance of the NIP and ANC and in identifying weaknesses or gaps.		
Is an AEFI reporting system in place?	Surveillance	N/A	A system to monitor AEFI is essential to capture AEFI that may only become apparent once the vaccine is used on a large scale. It also enables countries to be able to deal promptly with severe AEFI to ensure that public confidence in the NIP and ANC services is maintained.		
Does the AEFI reporting have the capacity to identify pregnant women?	Surveillance	N/A	A system with the capacity to identify pregnant women is essential to facilitate any early detection of a safety signal within the target population and to ensure public confidence in the NIP and ANC service		
Is a health information system (including maternal vaccination) in place? If there is a health information system in place, does it capture maternal vaccination by private providers?	Monitoring and evaluation	N/A	A health information system that is able to use existing antenatal records can assist facilities in recording and reporting maternal immunization coverage (and thereby reportable targets). Recording ANC services and vaccination provided by the private sector should be considered depending on the country context (e.g., how much ANC is accessed through the private system). This will help ensure accurate coverage data particularly in settings where private providers cover considerable proportions of the population		
Is there evidence of vaccine hesitancy among your pregnant population? Are demand creation activities for maternal immunization such as a communication strategy planned and/or in place?	Vaccine hesitancy Demand Creation/ Communication	Vaccine hesitancy refers to delay in acceptance or refusal of vaccination despite availability of vaccine services Demand creation is the process of increasing the demand for a product or service	High levels of vaccine hesitancy may lead to low vaccine demand. Working with communities to achieve high levels of maternal immunization acceptance may help reduce barriers to vaccine introduction. Communication strategies to educate pregnant women, health staff and communities about the benefits of vaccinating pregnant women and to respond to potential concerns about the efficacy and safety of the vaccine are necessary to raise awareness, mitigate against vaccine hesitancy and create demand.		

**Table 2.** Abbreviations used in Table 1.

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N/A-	not applicable
HW-	health workers
NIP-	National Immunization Programme
TT-	Tetanus toxoid containing vaccine
Td-	Tetanus and diphtheria containing vaccine
PAB-	protection at birth
ANC-	antenatal care
MNCH-	maternal neonatal child health
VPD-	vaccine preventable disease
NITAG-	National immunization technical advisory group
TT2+	the proportion of pregnant women receiving at least two doses of Tetanus toxoid containing vaccine
DTP3-	third dose diphtheria-tetanus-pertussis immunization in children
ANC4+	antenatal care visits (four or more)
AEFI-	adverse event following immunization

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In low-resourced countries, the introduction of new vaccines can be a challenge to health systems with limited capacity. However, in many higher resourced countries, experience with new vaccine introduction showed a positive impact with regards to health service strengthening.<sup>8</sup> In recognition of this, SAGE has endorsed six guiding principles for countries to follow when planning and implementing a new vaccine.<sup>9</sup> These include (but are not limited to) country-led, evidence-based decision-making; a stringent planning and prioritization process; a well-performing and responsive immunization program; a well-trained workforce; adequate allocation of human and financial resources; functional cold storage, logistics and vaccine management; and systems for disease surveillance and monitoring of adverse events.

To assist countries to make informed decisions and guide the planning for a smooth introduction, the WHO has published a document outlining the principles and considerations for adding a new vaccine to the national immunization program.<sup>10</sup> This is not specific for pregnant women or for one particular vaccine to cover the areas of decision-making, planning and managing the introduction, and monitoring and evaluation. Specifically for pregnant women, the WHO has also published a guide to assist countries with the introduction of influenza vaccination for pregnant women.<sup>11</sup>

In addition, when deciding to add new vaccines into antenatal care (ANC) services, factors such as access to these services during pregnancy need to be considered as well as the number and timing of ANC visits. This is particularly relevant for maternal vaccines with a recommended optimal gestational window for vaccination. In 2016 the WHO released updated recommendations on ANC which include eight contacts during pregnancy and guidance to the specific interventions to be included at each visit.<sup>12</sup> A key focus of the updated WHO recommendations was not only on the number of contacts and evidence-based interventions to be included but also on appropriate communication and support. The overarching goal of these updated recommendations was to aim for quality ANC by providing individualized, person-centered care at every antenatal contact, implementing evidence-based effective practices in a timely manner, and providing information and psycho-social and emotional support from practitioners with good clinical and interpersonal skills. Quality ANC is thus expected to lead to a positive pregnancy experience, which is defined as maintaining physical and sociocultural normality, maintaining a healthy pregnancy for both mother and baby and an effective transition to a positive birth experience and into motherhood.<sup>12</sup>

## The checklist

Introduction of new maternal vaccines is expected in the second half of this decade. The coming years may thus provide opportunities for countries to expand the capacity of their immunization programs to include vaccination strategies across the life course and to increase the integration of current maternal vaccines into their antenatal care services. To ensure that efforts to strengthen country health systems remain targeted and within reasonable cost, the concept of a “readiness checklist”, i.e. a tool supporting countries to identify potential barriers through a self-assessment of their readiness for introducing an additional maternal vaccine was considered advantageous by an international expert group advising the WHO on the Maternal Immunization Antenatal Care Situational Analysis (MIACSA) project. The MIACSA project was an effort to analyze current practices in low- and middle-income countries (LMICs) in relation to maternal tetanus immunization programs and future preparedness for the introduction of additional maternal vaccines.<sup>13</sup> Based on suggestions by this multidisciplinary expert group, a “checklist concept”, was drafted by the authors of this article and reviewed by regional and national experts at the WHO MIACSA Dissemination Meeting in March 2019.

The checklist concept provides the key elements for tools that countries may wish to generate to self-evaluate their capacity and readiness to introduce a vaccine targeting pregnant women (Table 1). National level stakeholders can use and complete it during the decision-making stage for the introduction of a new maternal vaccine. Ideally, it should be piloted by local teams consisting of representatives from the Ministry of Health, including the National Immunization Programme (NIP) and MNCH programs to evaluate its applicability in the local context. The aim is to determine readiness to introduce a new maternal vaccine, and to identify and monitor areas that need strengthening to allow for smooth implementation. This article outlines some of the key indicators considered and their rationale that should be included in any future checklist development.

## Discussion

With the success of the Maternal and Neonatal Tetanus Elimination (MNTE) initiative, the feasibility of maternal vaccination to save the lives of mothers and their babies in low-resource settings has been demonstrated. Before the introduction of additional recommended maternal vaccines countries should consider key factors that may affect successful implementation. These include understanding the country’s local epidemiology and burden of disease, provision of information, education and communication to pregnant women and HWs, facilitating access and reliable delivery of vaccine and ensuring that a surveillance program including for safety monitoring is in place.<sup>13</sup>

Unlike other “readiness” checklists such as the one developed to assess readiness to introduce Human Papilloma Virus (HPV) vaccine into school-based immunization programs,<sup>14</sup> the maternal immunization readiness checklist does not apply a scoring system. The idea is that a country’s readiness does

not hinge on a pre-defined score before considering introduction. Neither is there one single indicator that must be in place prior to the introduction of a new maternal vaccine. This concept proposes that countries are able to use a tool, or modify a tool for their local context to assess their capacity, the strengths and weakness of their existing NIP, ANC services and current maternal vaccination program.

It is envisioned that after completing such a “checklist” countries should be able to identify a list of priority actions to achieve implementation of maternal vaccines. This action plan to strengthen capacity with a view to introduction of a new maternal vaccine should consider an assessment of the feasibility of addressing any evidence gaps, human resources required, costs, and estimated timelines. It may be that this requires completion prior to the introduction of a new vaccine, or for some indicators, it may be appropriate to strengthen them simultaneously with the introduction of a new maternal vaccine. This decision will be context-specific.

Importantly, potential approaches to vaccine hesitancy in the antenatal context should also be considered. These may include evidence-based interventions that highlight vaccine safety during pregnancy and the benefit of maternal immunization to the infant.<sup>15</sup> In addition, culturally sensitive communication, in the form of a narrative approach from a trusted individual may be more effective than simply presenting facts verbally or in a leaflet.<sup>16</sup> In the antenatal context, written information about vaccines for consumers should be used to supplement a more in-depth personal discussion particularly with vaccine-hesitant women, acknowledging her commitment to both her own health and that of her child.<sup>16</sup>

For countries considering the introduction of a new maternal vaccine, this checklist concept may also confirm that they are indeed “ready” to introduce the vaccine, thereby addressing any perceived resistance or barriers.<sup>17</sup> The goal is that this checklist will be quick and simple to use, and that it will be able to be applied broadly across a range of potential vaccines and settings. Such a checklist may also be developed with the scope to adapt and self-evaluate (an iterative process) during implementation – ensuring that there is monitoring of the program implementation over time. Importantly, next steps with this checklist would be to pilot it in-country in future pre-implementation research efforts.

Countries that are considering future maternal vaccine introductions could integrate the checklist into existing program review and evaluation mechanisms. In order to achieve equitable access to new maternal vaccines, a concerted international effort could be envisaged to support countries with limited resources financially and with technical support. As part of such an effort, the checklist could further inform the necessary expert discussions related to disease burden, economic, operational, and health systems aspects, including safety, regulatory issues, ethics, and advocacy/communications. The ultimate aim of the checklist approach is that this will stimulate discussions among key stakeholders in countries to advance maternal immunization.

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## ORCID

Michelle L. Giles  <http://orcid.org/0000-0003-3007-1822>

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