Maternal influenza immunization

Perceptions of decision-makers, health care providers, and the community in Malawi

October 2016
## Contents

**Acronyms** .......................................................................................................................................................................... 3

**Acknowledgements** .................................................................................................................................................................. 4

**About PATH** ............................................................................................................................................................................ 4

**Executive summary** ............................................................................................................................................................... 5

**Introduction** ............................................................................................................................................................................. 6

**Study participants and findings** .................................................................................................................................................. 8

Maternal immunization delivery strategy .................................................................................................................................. 9

  Combining the ANC platform with immunization outreach to maximize coverage of maternal vaccines ................................. 9

Perceived challenges reaching pregnant women ......................................................................................................................... 11

Perceived challenges with changing vaccine formulations annually .......................................................................................... 11

Perceived challenges related to monitoring vaccine administration and tracking adverse events .................................................. 11

Lessons learned from vaccine introduction in Malawi ................................................................................................................ 12

Maternal immunization communication strategies and community mobilization ....................................................................... 13

Seasonal influenza: overall knowledge, priority, and perceived vulnerable populations ............................................................ 13

Seasonal influenza: knowledge regarding modes of transmission and treatment ......................................................................... 14

Sources of vaccine information and support for pregnant women ............................................................................................. 14

Acceptance of vaccination during pregnancy .......................................................................................................................... 15

Barriers to receiving health services and vaccines during pregnancy .......................................................................................... 15

Political support and advocacy for introducing maternal influenza immunization ................................................................ 16

Developing vaccine policies in Malawi ....................................................................................................................................... 16

How maternal influenza immunization fits with Malawi’s current health priorities .................................................................. 17

Information requested by policymakers to inform decision-making ............................................................................................ 17

Policymaker recommendations for promoting maternal vaccines ................................................................................................ 17

**Conclusions** ............................................................................................................................................................................... 18

Opportunities .................................................................................................................................................................................. 18

Challenges ..................................................................................................................................................................................... 18

Recommendations for future activities ........................................................................................................................................... 19

**References** ................................................................................................................................................................................ 21
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
</tr>
<tr>
<td>CHAM</td>
<td>Christian Health Association of Malawi</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program on Immunization</td>
</tr>
<tr>
<td>FANC</td>
<td>Focused Antenatal Clinic</td>
</tr>
<tr>
<td>Gavi</td>
<td>Global Alliance for Vaccines and Immunization/Gavi, the Vaccine Alliance</td>
</tr>
<tr>
<td>HIS</td>
<td>Health Information System</td>
</tr>
<tr>
<td>HPV</td>
<td>Human Papillomavirus</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NGO</td>
<td>Nongovernmental Organization</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>PMPB</td>
<td>Pharmacy, Medicines, and Poisons Board</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>TT</td>
<td>Tetanus Toxoid</td>
</tr>
<tr>
<td>TWG</td>
<td>Technical Working Group</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Acknowledgements

This document was compiled from research funded by the Bill & Melinda Gates Foundation through the World Health Organization (WHO). The research was coordinated by PATH.

Dr. Jessica Fleming was the principal author of this document. The author would like to thank Drs. Niranjan Bhat, Deborah Atherly, Kathleen Neuzil (University of Maryland Center for Vaccine Development), Justin Ortiz (WHO), Philipp Lambach (WHO), and Ms. Katie Regan for their technical review, Mr. Scott Wittet for editorial assistance in preparation of this paper, and Mr. Glen Zinck for proofreading and finalization.

The author also would like to thank the research team in Malawi—The Centre for Social Research, University of Malawi—and in particular Dr. Alister Munthali, the Principal Investigator and his fellow co-investigators: Dr. Bagrey Ngwira (Malawi Polytechnic), Mr. John Kadzandira, Ms. Monica Jamali-Phiri, and their very capable team of research assistants.

About PATH

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

PATH’s Center for Vaccine Innovation and Access brings together our expertise across every stage of vaccine research, development, and introduction to make lifesaving vaccines widely available to women, children, and communities across the world. Learn more at www.path.org.

The views expressed herein are solely those of PATH and do not necessarily reflect the views of WHO or the Bill & Melinda Gates Foundation.

For more information about PATH’s maternal influenza immunization program, please contact:
Jessica Fleming, PhD, MSc
Senior Research Scientist
Center for Vaccine Innovation and Access
2201 Westlake Ave Suite 200
Seattle, Washington USA 98121
info@path.org


Cover photo credit: PATH/Siri Wood

Copyright © 2016, PATH. All rights reserved. The material in this document may be freely used for educational or noncommercial purposes, provided that the material is accompanied by an acknowledgment line.
Maternal influenza immunization: Perceptions of decision-makers, health care providers, and the community in Malawi

Executive summary

Influenza is a major cause of death and suffering globally. With pregnant women and children younger than six months of age at especially high risk of severe influenza-related illness, maternal immunization is an effective strategy to protect both pregnant women and young infants from influenza. Decision-making around the introduction of any new health intervention must take into account country-specific evidence and experience including its perceived social acceptability, priority, and the operational feasibility of its delivery, and the current political environment.

In 2014-2015, PATH and the University of Malawi’s Centre for Social Research conducted formative research to gather the perspectives and viewpoints of a broad spectrum of key stakeholders in the maternal immunization arena in Malawi. Researchers documented information and lessons learned around maternal immunization including the vaccine policy decision-making process, potential programmatic implications of vaccine delivery for pregnant women, and perceptions and concerns about influenza disease and influenza vaccine among community members and health workers.

A total of 273 individuals in three districts of the country (Dowa, Rumphi, and Zomba) participated in focus group discussions, semi-structured interviews, clinic exit interviews, or key informant interviews. Respondents included pregnant women, family decision-makers, community leaders, health workers, regional and national public health program managers, and policy makers.

In terms of gaining support for maternal influenza immunization adoption and acceptance in Malawi, our study identified both opportunities (including supportive global policy, multiple immunization service delivery options, and strong vaccine acceptance and prioritization by the community) and challenges (including gaps in disease burden data, lack of country priority, and inherent operational challenges with delivery and monitoring). This report organizes our study findings into three areas:

1. Maternal immunization delivery strategies
2. Maternal immunization communication strategies and community mobilization
3. Political support and advocacy for introducing maternal influenza immunization programs

The final section of the report discusses opportunities and challenges to maternal influenza vaccine introduction in Malawi and offers recommendations for activities that could further inform policy decisions, if the country considers adding the vaccine to its immunization program in the future.
Introduction

Influenza A and B viruses cause seasonal epidemics, with a global estimate of five to ten percent of adults and 20 to 30 percent of children acquiring influenza virus infection every year.¹ One epidemiological review of influenza in sub-Saharan Africa suggests that the disease accounts for about ten percent of all outpatient visits and six percent of hospital admissions for acute respiratory infections in children.² Disease burden likely is underestimated in the tropics and subtropics. Recognizing the significant morbidity influenza causes worldwide, the World Health Organization (WHO) considers influenza a public health problem with significant socioeconomic implications.³ WHO classifies pregnant women and children younger than six months of age as being at high risk of severe illness from influenza.⁴

While influenza vaccines are recommended for use during pregnancy, no influenza vaccines are licensed for use by children less than six months of age. As maternal antibodies can cross the placenta during pregnancy, immunization of pregnant women is thought to be the best option available to reduce influenza morbidity and mortality in both pregnant women and infants. The WHO recognized the important health impact that influenza vaccination during pregnancy could have in its 2012 influenza recommendations, which call for countries considering the initiation or expansion of their programs to give pregnant women “the highest priority for seasonal influenza vaccination.”³ Despite this recommendation and evidence that influenza vaccines are safe and effective in pregnant women, most low- and middle-income countries do not have maternal influenza immunization programs.

Gavi, the Vaccine Alliance, (Gavi) considered maternal immunization with seasonal influenza vaccine as part of its 2014–2020 Vaccine Investment Strategy review, but ultimately opted not to support the intervention, citing several additional data needs, including more information related to feasibility and demand at the country level. This included knowledge of and priority given to influenza among the population, attitudes toward maternal immunization, and potential health system and operational effects related to introducing the intervention. In late 2013, WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) also acknowledged the need for gathering additional evidence to both improve and to promote maternal immunization.⁵

WHO and PATH formed the Maternal Influenza Immunization Project in 2014, in an effort to establish favorable conditions for the adoption of maternal immunization in conjunction with antenatal care services in low-resource countries, by providing solutions to key barriers related to evidence, regulation, implementation and vaccine supply. As a component of this project, PATH conducted qualitative research to assess current country experiences with maternal immunization and to document lessons learned to share with countries considering the introduction or expansion of seasonal influenza immunization programs.

The project team was interested in evaluating maternal immunization in a country that had not yet introduced influenza vaccine as well as in one that had an existing program. Research countries were chosen based on the following additional criteria: (1) classification as a low or lower-middle income country (as defined by the World Bank), (2) representation of different WHO regions, (3) strength of the antenatal care (ANC) program (as indicated by percent coverage of ≥1 and ≥4 antenatal care visits per pregnancy), and (4) expressed country interest in the study.

The team selected Malawi and El Salvador as representative countries for the research. Malawi has not yet introduced the influenza vaccine for pregnant women, but has a strong maternal tetanus immunization program (as indicated by high reported coverage of ≥2 doses of tetanus toxoid vaccine in women of childbearing age). In
contrast, El Salvador has been offering maternal influenza immunization in the public health system for several years. This report describes the findings from Malawi; a companion report summarizes results from El Salvador.

The Malawi study was conducted in 2014 through 2015 in collaboration with the University of Malawi’s Centre for Social Research. The study sought to understand community attitudes and concerns regarding influenza and vaccination during pregnancy, to identify the potential operational and programmatic effects of adding the vaccine to the existing antenatal care platform, and to investigate the factors that may lead national policymakers to adopt the intervention. The study was intended to provide information useful to vaccine introduction decision-makers, rather than directly advocate for maternal influenza vaccine adoption in Malawi. Findings have been discussed with Malawi’s key maternal health and immunization stakeholders, policymakers, and partners, and will also be shared with global public health policy institutions and funders, such as the WHO, Gavi, and the Bill & Melinda Gates Foundation.

This report describes perspectives and viewpoints of a broad spectrum of key stakeholders in the maternal immunization arena in Malawi. It documents information and lessons learned around maternal immunization including the vaccine policy decision-making process, potential programmatic implications of vaccine delivery for pregnant women, and perceptions and concerns about influenza and influenza vaccine among community members and health workers. It was not intended as a program evaluation nor an operational assessment of Malawi’s maternal immunization program. The report groups the study findings into three areas critical to successful vaccine introduction into public health programs:

3. Political support and advocacy for introducing maternal influenza immunization.

The final section of the report discusses opportunities and challenges to maternal influenza vaccine introduction in Malawi and offers recommendations for activities that could further inform policy decisions, if the country considers adding this intervention to its immunization program in the future.
Study participants and findings

A total of 273 individuals from three districts representing the Northern, Central, and Southern regions of the country (Rumphi, Dowa, and Zomba, respectively, Figure 1) participated in focus group discussions, semi-structured interviews, clinic exit interviews, or key informant interviews. Respondents included pregnant women (both users and non-users of ANC and immunization services), family members of pregnant women (including husbands and female family decision-makers such as mothers or mothers-in-law), community leaders, health workers, regional public health program managers, and national-level program coordinators and policy makers.

Recent pregnancy-related statistics for Malawi are described in Table 1. Reported coverage of initiating antenatal care in the country is relatively high compared to other low- and lower-middle income countries; The United Nations Children’s Fund (UNICEF) reports that 96 percent of pregnant women attended at least one antenatal care (ANC) visit during pregnancy in 2013-2014. However, coverage drops to 45% for all four recommended visits. Reported coverage with two or more doses of tetanus toxoid among pregnant women was similarly low. In 2015, reported all-cause maternal mortality was 634 deaths per 100,000 live births and all-cause infant mortality was 43 deaths per 1,000 live births. Nearly 90% of births are reported to be attended by a skilled provider.

![Map of Malawi highlighting the three districts where research was conducted](image)
Table 1: Pregnancy-related statistics in Malawi

<table>
<thead>
<tr>
<th>ANC1</th>
<th>ANC4</th>
<th>TT2+</th>
<th>Maternal mortality ratio</th>
<th>Infant mortality ratio</th>
<th>% Births attended by a skilled birth attendant</th>
</tr>
</thead>
</table>

ANC1: The percentage of women aged 15 to 49 with a live birth in a given time period that received antenatal care provided by skilled health personnel (doctor, nurse or midwife) at least once during pregnancy.

ANC4: The percentage of women aged 15 to 49 with a live birth in a given time period that received antenatal care provided by skilled health personnel (doctor, nurse or midwife) four or more times during pregnancy.

TT2+: The proportion of pregnant women who have received their second or superior tetanus toxoid dose in a given year.

Maternal mortality ratio: Maternal deaths per 100,000 live births (maternal death defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.

Infant mortality ratio (World Bank) Deaths/1000 Live Births: infant deaths per 1,000 live births (infant defined as child <1 year of age).

% Births attended by a skilled birth attendant: the proportion of total live births that are attended by a skilled birth attendant trained in providing life-saving obstetric care.

Maternal immunization delivery strategy

Combining the ANC platform with immunization outreach to maximize coverage of maternal vaccines

In Malawi, ANC services are provided by public health facilities, the Christian Health Association of Malawi (CHAM, an association of health facilities and training colleges affiliated with the Christian church), private clinics, and through routine public health outreach into communities. In 2003, Malawi adopted the WHO’s recommended approach to ANC—known as Focused Antenatal Clinics (FANC)—which advocates for four ANC visits per pregnancy.11, 12 Our study findings indicate that in health facilities, nurses routinely provide ANC services which include health education, physical examinations, HIV and syphilis testing and counseling, urine testing, malaria treatment, the provision of iron tablets, and tetanus toxoid (TT) vaccination. The primary health care worker at the community level is the Health Surveillance Assistant (HSA), who serves as the link between a health facility and the community. HSAs conduct outreach in community gathering areas such as churches, schools, and market places, and provide routine immunizations to children and TT vaccine to women of childbearing age, including pregnant women.
Since maternal TT vaccine in Malawi is provided both through routine ANC in health facilities and through outreach based in the community, coverage is high. Similar to the 2014 coverage reported by WHO, Malawi’s National Statistical Office reported 90 percent of women of childbearing age with a live birth in the last two years reported receiving at least two doses of TT vaccine (TT2+) within the appropriate interval prior to their most recent birth. The success of this two-pronged approach to maternal immunization—integrating TT vaccination into routine ANC services at health facilities and making it available through outreach in the community—suggests that using both of these methods may be the most efficient and effective avenue for introducing additional vaccines targeting pregnant women, including influenza vaccine. However, while tetanus vaccination is an established practice, the addition of seasonal influenza vaccine poses unique challenges (see inset) that will need to be addressed to enable low- and middle-income countries, like Malawi, to successfully introduce the vaccine for pregnant women. These issues are explored throughout this report.

In terms of vaccine delivery, some health workers interviewed supported integrating maternal vaccines into existing ANC services rather than establishing separate immunization campaigns, citing that it could:

- Save time for both health workers and patients by negating the need for a separate visit for vaccination.
- Improve ANC coverage if the vaccine is seen as an incentive to receiving routine ANC.
- Minimize missed opportunities to receive a full set of health services.

For example, one HSA in Zomba Region suggested that integrating tetanus immunization with routine ANC services had increased vaccine coverage in her area:

“... we now have less work when it comes to tracking women who are supposed to receive TT vaccine. This is because if the woman is attending ANC services and is due to get a vaccine, they show up. Most women . . . come to the clinic because they are due to receive other ANC services ... our coverage of TT increased due to the integration with ANC.”

HSA, Zomba Region

However, other health workers voiced concerns about adding another vaccine to the list of services they currently provide at each visit, fearing the addition may:

- Increase their workload to an unmanageable level due to the additional community education and sensitization required.
- Cause a decline in HSA performance and negatively impact overall vaccination coverage (there were reports to this effect after a recent new vaccine introduction into pediatric schedules).
- Raise concerns about potential side effects of concomitant administration with TT vaccine (note: respondents were not provided details about the safety of influenza vaccines prior to interviews).
Perceived challenges reaching pregnant women

Health workers and Expanded Program on Immunization (EPI) managers interviewed in our study noted inherent difficulties in accurately estimating the target population and planning for the use of a vaccine solely targeting women who are pregnant during, or just prior to, the influenza season. Two primary reasons were provided:

- Since influenza virus circulation in Malawi is not routinely tracked outside of a few research sites, accurate projections of the influenza season are not available, which makes it difficult to plan for optimal vaccination timing.
- Some women do not realize they are pregnant and/or do not attend ANC services until late in their pregnancies, so may inadvertently miss opportunities to be timely vaccinated.

Health staff therefore posited that if immunization were restricted to specific times during pregnancy, such as the first or second trimester, many women could be missed. In addition, some managers were concerned that despite the high TT vaccination acceptance reported among women of childbearing age (discussed later in this report), a vaccine available only to pregnant women could raise misconceptions that it is intended as a means of birth control. Another concern cited was that other family members, particularly husbands, might also demand to be vaccinated, since they too are susceptible to influenza, as illustrated by the following quote from one health manager:

“The main challenge will be partners of pregnant women. Currently the government has put in place a policy on male involvement (in women’s health care during pregnancy). Therefore these partners may insist on being vaccinated … if they insist, that will be a challenge to us.”

Health manager, Rumphi Region

Perceived challenges with changing vaccine formulations annually

Study respondents noted that since a new influenza vaccine formulation would be required each year, properly destroying unused vaccine at the end of each influenza season would require extra attention and effort, including focused training of health workers. Currently, proper disposal of any unused or expired vaccines in Malawi requires national Pharmacy, Medicines, and Poisons Board (PMPB) certification. PMPB staff suggested that if influenza vaccine was introduced into the public health system, collection of expired and/or unused vaccines at the end of each influenza season may have to involve the vaccine suppliers, as the central level would likely not have the resources to monitor all immunization distribution and storage sites. Furthermore, accurate forecasting of the number of doses required was cited as crucial to minimize the amount of unused vaccine that would have to be destroyed at the end of each season, but perceived as very difficult to calculate. The additional need for educating health staff was highlighted by one health manager:

“The challenges will include sustainability and logistics for briefing health workers each time the vaccine is updated. This means that the government will need funding for training health workers.”

Health manager, Rumphi Region

Perceived challenges related to monitoring vaccine administration and tracking adverse events

Study findings indicate that outside of health facilities, vaccination coverage information for each pregnant woman in the community is recorded by HSAs in village health registers. However, during health facility visits, TT vaccine information is noted for each individual in a “health passport”, which women retain and are requested
to bring to each ANC visit. Health passports include information on general medical history, laboratory results, prescribed treatments, and information on family planning, ANC services, and past deliveries. There is currently no central record-keeping mechanism in Malawi health facilities that track an individual’s vaccination status. It is also noteworthy that data on adverse events following immunization are not currently recorded in Malawi for any vaccines, and some health workers and managers reported having never received a complaint for an adverse event from a vaccine recipient:

“We have never had an adverse event associated with TT and we do not have a system in place to record any adverse events. Women are advised that if they react to TT, they should inform the TT service providers at their local health facility.”

Health manager, Dowa Region

That said, Malawi does have a functional HIS that tracks population-level vaccination coverage data, including the percentage of pregnant women receiving two or more doses of TT. Managers were asked if they felt that the current HIS could be expanded to capture seasonal influenza immunization coverage as well as adverse event data following maternal vaccination. They responded positively and suggested the system could easily be adapted to include maternal vaccine coverage, however, timely submission of vaccine coverage data was identified as a problem in most areas. Health workers and managers cited concern about the time and effort that would be required to report on a new vaccine. In Dowa, staff specifically remarked that it would likely be necessary to hire extra data entry personnel to manage the increased workload associated with additional vaccine reporting.

Lessons learned from vaccine introduction in Malawi

Recent vaccine introductions in Malawi include pneumococcal conjugate vaccine in 2011, rotavirus vaccine in 2012, and human papillomavirus vaccine (HPV), through demonstration projects, in 2014. As a result of those experiences, health workers, EPI managers, and policy makers identified several factors that would be key to successfully introducing a new vaccine:

• Adequate funding must be available for the new vaccine program. In addition to support for vaccine supplies and delivery, sufficient funding must be specifically designated for training and social mobilization, as highlighted by one manager:

“[With the previous new vaccine introduction,] the government only provided funding for [training] five people per health facility. Rumphi District Health Office management had to source other funds for training the remaining staff members, and these funds have not been paid [reimbursed] up to now.”

Health manager, Rumphi Region

• Vaccine-specific training must be implemented at all levels of the health system before introduction begins. Respondents mentioned that health worker training should include information on the disease, the benefit of vaccination, the reasons for targeting certain populations, the mode of vaccine administration, the number of doses required, and possible side effects of the vaccine.

• The community must be sensitized to the importance of the vaccine, particularly seasonal influenza, since influenza itself is not easily distinguished from other diseases with similar symptoms. Respondents recommended proper social mobilization of community members as an effective way to increase vaccine acceptance, help dispel misconceptions, and reduce vaccine resistance based on misinformation. The value of advocacy and communication was highlighted by one health manager:
“The most important thing is to train all health workers on the new vaccine and community mobilization so that members of the community know about the new vaccine.”

Health manager, Rumphi Region

Preferences varied among district-level health managers on how new vaccines should be introduced. Some felt the new product should be introduced at the same time across the country to avoid perceptions of preferential treatment or discrimination (which were reported with past introduction efforts). Others, however, felt it would be more prudent to take a phased approach, introducing the vaccine in select areas first and then expanding countrywide over time to allow opportunity to identify any challenges and apply lessons learned from initial introduction sites.

Maternal immunization communication strategies and community mobilization

Seasonal influenza: overall knowledge, priority, and perceived vulnerable populations

Our study found high variability in general knowledge of influenza at the community level. There is no direct translation of the word “influenza” in either of the primary local languages used in the study areas (Chichewa and Chitumbuka). While community members were initially unable to specifically distinguish influenza from a common cold or tuberculosis, most respondents recognized the disease once interviewers described its signs and symptoms. Most reported they had experienced it themselves or seen it in their communities:

“With malaria you feel very cold and you can even put on two blankets. With flu you cough and sneeze and it takes a long time for it to go.”

Focus group discussion with male family members, Rumphi Region

As illustrated in the two quotes below, health workers had inconsistent knowledge of influenza and its severity, with community HSAs generally possessing less formal knowledge than facility-based health workers:

“Although I do not have much knowledge about influenza, I think it is dangerous because I relate it to bird flu.”

HSA, Zomba Region

“Because it is caused by viruses and not bacteria, it is difficult for a person to be treated.”

Health manager, Dowa Region

Some health workers interviewed had experience working during the 2009 A/H1N1 influenza pandemic, and they indicated that influenza was a serious disease, citing its difficulty to treat and likelihood to cause death. In general, health workers perceived pregnant women and children younger than five as the populations most vulnerable to influenza, mainly because “their immunity is low and they can easily suffer from any disease.”

Community members asked to identify the most important diseases affecting pregnant women and infants prioritized malaria for both groups. A serious complication of influenza—pneumonia—was the second priority identified for infants. Other top health priorities mentioned for both groups were cough, HIV, and high blood pressure for pregnant women, and cough and diarrhea for infants. “Flu” ranked fifth for both groups (along with pneumonia and diarrhea for pregnant women).
Seasonal influenza: knowledge regarding modes of transmission and treatment

The majority of community members understood that influenza is most commonly spread through the air, specifically through “exchange of breath, coughing, and sneezing.” Respondents reported transmission was due to “sharing cups for drinking water, handshakes, sharing bedding, and playing in dust.” Overcrowding was also implicated:

“If in a house there are a lot of people ... and if there is no proper ventilation ... influenza can spread.”
Focus group discussion with pregnant women, Dowa Region

Community members commented that influenza is difficult to prevent since it is airborne and a vaccine against it was not available in their communities. One suggestion for preventing the spread of influenza was to stay away from those with the disease:

“When you know that this village has influenza you just stop going there until it ends.”
Community leader, Rumphi Region

There were no reports of traditional stigma nor discrimination against people with influenza, however there was a belief expressed by some community members that pregnant women with influenza could commonly pass the virus to their unborn babies (as with HIV).

Several study respondents reported that treatment for influenza-like symptoms is sought from health facilities or HSAs in the community, suggesting that it is generally not sought from traditional healers. One community leader recommended seeking treatment for influenza only at a hospital:

“At the hospital they have equipment for scanning or they are able to diagnose disease, but at traditional healers you waste your time.”
Community leader, Rumphi Region

Sources of vaccine information and support for pregnant women

Most pregnant women identified HSAs as their primary resources for information on vaccines. HSAs conduct home visits during which they check the health passports of pregnant women and encourage those due for immunization to go to the health facility. Some health workers also conduct sensitization meetings in the communities about the importance of vaccination. Some first-time mothers also cited family members (for example, mothers or mothers-in-law) as sources of information for health care during their pregnancies.

Throughout all study areas, village chiefs were also cited as playing an important role in encouraging uptake of health services, including vaccination in pregnant women. In one study site in Dowa Region, female family members indicated that a letter from the chief was provided to pregnant women, which facilitated access to services at the local health facility. In addition to these positive incentives, local governments used negative reinforcements as well. In some areas, local bylaws require TT vaccination and ANC attendance (including the levy of a fine if a visit is missed or a baby is delivered at home instead of a health facility), as one HSA explained:

“... there is a rule, it is difficult for [pregnant women] to refuse [vaccination] because if they refuse, they will not be able to get ANC services. They will be sent back to get TT vaccine.”
HSA, Dowa Region
The majority of pregnant women and family members in the communities we surveyed reported that women do not need specific permission from their husbands or other family members to receive health services or vaccines when they are pregnant. They may, however, voluntarily inform them of their intentions before receiving services. As cited earlier, the government encourages male involvement in ANC, and in some areas women are preferentially treated at health facilities if accompanied by their partners (they move to the front of the queue of women waiting to be seen).

Acceptance of vaccination during pregnancy

Our study found high acceptance of vaccination during pregnancy by pregnant women, community members, and health workers in Malawi. During ANC exit interviews, 96 percent of pregnant women reported “no concern” with receiving a vaccine during pregnancy. Citing their experience and knowledge of tetanus and TT vaccine, pregnant women were aware that vaccines can protect both the newborn child and the mother from disease. Moreover, neither women, their social networks, nor health workers expressed concerns when asked about sensitivities around receiving two vaccines at the same time during pregnancy (for example, TT and influenza vaccines).

Pregnant women and community members identified several interventions that would encourage women to seek vaccination during pregnancy, including:

- Information regarding the purpose and benefits of the particular vaccine, and any consequences of not receiving it.
- Information on expected side effects of the vaccine.
- Encouragement from village chiefs, since they are seen as the primary authorities in their communities.

The importance of community education in vaccine acceptance was highlighted by both health workers and community members as illustrated by the following quotes:

“... in the early days of the introduction of the vaccine, we know people will have a lot to say ... and if they are not well informed ... they would probably express a lot of fear in case of any complications. As a result they would discourage their friends who have not yet received [the vaccine].”

HSA, Dowa Region

“In our village, the village headman should send messages on any new initiatives so that women can stop their primitive ways. On the other hand, the HSAs should help as they are the ones that meet the pregnant women.”

Focus group discussion with male family members, Rumphi Region

Barriers to receiving health services and vaccines during pregnancy

Pregnant women and community members cited the following challenges to accessing health care during pregnancy:

- Long distances to health facilities.
- Inconsistent or unreliable services and supplies (i.e., frequent health worker strikes or supply stock-outs).
- Unfriendly attitudes of health workers and/or perceived coercion to accept services.
• Fear of being tested for HIV (pregnant women and their partners are strongly encouraged to get tested for HIV when a woman begins ANC, and some respondents voiced feeling pressured to be tested against their will).
• Religious convictions that forbid formal health services (some religious groups do not allow the use of modern medicine, including vaccines).

The challenge of stock-outs and strikes was described by one pregnant women in Zomba Region:

“The first time I came [for ANC] ... I was told to come on Wednesday because all health personnel were on strike. When I came on Wednesday I found out that there was no vaccine. The second ANC visit, I came and they told me to wait. It was discovered that the vaccine was not there again, and they said they had no syringes. Up to now, I have been told to come and wait here at the hospital for delivery, but I have not been given the vaccine.”

Semi-structured interview with pregnant woman, Zomba Region

Another pregnant woman attributed her reluctance to receiving health care to the teachings of her church:

“[Members of the] Zionist [church] don’t take medication ... neither my 10 children nor I have received the [TT] vaccine.”

Non-user of immunization services, Dowa Region

In addition to more general difficulties with health care utilization, the following barriers to receiving vaccines during pregnancy were mentioned:

• Fear of pain associated with injections (some women reported that this prevented them from receiving TT vaccine).
• The need for multiple vaccine doses (i.e., the five-dose regimen of TT vaccine for women of childbearing age was felt to be excessive).
• Concern that an injectable contraceptive could be added to vaccine formulations or that vaccines may actually be a contraceptive (Depo Provera is the most common contraceptive used in Malawi and injections are similarly provided in the community through HSAs).

Political support and advocacy for introducing maternal influenza immunization

Developing vaccine policies in Malawi

Currently, Malawi’s only policy relevant to maternal vaccination supports TT vaccine administration in women of childbearing age (15-49 years).

At the time of data collection, Malawi did not have a National Immunization Technical Advisory Group (NITAG) to guide immunization policies. Specific Technical Working Groups (TWG) organized by the Ministry of Health (MOH) made decisions on new health interventions, including vaccines. TWGs are multi-disciplinary and multi-organizational, and include members from the MOH, multilateral organizations such as WHO and Unicef, nongovernmental organizations (NGOs) such as Jhpiego, the private sector, and other partners. At the time the
study was conducted, the two groups relevant to immunization policymaking for pregnant women included the EPI TWG and the Reproductive Health TWG.

While this study was being implemented, a new advisory committee on vaccines was formed to work with the TWGs on decisions relevant to new vaccine introduction and vaccine specific issues, culminating in the establishment of a formal NITAG in October 2015.

**How maternal influenza immunization fits with Malawi’s current health priorities**

Influenza vaccine is not currently part of Malawi’s Essential Health Package, interventions (including immunization, reproductive health, and nutrition) considered by the government to be of the highest priority. In 2009, however, with global outbreaks of the pandemic A/H1N1 virus, high-risk groups (including health workers and pregnant women) in some study areas were provided pandemic influenza vaccine through the public health system. A few study respondents reported that infants and young children also received pandemic influenza vaccine during this time.

**Information requested by policymakers to inform decision-making**

In order to consider introducing influenza vaccine, key national stakeholders reported needing:

- Information about the disease including accurate estimates of disease burden.
- Information about the vaccine including its presentation and packaging; data on vaccine effectiveness and safety; potential side effects and adverse events; cost and cost effectiveness; and infrastructure, storage, and transport requirements.
- Information related to operationalizing the new program including human resources required for implementation and identification of a sustainable funding mechanism for the vaccine and its operational costs.

Although respondents preferred data specific to Malawi to inform policy-making decisions, this was not seen as a requirement. Several respondents noted that policymakers in Malawi often use high quality data generated from countries with similar geographies and environmental and socioeconomic indicators to inform public health decision-making.

**Policymaker recommendations for promoting maternal vaccines**

Key stakeholders at the national level highlighted the following issues relevant to future efforts to introduce a new vaccine targeting pregnant women:

- Advocacy and communication are critical elements of vaccine introduction.
- Communication efforts should emphasize the benefits of influenza vaccination to both the pregnant woman and her infant, instead of prioritizing one over the other.
- Simple, direct communication messages are the most effective, such as, “If you are pregnant, come!” This facilitates simple, accurate translation into local languages.
- To increase coverage, the vaccine should be offered at any time during pregnancy, not only during a specific trimester, because many women are not aware of their conception date and some women attend only one ANC visit during their pregnancy.
Conclusions

Based on interviews with policy-makers, public health managers, health care workers, and community members, it is clear that additional information will be required if Malawi should choose, in the future, to create a foundation for successful immunization of all pregnant women against influenza. The data presented in this report highlight both opportunities and challenges to successfully introducing maternal influenza immunization.

Opportunities

There are a number of unique opportunities that support maternal influenza immunization adoption and acceptance in Malawi.

Supportive global policy: At the global level, WHO has a strong policy in favor of prioritizing pregnant women in influenza vaccination programs. As health policymakers in Malawi highly rely on WHO recommendations when making new vaccine introduction decisions, this support could be used to advocate for country introduction to this population.

Good service delivery options: At the country level, Malawi has successfully encouraged uptake of ANC services, including TT vaccination, not only by providing incentives to pregnant women who receive services in health facilities, but also by providing opportunities for women to receive vaccines in their own communities through outreach services offered by HSAs. The most effective approach to offer additional maternal vaccines may be through utilizing both of these avenues. That said, it will be important to adequately train health workers and appropriately plan and allocate funding so as not to overburden personnel and adversely affect the provision of existing health services.

Strong vaccine acceptance: Our study suggests that maternal influenza vaccine, even when provided in combination with existing vaccines (like TT), would be accepted by pregnant women and their social networks in Malawi. As with any new vaccine introduction, effective advocacy and communication will be required at all levels (pregnant women, family decision-makers, health personnel, and policy makers) to provide accurate information and avoid any misconceptions about the vaccine.

Health priority for community: Once its signs and symptoms were described, “flu” was among the top health priorities cited for both pregnant women and infants, and community members acknowledged that the disease is dangerous. Pneumonia, a serious complication of influenza, was also mentioned as a priority. Comprehensive awareness-raising campaigns before and during vaccine implementation could build on this understanding and increase demand for the vaccine.

Challenges

Malawi also faces a number of challenges to introducing maternal influenza immunization.

Lack of priority for country and for global financers. To date, neither country policy-makers in Malawi nor major global funders have prioritized influenza vaccine. Seasonal influenza vaccine is not part of the Essential Health Package in Malawi and the largest vaccine funder for low- and middle-income countries, Gavi, does not currently support this intervention. As such, influenza disease is not currently considered a health priority.
Uncertain disease burden. Current disease surveillance efforts in Malawi are limited, including for influenza, and country policymakers expressed a need to understand the extent to which influenza is a problem and whether introduction of the vaccine would be cost-effective. The target for maternal influenza vaccines are women who are pregnant during or just before influenza season, and ideally vaccination would be timed to precede the annual influenza season. Without additional individual-level monitoring and more extensive disease surveillance, it will be challenging to accurately estimate both the number of vaccine doses needed each year and the optimal timing of immunization efforts in different parts of the country.

Lack of monitoring systems. An effective monitoring and evaluation system for tracking individual vaccination coverage and adverse events following immunization does not currently exist in Malawi. It will be increasingly important to develop and support such systems as additional vaccines are considered for populations traditionally considered high-risk, such as pregnant women.

Inherent challenges with the vaccine. Since the predominant circulating influenza strains change each season, procurement and distribution of new vaccine formulations are required every year and their short expiration dates require that unused vaccine must be destroyed at the end of each season. These requirements will introduce financial, operational, and human resource challenges and the additional planning and logistics required for this could strain MOH systems.

Recommendations for future activities

The following activities would be of high value to further inform policy decisions and planning in regards to the introduction of maternal influenza immunization in Malawi:

- **Improving disease surveillance** to generate accurate country-specific disease burden estimates and information on disease epidemiology, predominant circulating strains, and seasonality.

- **Identifying the communication and advocacy strategies** that have been most effective in support of TT vaccination for women of childbearing age, and evaluate whether similar messages would be appropriate for the pregnant woman audience.

- **Conducting an evaluation of the cost-effectiveness** of maternal influenza immunization.

- **Conducting a detailed situational analysis** of how introduction of influenza vaccine may affect vaccine logistics (transport, storage and tracking) and operations, and identify the most likely mechanisms to mitigate any negative effects.

- **Planning for adequate financial and human resources** for advocacy, community mobilization, and health worker training. Advocacy and communication plans should use data from this study and from other new vaccine introductions to guide strategies and messaging, highlighting nuances specific to influenza such as the benefits conferred to both mother and infant, the safety of concomitant administration, and the need for annual vaccination. Engagement of family decision-makers and local leaders appears to be valuable to support ANC attendance and maternal immunization.
In addition to the information and insights described in this report, incorporating lessons learned from recent immunization programs would be valuable for informing decision-making around new vaccine introduction in Malawi and in guiding program design to achieve maximum coverage. Malawi has a strong record of reaching women with ANC services, including vaccination with TT, and with appropriate planning and preparation, this experience could contribute to future success in providing additional vaccines to pregnant women, such as influenza.
References


