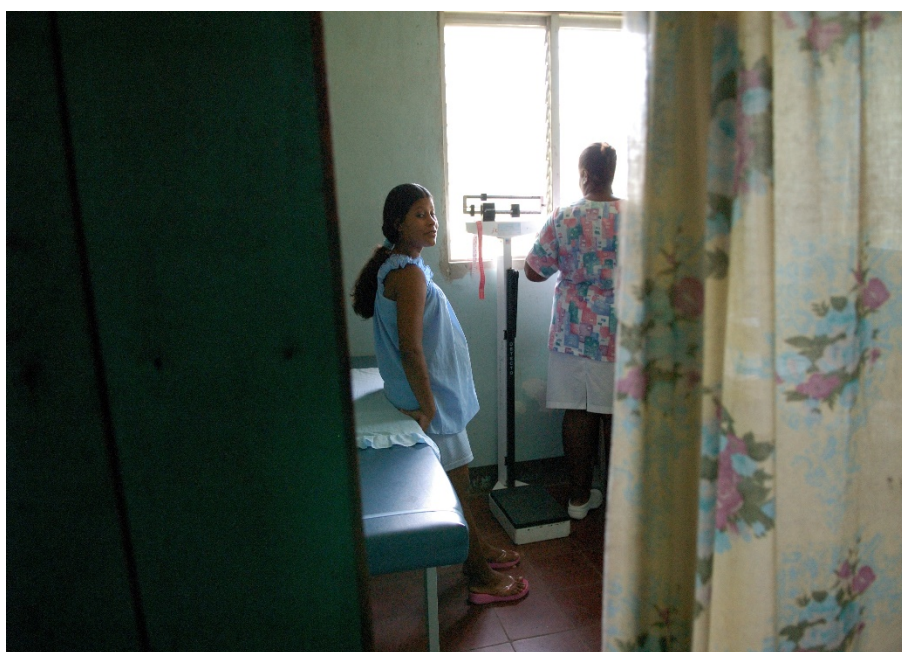


# Maternal influenza immunization

Lessons from vaccine introduction and use in El Salvador



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## Acronyms

AEFI	Adverse event following immunization
ANC	Antenatal care
CAPI	The Committee on Appropriate Immunization Practices ( <i>Comités Asesores de Prácticas de Inmunización</i> )
CDC	US Centers for Disease Control and Prevention
DIGESTYC	National Institute of Statistics and Censuses ( <i>Dirección General de Estadística y Censos</i> )
DVS	Directorate of Health Surveillance ( <i>Dirección de Vigilancia Sanitaria</i> )
ECOS	Specialized Family and Community Health Teams ( <i>Equipos Comunitarios de Salud</i> )
FGD	Focus group discussion
MINSAL	The Ministry of Health of El Salvador
NITAG	National Immunization Technical Advisory Group
PAHO	Pan American Health Organization
SAGE	WHO Strategic Advisory Group of Experts on Immunization
Td/Tdap	Tetanus-diphtheria/ tetanus-diphtheria-acellular pertussis
UNICEF	United Nations Children's Fund
VWA	Vaccination Week of the Americas
WHO	World Health Organization

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## 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.

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# Maternal influenza immunization: Lessons from vaccine introduction and use in El Salvador

## Executive summary

Influenza affects populations worldwide, particularly those in low-income countries. The World Health Organization (WHO) has determined that pregnant women and young infants are at increased risk for severe influenza illness compared to the general population, yet options for prevention and care are limited in resource-constrained settings. Maternal immunization with influenza vaccine is one effective intervention for protecting both mother and infant. It has been implemented in multiple high and middle-income countries, and those experiences can inform our understanding of the acceptability and feasibility of this strategy in other contexts. Inaugurating their maternal influenza immunization program in 2006, El Salvador joined several other Pan American Health Organization (PAHO) countries introducing this potentially important initiative into their public health system.

From 2015-2016, PATH, in partnership with local researchers, conducted a qualitative research study to gather the perspectives and viewpoints of a broad spectrum of key stakeholders in the maternal immunization arena in El Salvador. Researchers documented lessons learned around seasonal influenza immunization including the vaccine policy decision-making process, the operational implications of vaccine delivery for pregnant women, and perceptions and concerns about the disease and the vaccine among community members and health workers.

The study was conducted in all three regions of the country (*Centro, Occidente, and Oriente*) representing a range of diverse settings. Information was collected through focus group discussions, clinic exit interviews and semi-structured, key informant interviews. Three hundred and twenty-six individuals participated, including pregnant women, family decision-makers, community leaders, public health practitioners, private physicians, program managers, representatives from key international organizations, health communication professionals, and national policymakers.

Our study identified both successful strategies (including engaging policy makers, increasing vaccine access through the use of multiple delivery platforms, prioritizing community outreach and education, and taking advantage of regional expertise) and challenges (including annual vaccine forecasting, the potential for campaign logistics to overwhelm basic health service delivery, and difficulties accessing populations living in insecure areas) to influenza immunization in El Salvador.

This report organizes our study findings into three areas:

1. Decision-making for seasonal influenza immunization
2. Delivery of maternal influenza immunization
3. Community perceptions of maternal influenza immunization

The final section of the report offers recommendations by policymakers, public health partners, and the study team for countries considering the introduction of maternal influenza immunization.

## Introduction

Influenza A and B viruses are responsible for seasonal influenza epidemics that affect an estimated 5 to 10 percent of adults and 20 to 30 percent of children worldwide every year.<sup>1</sup> While influenza disease burden is well characterized in upper-income, temperate countries with years of comprehensive disease surveillance, much less is known about morbidity and mortality in lower-income countries.

WHO notes that pregnant women and children younger than six months of age are at increased risk of severe illness from influenza in both developed and developing countries.<sup>2</sup> While influenza vaccines are recommended for use during pregnancy, there are no vaccines available for use in children younger than six months.

Immunizing pregnant women, which passively immunizes her infant through the transfer of antibodies across the placenta, is thought by many to be the best option to reduce influenza morbidity and mortality in both of these populations. WHO recognized the important health impact of influenza vaccination during pregnancy in its 2012 recommendations, which encourage countries considering the initiation or expansion of their influenza programs to give pregnant women “the highest priority for seasonal influenza vaccination.”<sup>3</sup> Despite this recommendation, most low and lower-middle income countries do not currently provide influenza vaccine to pregnant women. Reasons for this may vary, but likely include lack of information on a number of key issues, including disease burden, cost-effectiveness, anticipated program impact, and the feasibility of delivery.

The Pan American Health Organization (PAHO) is the WHO Regional Office for the Americas, providing public health technical assistance to countries and territories of the region.<sup>4</sup> Many of the countries of PAHO are among the most progressive globally in incorporating influenza vaccine into their maternal health programs. As of 2014, 29 out of the 45 PAHO countries/territories with seasonal influenza immunization policies have included pregnant women in their target populations.<sup>5</sup> El Salvador introduced seasonal influenza vaccine in 2004 for some initial high-risk groups, and expanded these groups to include pregnant women in 2006. Although El Salvador is a middle-income country, as are most of the PAHO states, lessons learned regarding the challenges and dynamics of vaccine introduction could be informative for lower resource settings as well.

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

The project team conducted research in two countries. El Salvador was chosen to represent a country with an existing maternal influenza immunization program and Malawi was chosen to represent one that has not yet introduced the vaccine but has a strong maternal tetanus immunization program. Additional selection criteria for study countries included:

- Classification as a low or lower-middle income country (as defined by the World Bank)
- Representation of different WHO regions
- Strength of the antenatal care program (as indicated by percent coverage of  $\geq 1$  and  $\geq 4$  antenatal care visits per pregnancy)
- Expressed country interest in the study.

From 2015 to 2016, PATH and a team comprised of an independent medical consultant and researchers from the *Universidad Francisco Gavidia* in San Salvador generated the findings documented in this report. A companion report summarizes results from Malawi.

This report documents perspectives and viewpoints of a broad spectrum of key stakeholders in the maternal immunization arena in El Salvador. It documents lessons learned around seasonal influenza immunization including the vaccine policy decision-making process, the operational implications of vaccine delivery for pregnant women, and perceptions and concerns about the disease and the vaccine among community members and health workers. It was not intended as a program evaluation nor an operational assessment of the seasonal influenza immunization program. Study findings are organized into three areas:

1. Decision-making for seasonal influenza immunization
2. Delivery of maternal influenza immunization
3. Community perceptions of maternal influenza immunization

The final section of the report offers recommendations by policymakers, public health partners, and the study team for countries considering the introduction of maternal influenza immunization.

## Study participants and findings

The study involved 326 individuals from two departments in each of the country's three regions (*Centro* [Central], *Occidente* [West], and *Oriente* [East]) (see Figure 1), representing rural, semi-urban, and urban areas with varying degrees of access to health care. All sites were considered safe for study researchers and participants in terms of security from gang violence that currently affects many parts of El Salvador. Researchers organized focus group discussions (FGDs), clinic exit interviews, and key informant interviews with stakeholders across the health system, including pregnant women, male and female family decision-makers, community leaders, public health practitioners, private physicians, program managers, representatives from key international organizations, health communication professionals, and national policymakers.





**Figure 1.** Map of El Salvador highlighting the three regions and six departments where research was conducted

Recent pregnancy-related statistics for El Salvador are described in Table 1. Antenatal care coverage 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 and 90 percent completed all four recommended visits in 2014. Tetanus toxoid coverage among pregnant women was similarly high. In 2015, all-cause maternal mortality was 54 deaths per 100,000 live births and all-cause infant mortality was 14 deaths per 1,000 live births. Nearly all births are reported to be attended by a skilled provider.

**Table 1:** Pregnancy-related statistics in El Salvador

ANC1 <sup>a</sup>	ANC4 <sup>b</sup>	TT2+ <sup>c</sup>	Maternal mortality ratio <sup>d</sup> (deaths/100,000 live births)	Infant mortality ratio <sup>e</sup> (deaths/1000 live births)	% Births attended by a skilled birth attendant <sup>f</sup>
96% <sup>6</sup> (UNICEF, 2014)	90% <sup>6</sup> (UNICEF, 2014)	94% <sup>7</sup> (WHO, 2014)	54 <sup>8</sup> (WHO, 2015)	14 <sup>9</sup> (World Bank, 2015)	98% <sup>10</sup> (WHO, 2006-2014)

<sup>a</sup>**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.

<sup>b</sup>**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.

<sup>c</sup>**TT2+:** The proportion of pregnant women who have received their second or superior tetanus toxoid dose in a given year.

<sup>d</sup>**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).

<sup>e</sup>**Infant mortality** (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.

## Decision-making for seasonal influenza immunization

### Key partners involved in the seasonal influenza immunization decision-making process

Study interviews at the national level among health policymakers and representatives from key international organizations identified the following stakeholders as important in advancing the overall agenda for influenza disease and specifically vaccination in pregnant women:

- The Committee on Appropriate Immunization Practices (CAPI [*los Comites Asesores de Prácticas de Inmunización*]) (a National Immunization Technical Advisory Group [NITAG], the nongovernmental advisory body of experts that reviews technical information on vaccines and provides recommendations on their use)
- The Ministry of Health of El Salvador (MINSAL) Vaccine and Immunization Program (reviews technical data and recommendations from CAPI and partner organizations and officially requests the National Legislative Assembly to include the new vaccine to the national vaccination schedule)
- International organizations such as WHO/PAHO, US Centers for Disease Control and Prevention (CDC), the WHO Strategic Advisory Group of Experts on Immunization (SAGE), and UNICEF (provide global vaccine recommendations and technical advice)
- The National Legislative Assembly (approves immunization budgets)
- The National Health Commission (includes representatives of political parties who offer analysis and oversight on health-related legislation)
- National medical societies (train health practitioners and advocate for transparent, well-informed, and responsible decision-making regarding decisions affecting public health)

### What prompted El Salvador to introduce seasonal influenza vaccine?

According to national level stakeholders, seasonal influenza has long been considered an important contributor to morbidity in El Salvador. An extensive influenza epidemic in the Americas in 2003 compelled PAHO's Technical Advisory Group on Vaccine-preventable Diseases to recommend seasonal influenza vaccination of high risk groups, including "older adults, chronically ill individuals, immunodeficient populations, health professionals, pregnant women, and children aged 6-23 months" in 2004.<sup>11</sup> The same year, MINSAL initially introduced seasonal influenza vaccine for vulnerable adult populations, including older adults (>60 years) and health workers, but did not include pregnant women. In 2006, the policy on seasonal influenza immunization in El Salvador was expanded to include additional vulnerable groups, including children (6-23 months) and pregnant women.

Using seasonal influenza vaccine as an example, policymakers and public health partners were asked to identify the key considerations used in prioritizing the introduction of a new vaccine. The following information was identified as being critical (note that for seasonal influenza vaccine, country-specific data were not available for all areas and in those cases information from other countries in the region or globally were used):

- Vaccination recommendations by WHO/PAHO
- Vaccination recommendations by El Salvador CAPI
- Disease burden data
- Vaccine safety, effectiveness, and impact estimates
- Evidence of circulating virus strains and disease seasonality
- Economic burden of disease estimates, including direct and indirect costs (i.e., treatment costs, lost productivity, etc.)
- Overall program cost estimates, including cost-effectiveness of the vaccine
- Projected logistical and operational impacts of procuring a new vaccine formulation every season

International public health partners interviewed for this study, such as the CDC and PAHO, indicated that advocacy targeting political leaders including MINSAL, the legislature, and funding bodies was central to raising support for seasonal influenza immunization. Study participants underscored the importance of having the information presented in a format that was accessible to politicians—i.e., less technical than what is standard practice for a specialist audience—and presented in a way that could easily be conveyed to their constituents, as one partner describes below:

*“It depends on how [the new vaccine] is presented to national authorities and how [policymaking] will be achieved....Therefore, it must be justified very well and with the best possible evidence, and with the best translations into political language, because that is not the same as having technical evidence...one must know how to explain it.”*

*International partner, Central Region*

Advocacy also was important in promoting expansion of vaccination to pregnant women.

*“All the information that we could have had . . . could have been of the best quality, but if the political element hadn’t been addressed effectively, women would not have been vaccinated here.”*

*International partner, Central Region*

### **What data informed the choice between vaccine formulations?**

Situated north of the equator but below the Tropic of Cancer, El Salvador initially introduced the northern formulation of seasonal influenza vaccine. According to interviews, MINSAL’s decision to change vaccine products from the northern to the southern formulation was based on a review of surveillance data from a number of years indicating that the southern formulation of the vaccine, which is available around March or April, would be more appropriate based on the country’s summertime peaks in influenza virus transmission. This experience highlights the importance of sustaining disease and virus surveillance after vaccine introduction, as one international partner explained:

*“There was clear and strong evidence that the seasonality pattern of the disease in El Salvador is of the southern type. This helped authorities make the decision in 2011 to change the formulation of the vaccine and the time of vaccination... We mark it in our files as a ‘milestone’ of the conjunction of technical and political work to enact a change in health policy.”*

## Delivery of maternal influenza immunization

### **A comprehensive, multi-faceted delivery strategy**

Currently, the top priority target populations for seasonal influenza vaccine in El Salvador are pregnant women, children, and health workers; second priority populations include the elderly and those with chronic illnesses. The primary means of delivering the vaccine to target populations is through Vaccination Week of the Americas (VWA), an annual, large-scale, public health campaign organized by PAHO member states. VWA was first organized in 2003 in response to a large measles outbreak in Venezuela and Colombia.<sup>10</sup> The current emphasis of the campaign is the provision of seasonal influenza vaccine, but other routine vaccines and health services are also provided during VWA (such as tetanus-diphtheria [Td] or tetanus-diphtheria-acellular pertussis [Tdap] vaccines for pregnant women).

The campaign generally starts the last week of April, several weeks before influenza season begins in the region (in El Salvador, influenza season typically extends from May to June—the rainy season—and from October to December—winter). VWA is a highly organized and extensive endeavor in which large numbers of health workers and volunteers are mobilized. Detailed microplanning and mapping of all pregnant women is conducted at the community level in advance of the campaign to ensure all target individuals are identified and reached. The strategy used during VWA to achieve high coverage relies on making the vaccine easily accessible to the population. This is done by creating numerous temporary vaccination posts, located in high traffic areas such as shopping centers, parks, churches, schools, and bus stations, and extending the days and times that vaccination is available (vaccines are available every day of the week during the campaign and into the evening hours), as described by a member of MINSAL:

*Another strategy that has helped us a lot, and that has given us good results, is vaccinating in shopping centers, where you can get a lot of people, as well as in the churches . . . we can also seek out pregnant women at the main bus stops.*

*Member of MINSAL, Central Region*

Effective advocacy and communication around VWA is credited for the high vaccination coverage reported. MINSAL and partners create a festive atmosphere during VWA, recruiting high level politicians and public figures as spokespersons to promote vaccination and investing in high visibility communication and community mobilization to emphasize the benefit of influenza vaccination for target populations, including mothers and young children. VWA also presents an opportunity to provide education to the community about overall maternal and child health and related topics. Community members interviewed in our study indicated high awareness of the availability of influenza vaccine during VWA, including specific sites where vaccines are available.

After the completion of VWA activities (which, despite its name, often lasts a month or more), MINSAL provides seasonal influenza vaccine to pregnant women throughout the remainder of the influenza season and

until supplies are exhausted. Vaccination is offered through the ANC platform in health facilities and also in homes, delivered by community health workers, as described below:

*“...Even when we are [conducting the] campaign, [influenza vaccine] is administered [at the health facility]...if we have the stock, of course, it is offered to her. It is administered regardless of the gestational age. She is given counseling, we explain to the woman what it is, what benefits it will bring her, what reactions she might have and that if [she has any adverse reaction], she should seek help.”*

*Regional coordinator, Western Region*

Pregnant women receive influenza vaccine at home from either a community health promoter or a member of a health care team called Specialized Family and Community Health Teams (ECOS [*Equipos Comunitarios de Salud*]). Health promoters are community health care providers who offer basic health care at the household level within a geographically defined area, focusing mainly on families who are socially vulnerable, live far from a health facility, and/or are located in relatively isolated border areas. Health promoters typically live in communities with difficult access to a health facility and therefore are more commonly located in rural than urban areas. Each health promotor is linked to an ECOS team for obtaining supplies and reporting health data. Among other things, health promoters track vaccination status of individual women, provide all needed vaccines (influenza and Td/Tdap), and monitor the health of pregnant women in their areas.

*“... The pregnant woman is visited at home...we carry the three vaccines [Td, Tdap, influenza]. The strategy is to reach the home or the community in which she lives. What we also do in all of these visits, is that we verify whether the pregnant woman is getting checkups, and if she is not, we report this...It rarely happens that a pregnant woman who you haven’t known about arrives at the hospital.”*

*Health promoter, Eastern Region*

ECOS teams, consisting of a doctor, a nurse, and a health educator, are also familiar with the households in their area because they conduct national censuses. The teams act as a bridge between the community and the formal health sector.

*“(ECOS) has been an excellent strategy...what helps us is that they go to the homes, and they know the area really well because they carry out censuses...They know exactly how many people live in each house, if there are pregnant women, if they go to their check-ups, etcetera...They already know that – here, there is a pregnant woman, here we’re going to vaccinate, and by going to the house they take advantage also of being able to talk with the whole family so they know the importance of vaccinating against influenza.”*

*Member of MINSAL, Central Region*

Both health promoters and ECOS teams, in coordination with one another, ensure that pregnant women are enrolled in antenatal care and are vaccinated with all maternal vaccines, including seasonal influenza vaccine. This two-pronged approach, utilizing both health promoters and ECOS teams, is especially helpful in following up with pregnant women who have missed their antenatal checkup appointments for vaccinations, as described below:

*“...There are pregnant women who have begun antenatal checkups, but they are missing a vaccination. (In these cases) the community teams or the community facility teams are obliged to look for (identify) the pregnant woman at home and offer her the vaccine, and if possible vaccinate her at home (done by either the health promotor or the nurse), which isn’t the most recommended, but – yes – it’s acceptable.”*

*Regional coordinator, Central Region*

Interviews with private clinicians identified that although they are authorized to administer influenza vaccine to pregnant women who come to them for ANC, they typically do not include this service, mainly due to cost factors. MINSAL mandates that the vaccine is provided free of charge; in contrast, the operating model of private providers is to charge for the services they provide. Also, most private providers prefer to invest in equipment that can be profitable, such as a sonogram machine, rather than cold chain equipment and safe vaccine waste disposal systems. Finally, private providers also cited reservations about exposing themselves to the underlying risk of a client experiencing an adverse event following immunization (AEFI), which carries both administrative and possibly financial costs.

Providing multiple avenues to receive vaccines, including a national vaccination campaign, routine vaccine delivery linked to ANC services, and in-home vaccination for those not accessing organized services, contributes to El Salvador’s relatively high reported influenza vaccine coverage; nationally, 72 percent of pregnant women received influenza vaccine in 2015 (see Table 2). However, there is regional variation in vaccination coverage. There are a number of likely reasons for this, including socioeconomic factors, geographical differences, and disparities in access to health care services. Several stakeholders interviewed also noted concerns with the reliability of estimates of the size of the pregnant woman population (described below), which could affect coverage calculations and also contribute to regional differences.

**Table 2:** Seasonal influenza vaccine coverage in Salvadoran pregnant women by study department and nationally

	Department	Number of Pregnant women	Seasonal influenza vaccine coverage
Western Region	Ahuachapán	7,121	93%
	Santa Ana	8,846	84%
Central Region	La Libertad	9,536	75%
	San Salvador	17,912	67%
Eastern Region	San Miguel	6,128	61%
	La Unión	4,428	72%
<b>NATIONAL</b>		<b>86,898</b>	<b>72%</b>

Source: National System of Vaccine Records, Ministry of Health, El Salvador, 2015

### Challenges specific to maternal influenza immunization delivery

There were a number of unique challenges identified in delivering seasonal influenza vaccine to pregnant women in El Salvador. First, accurately estimating the number of vaccine doses needed for the target population of women who are pregnant during, or just prior to, influenza season is challenging. Official population estimates in El Salvador are generated by the National Institute of Statistics and Census (DIGESTYC [*Dirección General de Estadística y Censos*]), which publishes estimates of the number of pregnant women living in each municipality; the most recent census was conducted in 2007. Relying on data that is nearly a decade old, the DIGESTYC system estimates the number of pregnant women based on the number of live births, still births and miscarriages (which in themselves may be inaccurate and likely too low). Estimates are calculated regardless of timing in relation to influenza season. Inaccuracies may also occur because some births are not included, as they take place outside health facilities and are not registered. In some areas of El Salvador, accuracy is further undermined by the rise of violence instigated by two predominant gangs in the country (discussed further below), causing unpredictable and sudden migration in and out of some areas.

To enable more accurate procurement planning, some municipalities complement the census-derived figures with data collected by the ECOS teams. As mentioned in the previous section, the teams move from house to house to update family records, recording how many people live in each home, the number of pregnant women, and whether they attend prenatal visits, among other things. Ultimately, program managers review both sets of numbers to refine the quantity of vaccine they request from national and regional stores. A number of health workers and regional program managers interviewed suggested that they would prefer to rely primarily on the ECOS figures for planning purposes, since these numbers are believed to be more accurate, as suggested below:

*“We know that the population reported by ECOS is a real population, and we have been wanting to have this number be the official one that is taken into account . . .”*

*Senior health official, Western Region*

Another challenge is that during VWA the program relies on the infrastructure and logistics systems of the routine immunization program. With the large number of vaccines needed to be transported, stored and tracked in a relatively short period, the importance of accurate vaccine forecasting, well planned cold chain logistics, and adequate storage quickly become apparent at all levels of the health care system. Several program managers reported that at times, there is a lack of sufficient cold chain storage space at health facilities during VWA, when vaccine stocks quickly increase. Respondents indicated they mitigate the problem by arranging smaller, more frequent shipments from regional stores and by borrowing and lending vaccines among health facilities when necessary and possible. These approaches seem to work satisfactorily in terms of being able to keep enough of the vaccine on-hand for the primary target populations of pregnant women, children, and health workers. However, the inability to store more vaccine doses due to space limitations were reported to constrain the capacity of health staff vaccinating other target populations such as the elderly and individuals with chronic illnesses. Also noted, staffing levels are stretched during VWA, and this impacts the capacity of program managers and health care workers to quickly move stocks from one location to another in order to respond to immediate needs.

Since a new formulation of seasonal influenza vaccine is manufactured each year, any unused vaccine must be

destroyed at the end of each influenza season. Wastage of unused vaccine is prevented in El Salvador by providing the vaccine to second tier priority groups such as the elderly and those with chronic illnesses once the priority target groups of pregnant women, children and health workers have been vaccinated.

### **Monitoring seasonal influenza vaccine coverage and tracking adverse events**

El Salvador has a well-developed vaccine monitoring system that generates vaccination coverage data starting at the health facility. The Statistics Unit within the Directorate of Health Surveillance (*Dirección de Vigilancia Sanitaria*) has the mandate for registering all vaccination data into a unified, on-line system (*Sistema Único de Vacunación* [Single Vaccination System]). Using this information system, local level health facilities register the number of vaccine doses administered in their catchment area. In general, immunization nurses are responsible for documenting this information on a paper form, and the statistician at the health facility enters this data into the online system. Many, although not all, health facilities use this system to track vaccination coverage. In facilities without access to the computerized system, or in those that lack access to a reliable internet connection, the statisticians hand-carry a hard copy of the data to the regional center to ensure timely data entry. Program managers and technical staff at the regional and national levels access this computerized system to generate real-time reports on the number of vaccine doses that have been administered. The accuracy of the system is dependent on the accuracy and timeliness of data entry. While the system generates an estimate of overall coverage, it does not track the vaccination status of individual women, and it is therefore not possible to tell from the electronic registry whether a specific woman has received vaccine.

During registration at health facilities, pregnant women receive a prenatal health card (the *Historia Clínica Prenatal*) documenting the woman's reproductive health information as well as a card specific for tracking the vaccines she receives; vaccines given to women are also noted in hand written records kept at the health facility. The prenatal card has a designated space for noting receipt of influenza A/H1N1, but since the cards have yet to be updated, the same space is used to keep track of seasonal influenza vaccine. Nurses, who are responsible for managing the documentation process, described how vaccine receipt is documented at the facility level:

*“Before going in for the check-up, when the pregnant woman is getting checked in, the nurse checks to see if she already has the vaccination. If not, the nurse administers it to her, and documents this in her card, and in the [clinic] register.”*

*Nurse, Western Region*

During VWA, pregnant women are asked to present their vaccination card and their prenatal health card so the receipt of new vaccinations can be documented. The next time she goes to the clinic, her health facility records are updated with the new vaccine data. However, in the event that a pregnant woman is not carrying her prenatal card during VWA or loses her card, health facility staff indicated that they provide her with a new card which is updated during her next health facility visit, as one nurse relates:

Interviewer: *“What is the process if [women] happen to lose [their prenatal cards]?”*

Nurse: *“If they happen to lose it, another one is provided. If she comes to the appointment, there is all the information [about her immunizations in the health facility register], and we transcribe the same for the vaccine.”*



AEFI were reported to be routinely monitored, but surveillance is passive and based on voluntary and spontaneous reports of health workers.<sup>12</sup> Health workers indicated that mild adverse events are addressed at the local health facility level by health staff and severe events are evaluated by a regional multi-disciplinary team that collects and analyzes relevant information and reports to the national level. These cases are further analyzed individually at the national level by members of CAPI to determine whether there is a possible causal association between the vaccination and the adverse event, before making any report or recommendation to MINSAL.

Adverse events are tracked through a web-based information system that provides near-real-time information on adverse event trends. Respondents did not mention specifically reporting the findings of serious adverse events back to the local level, but explained that in such cases, MINSAL would provide any necessary information through public media channels.

### **Barriers to delivery of maternal immunization**

Crime and social violence committed by rival gangs have become dominant factors in El Salvador's social, economic, and security landscape over the last several years. Although our study was conducted in relatively safe areas of the country, community participants identified gang violence as an important barrier to pregnant women accessing health care. Violence affects health access in two ways. First, for some pregnant women who either live in or whose closest health facility is located in a gang-controlled area, the threat of violence is a strong disincentive to leaving home to attend health services. Some pregnant women may themselves be gang members and not able to travel to areas controlled by rival gangs, as described below:

*"...There are a lot of municipalities with crime problems. This makes access to some places difficult since there are opposite gang groups where the health facility is located, and it's necessary to ask for permission (to go to those areas)."*

*Regional coordinator, Central Region*

Second, gang-related insecurity can sometimes limit the ability of mobile health care teams to reach pregnant women in certain areas, which in turn impacts vaccination coverage.

*"The crime issue right now...there are some areas where the health staff can't go. I'm referring to the urban areas – and the maras [gangs] don't allow vaccination. They think that when we ask the National Civil Police for help, it's a crime, and we can't go in. They have already threatened our nurses..."*

*Regional coordinator, Eastern Region*

Several respondents also indicated that reaching pregnant women in areas affected by violence often requires extraordinary negotiations, as suggested below:

*"It is important to work with the National Civil Police...they often help us in areas that are high risk. As well, contact is made with community leaders to enter communities because of the issue of gangs. It's not a secret, sometimes you have to make alliances with [gangs] so [health workers] can enter*

*their communities. In the end, this gives [good] results because even they [gang members] ask to be vaccinated.”*

*Member of MINSAL, Central Region*

## Community perceptions of maternal influenza immunization

### **Seasonal influenza: knowledge, priority and perceived vulnerable populations**

Because the signs and symptoms of influenza are similar to those of a number of other respiratory pathogens, influenza is not differentiated and recognized in many areas of the world. However, pregnant women and community members interviewed in our study generally had a good understanding of influenza disease and accurately recognized influenza symptoms. Study participants cited coughing, sneezing, sharing cooking utensils, and a handshake or a kiss on the cheek as common transmission methods. A few respondents, however, also mistakenly implicated mosquitoes in influenza transmission. Pregnant women, children, and the elderly were identified by community members as being at highest risk of influenza-related complications.

When asked about the *most common* illnesses affecting them, pregnant women identified a wide variety of health issues, ranging from stomach ache and nausea, to preeclampsia, diabetes, dengue and Chikungunya. Among these, the three *most common* health concerns cited were headaches, colds and/or fevers, and urinary infections. Headaches, colds and/or fevers, and high blood pressure were perceived as the top three *most serious* health problems for pregnant women.

Symptoms related to influenza (e.g. fevers, pneumonia, respiratory problems, and colds) were cited as the most frequent and serious illnesses suffered by infants, and some community respondents recognized that an infection in a pregnant woman can have severe consequences for her fetus, although responses varied on what could actually happen. Possible consequences mentioned included the baby being born with influenza, respiratory problems, or immune system damage. Respondents also expressed concern about premature births and miscarriages.

*“[The pregnant woman] can be affected in the sense that if she is sick with influenza, she can have certain complications that can bring about an abortion, or the neonate might present with respiratory problems.”*

*Community leader, Western Region*

*“The baby can be born with the illness, because I’ve heard that this illness can cause the abortion [miscarriage] of a child.”*

*Male family member in FGD, Central Region*

That said, a number of stakeholders, including community leaders and family members, were not aware of the relationship between maternal influenza and the health of the fetus.

## Acceptance of vaccination during pregnancy

Recognizing that the views of trusted health advisors often affect vaccine acceptance, we asked pregnant women who they consult for advice about health care during pregnancy. Doctors, community health promoters, family members, and female friends were all mentioned, and health care workers in particular were reported to be highly trusted sources of health information.

According to national-level respondents, when the influenza vaccine was first introduced to pregnant women, MINSAL encountered resistance from a variety of stakeholders, including members of the medical community who were themselves hesitant to be vaccinated against seasonal influenza. A member of MINSAL explained that initial misunderstandings and lack of vaccine acceptance by health workers (even to be vaccinated themselves) and misinformation in the community directly affected acceptance of the vaccine among pregnant women, and unique advocacy efforts and government actions were required on a number of fronts to allay concerns.

*“The lack of [accurate] information [was originally] detrimental to us...After the influenza pandemic, [in 2009] [vaccine] coverage rates went down because of all the bad publicity [against the vaccine]. As well, people think that influenza is just a cold and they don’t see the complications that they can get. And, there have been a lot of complaints that influenza [vaccine] gives people colds. Even some doctors and medical personnel [discredited] the vaccine. All of this has affected us a lot—the rumors, everything people see on the internet, false things in the news...In the case of pregnant women... in the beginning it was a lack of information among gynecologists who didn’t know that we were administering the vaccine. Generally, we’re supporting more often the pediatricians in vaccination, family doctors, and of course nurses. But earlier, the gynecologists and internists didn’t really like the subject of immunization. We had to work a lot with them through the meetings we’ve had with CAPI [to educate them about the safety of the vaccine]...this has helped us a lot. Also, we had a letter distributed through the medical school and the health facilities...[indicating] that the gynecologist association supported the vaccine against influenza, and that the vaccine wasn’t harmful...this backing by a scientific association helped a lot.”*

*Member of MINSAL, Central Region*

National level respondents also noted that there was less resistance against the earlier introductions of maternal tetanus and diphtheria vaccines than for maternal influenza vaccine. This was attributed in part to the availability of quality scientific data from other countries on the benefits and safety of the vaccines and less misinformation in the media (particularly because their introduction preceded the age of social media), so both health workers and community members had confidence in the vaccine, as described below:

*"Although there may have been similar general questions of safety when tetanus [vaccine] was first introduced, there wasn’t the same level of “frightening media information” [as there was with maternal influenza vaccine]."*

*National policymaker, Central Region*

Both pregnant women and family members reported that they initially had a negative view of the vaccine due to perceptions that it could cause the recipient harm or exacerbate influenza symptoms. Similar to the comments of the national policymaker cited above, several community members reported that when influenza vaccine was first introduced to the public, some health personnel spread unfounded rumors about adverse events associated with

the vaccine, which affected their own acceptance of the vaccine. A number of stakeholders reported that acceptance of the vaccine at the community level has increased over time, and attributed this in large part to improving the knowledge and attitudes of health workers through targeted education and involving medical societies, as described above. In addition, the positive health benefits recognized over time with the implementation of maternal influenza vaccination further increased support for the vaccine from the health workers.

*“We, as a region have seen firsthand the great benefits [influenza vaccination] brings. There have been no maternal deaths due to influenza, due to pneumonia, or due to serious respiratory infections and I believe that this is very valuable....I wouldn’t hesitate [to recommend the influenza vaccine for pregnant women]....it is highly beneficial for her and for her newborn.”*

*Health manager, Western Region*

Because high levels of trust exist between the community and health workers, ensuring that health staff understand the safety and benefit of influenza vaccination, and that they are comfortable recommending it to their patients, were cited as being crucial to increasing coverage. According to health workers, it is now uncommon for pregnant women, their families, or community leaders to express concern about influenza vaccination. This progression of acceptance was echoed by policymakers and pregnant women themselves.

*“We have progressed a lot in that the population really knows...the advantages of the vaccine...I believe we’ve made progress since 2009.”*

*National policymaker, Central Region*

*“I accepted because they told me that it would prevent me from getting the illness and that it would also help the baby inside me. At first I didn’t want to but in the end I agreed to get it.”*

*Pregnant woman in FGD, Central Region*

### **Barriers to seeking health care**

Despite the high antenatal coverage reported in the country (refer to Table 1), barriers to receiving health services were cited by many pregnant women participating in FGDs across the three regions. While most women felt that their health care advisors—both formal and informal—were supportive of them attending health services and receiving vaccines, several indicated they had been counselled by a family member that ANC visits were a waste of time. In addition, community members noted that many women work outside the home and cited the unwillingness of their employers to allow them time off of work to attend prenatal visits.

*“When pregnant women are working, sometimes the bosses don’t want to give them leave to go to their check-ups. It may also be the case that when women work in domestic jobs, they don’t have a lot of leave...and the other problem is when the mothers don’t work, but are in charge of the home and have many children, and can’t leave the children with anyone else. So, this makes it difficult to get to the antenatal check-up.”*

Community leader, Western Region

Another challenge cited was the strong masculine pride, or *machismo*, that some study respondents reported in their husbands or partners, sometimes resulting in refusal to support vaccination and/or antenatal care in general. As one health manager explained:

*"Because of machismo there are still some cases where men don't allow [their wives] to go to their prenatal care appointments."*

Health manager, Western Region

Study participants working in health communication suggested that, at times, they needed to address sentiments of *machismo* in their health promotion messages.

*"...[S]ometimes the husband will not let [his wife] get the vaccine; that is machismo. In that case, if [the health team gives us] guidelines...we can create the right message [to encourage vaccination]."*

Health communication professional, Central Region

### **Crafting effective communication and advocacy strategies to promote immunization**

As mentioned earlier, advocacy and communication were important in achieving vaccine acceptance and increasing coverage of influenza vaccination. Since health workers are a principle, and trusted, source of information about vaccination (and other health issues), training and supporting health personnel to provide accurate answers to community questions about health care and vaccination has been an effective way to reach women with important information, as one regional coordinator explained:

*"A prenatal care visit does not only mean that the woman goes to see the doctor. Besides the doctor, there's also a nurse that provides...subsequent information to the women. This means that 100% of all pregnant women get counseling before leaving. The topics they provide depend on the gestational stage of the ladies. They get counseling regarding healthy life styles, violence, signs and symptoms of [pregnancy] dangers, proper nutrition, and the importance of vaccination and healthy habits."*

Regional coordinator, Central Region.

In addition to pregnant women receiving health information face-to-face, they also mentioned the internet, social media, and TV or radio as frequently used sources of information. MINSAL has used the rise in popularity and access to social media to support their education efforts by encouraging young volunteers to post accurate information and stories about the vaccine.

*"Because of the boom in social networks, we are sending messages in Facebook and Twitter. The videos that we use for the waiting rooms, called ISTV, are uploaded to YouTube. We send little messages...at least daily. But if it is a campaign where we need more weight, a promotional video is made for TV...Since there are people that don't have access to the internet, we need to use traditional media, such as radio and TV, so that they get the message too."*

Health communication professional, Central Region

## Conclusions

Study interviews and focus group discussions with policymakers, regional health managers, health practitioners, and community members suggest that maternal influenza immunization is well accepted in El Salvador, particularly among pregnant women. There are a number of lessons from El Salvador including the process of vaccine decision-making, successfully integrating the vaccine into existing health programs, and promoting influenza immunization that may be helpful to other countries considering seasonal influenza vaccine for pregnant women.

### Successful strategies employed by El Salvador

**Engaging policy makers:** While a large influenza outbreak in the region of the Americas in 2003 was the sentinel event that raised the importance of seasonal influenza in the region, timely introduction of the vaccine in El Salvador was the result of strong political will by engaged policy makers. Advocacy played a central role in raising support for the program.

**Use of campaigns to achieve high seasonal vaccination coverage:** VWA is a successful strategy to vaccinate a large number of people in a relatively short period. It works especially well for diseases with a distinct seasonal pattern. Providing Td/Tdap to pregnant women during VWA increases coverage of those vaccines as well.

**Multiple venues increase access:** Providing influenza vaccine through a variety of avenues including wide-scale vaccination campaigns, through ANC services at health facilities, and directly at home increases the opportunity for women to receive the vaccine. These alternatives are particularly important for those with limited access to traditional facility-based services due to work place restrictions or community safety concerns.

**Effective community outreach:** The El Salvadorian health promoters and ECOS teams know their communities, so they can follow up to be sure women are vaccinated and pregnancies are going well.

**Investments in provider and community education increase acceptance:** Influenza vaccine acceptance has increased over time through educating health workers, who are trusted advisors of pregnant women, and through strong communication messages using channels that are already accessed by many pregnant women (including social media).

**Taking advantage of regional expertise:** For countries in the Americas, the strong regional WHO office (PAHO) provides guidance, technical assistance, and recommendations, and organizes member states around common public health goals, like influenza prevention. PAHO also helps countries pay for vaccine through combined bulk purchasing.

## Challenges for the program

**Vaccine forecasting and management:** As a primary means for estimating population numbers, census figures are often outdated and potentially unreliable, leading to difficulties in accurately determining the number of vaccine doses needed for specific target populations; accurately estimating the number of pregnant women was highlighted as particularly challenging. In addition, since influenza vaccine formulations change every year, any unused vaccines must be destroyed before the new season begins. This requires additional management, monitoring and financial resources.

**Logistics during campaigns:** While successful, VWA requires tremendous effort and coordination to assure optimal use of health personnel and logistical and cold chain resources. The provision of other important health services may be negatively affected due to the preoccupation of health workers focusing on campaign activities or overburdening existing health infrastructure.

**Service delivery:** Gang violence is a serious problem in El Salvador impacting vaccine service delivery to pregnant women. MINSAL and health workers have looked for ways to work with the community to gain trust and sometimes negotiate agreements with gangs to access vulnerable populations to increase access to health services in general and immunization in particular.

## Recommendations for other countries

MINSAL members and national policymakers were asked what advice they would give to colleagues thinking about designing a maternal immunization program. Their comments, along with recommendations from the research team, follow:

- **Generate or gather comprehensive, accurate data** in advance of planning, including an epidemiological profile of the disease. This information will need to be "translated" and packaged in different ways for different audiences.
- **Convene a well-respected technical advisory committee** to answer questions about the vaccine and provide recommendations to policymakers.
- **Develop a long term vision and plan for sustainability.** Respondents noted that a budget is not only about money, but is also about time and human resources. Moreover, the budget must consider not only the vaccine itself, but also the costs of storage and transport, syringes, waste management, reporting, training, community education and mobilization, and vaccination monitoring.

*"...[for planning it is crucial to] determine how much budget is required...Make a projection for at least five years...I think that is extremely important to succeed. We must have a long-term vision...[taking into account] financial resources, human resources, and technological resources.*

*National policymaker, Central Region*

- **Create a strong vaccination monitoring system** for tracking coverage and adverse events and establish



a robust system for responding to AEFIs.

- **Ensure that staff at all levels are trained** to provide accurate communication about the disease and the vaccine. Communication and advocacy efforts should not be limited to doctors and nurses alone; staff such as community health promoters and clinic-based health educators may have even more opportunities to interact with families. Creating spaces where women can discuss their doubts and where misinformation can be corrected is critical to interrupting the flow of inaccurate and negative information, particularly in this age of social media where misinformation can easily reach many people quickly. Program managers must recognize that addressing misinformation about the vaccine will be an ongoing process and will require planning for the long term.

New vaccine introduction is complicated and countries must take many factors into consideration when deciding to add a new vaccine to their public health system. El Salvador's success in introducing the seasonal influenza vaccine, and maintaining impressive levels of coverage, can provide useful guidance, and may suggest potential solutions to challenges faced in other countries.

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