



## Pregnant women's attitudes toward influenza vaccination while breastfeeding

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### ABSTRACT

**Objective.** The goal of this study was to assess the concerns pregnant women have about influenza vaccination while breastfeeding and to determine if having these concerns represents a barrier to vaccination uptake.

**Methods.** The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) conducted a prospective cohort study in the US and Canada of influenza vaccine safety among pregnant women, oversampling vaccinated women. Data for the present paper are from an additional cross-sectional telephone survey completed during the 2010–2011 and 2012–2013 influenza seasons.

**Results.** We surveyed 431 pregnant women about their attitudes regarding influenza vaccination while breastfeeding. Almost half of the participants identified one or two concerns and 4% reported three or more concerns. About one quarter reported that they would be unlikely to have an influenza vaccination while breastfeeding. In the multivariate model, those reporting 1–2 concerns (OR = 0.16, 95% CI 0.09–0.28) and those reported 3 or more concerns (OR = 0.07, 95% CI 0.02–0.22) had lower odds of being likely to vaccinate.

**Conclusions.** Pregnant women and postpartum women who are breastfeeding could benefit from receiving information and recommendations specific to vaccination from their healthcare providers, with a focus on discussing known risks and benefits to the baby's health.

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### Introduction

Breastfeeding women represent a high priority group for seasonal influenza vaccination (CDC, 2010). Infants cannot get the vaccination, but are especially vulnerable during their first six months and have significantly higher rates of influenza-related hospitalization than older children (Izurieta et al., 2000; Rasmussen et al., 2012; Yen et al., 2012). Physical changes that occur during pregnancy put postpartum women at high risk for severe illness and complications (Louie et al., 2011; Rasmussen et al., 2012). While influenza vaccination is a priority during pregnancy, (Callaghan et al., 2010; CDC, 2010; Creanga et al., 2010) not all pregnant women get vaccinated, which may put them and their infants at higher postpartum risk (Maertens et al., 2014). Pregnant women are more likely to have an influenza vaccination when they feel more susceptible to influenza, perceive greater vaccine effectiveness, are recommended to do so by a healthcare provider, anticipate greater regret for not being vaccinated, and express fewer concerns about potential adverse side effects to themselves and their baby (CDC, 2011; Fisher et al., 2011; Fridman et al., 2011; Goldfarb et al., 2011; Gorman et al., 2012; Henninger et al., 2013; Yudin et al., 2009).

Factors influencing decisions about vaccination while breastfeeding are not known.

Breast milk offers a protective effect to infants, including for infant mortality, gastrointestinal tract infection and respiratory tract infection, and is recommended for at least the first six months of life (Eidelman et al., 2012). For women who receive an influenza vaccination during pregnancy, there is some evidence of a protective effect from the transfer of maternal antibodies either through the placenta or the breast milk (Schlaudecker et al., 2013; Zaman et al., 2008). However, the potential impact of breastfeeding mother's influenza vaccination on her child's health, including risks and benefits, has not been determined. While the CDC states that influenza vaccination (live or attenuated) is not contraindicated during breastfeeding (CDC, 2010), mothers have little on which to base their decisions. Potential benefits are suggested by research involving women who receive an influenza vaccination during pregnancy, but breastfeeding mothers may remain concerned about the safety due to the lack of evidence and potential adverse infant outcomes associated with some live attenuated vaccines given to breastfeeding mothers (Alain et al., 2012; Lynch et al., 2012).

Public health efforts promoting influenza vaccination among pregnant women have resulted in greater uptake (CDC, 2011; Ding et al., 2014). However, such efforts have not extended to postpartum, breastfeeding mothers. It is unclear how many breastfeeding mothers decline vaccination or for what reasons. The goal of this study was to

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assess pregnant women's concerns about influenza vaccination while breastfeeding and to determine if having these concerns represent a barrier to vaccination.

## Methods

### Vaccines and Medications in Pregnancy Surveillance System (VAMPSS)

The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) influenza vaccine and medications study was initiated in 2009 to monitor and evaluate fetal and maternal risks of H1N1 vaccine, seasonal influenza vaccine, and antiviral medications (Chambers et al., 2013; Schatz et al., 2011). There are two parallel arms of VAMPSS, one a prospective cohort study and the other a retrospective case-control study.

### Design of the cohort arm of VAMPSS

Participants in the prospective cohort arm of the VAMPSS study are currently pregnant women who are self-referred, referred by their physicians, or referred by a network of 13 Teratogen Information Service call centers, located in academic centers and health departments that respond to calls from across the U.S. and Canada. These centers provide free, evidence-based counseling and referral to about 70,000–100,000 callers each year about exposures during pregnancy and potential risks for adverse birth outcomes. The cohort study planned to recruit a sample of 1100 women, over-representing vaccinated women with approximately similar numbers vaccinated in each trimester. In the overall sample, 82% were vaccinated during any trimester of pregnancy. The remainder who were unvaccinated in any trimester of pregnancy served as a comparison group. The study was designed to test specific hypotheses related to adverse pregnancy outcomes in vaccinated compared to unvaccinated pregnancies including risk of major birth defects, preterm delivery, small for gestational age infants and post-natal growth deficiency in the first year of life.

### Additional survey

Participants in the VAMPSS prospective cohort study were invited to take an additional cross-sectional 15-minute telephone survey on their beliefs about seasonal influenza vaccination during pregnancy and breastfeeding. Not all cohort study participants were asked to complete the additional survey due to telephone interviewer schedules and time limitations for the participants. Surveys were conducted during two influenza seasons (2010–11, 2012–13). Of 869 potentially eligible women enrolled in the cohort study during the survey time frames, 444 women (51%) completed the additional survey. The University of California, San Diego Institutional Review Board approved the study.

### Measurement

Likelihood of influenza vaccination while breastfeeding was assessed using the following question: "Please imagine that you have not had a seasonal flu shot, have given birth, and are now breastfeeding or pumping breast milk for your baby. How likely would you be to have a flu shot?" Those who responded "very likely" or "somewhat likely" were defined as "likely" to have an influenza vaccination while breastfeeding. Those who responded "very unlikely" or "somewhat unlikely" were defined as "unlikely" to do so. Participants were then asked the open-ended question, "What are your concerns about having a flu shot while breastfeeding or feeding your baby breast milk?" Participants either reported having "no concerns" or reported having concerns of one or more type. We developed an initial list of categories describing potential concerns based on a review of the literature and expanded it based on responses. The final list included 10 categories of concern. We then summed the number of concerns, creating three groups:

"None", "1–2", and "3 or more". Demographics, reproductive history, and risk behavior during pregnancy were obtained during VAMPSS intake interviews.

### Analysis

In bivariate analyses, categorized continuous variables and compared demographics, risk behaviors, reproductive history, influenza vaccination, and number of concerns reported by likelihood of vaccination while breastfeeding, using chi-square tests and Fisher's exact test where appropriate. We developed a logistic regression model with likelihood of vaccination as the outcome variable. We used forward selection stepwise logistic regression, retaining only those variables with  $p < 0.05$ . Prior year vaccination status, an indicator of annual vaccination behavior, was considered for inclusion in the model. Finally, using chi-square or Fisher's exact test, we compared the proportion in each likelihood group (i.e., those not likely and those likely to have an influenza vaccination while breastfeeding) who identified each area of concern. We analyzed data in SAS Version 9.4 (SAS Institute, Inc., Cary, North Carolina) using two-tailed tests (critical alpha < 0.05).

## Results

### Participant characteristics

This study includes 431 pregnant women (average 25 week gestation) who provided information about likelihood of influenza vaccination while breastfeeding. Most participants were white (non-Hispanic) (80%), of high socioeconomic status (81%), nulliparous

**Table 1**

Respondent characteristics as correlates of likelihood of vaccination while breastfeeding (N = 431).

	Not likely (n = 112) n (%)	Likely (n = 319) n (%)	p <sup>a</sup>
<b>Demographics</b>			
Age at EDD			0.073
Younger than 30 years	41 (36.6)	88 (27.6)	
30 years or older	71 (63.4)	231 (72.4)	
Socio-economic status <sup>b</sup>			0.002
Low	11 (9.9)	22 (7.0)	
Medium	21 (18.9)	25 (7.9)	
High	79 (71.2)	269 (85.1)	
Race/ethnicity			0.47
White (non-Hispanic)	85 (75.9)	258 (80.9)	
Black	7 (6.3)	9 (2.8)	
Hispanic/Latina	14 (12.5)	35 (11.0)	
Asian/Pac Islander	4 (3.6)	13 (4.1)	
Other/Unknown	2 (1.8)	4 (1.3)	
EGA at time of survey			0.41
Fewer than 25 weeks'	55 (49.1)	171 (53.6)	
25 weeks' or greater	57 (50.9)	148 (72.2)	
<b>Risk behaviors during current pregnancy</b>			
Any smoking	5 (4.5)	13 (4.1)	0.79
Any alcohol use	53 (47.3)	141 (44.2)	0.57
<b>Reproductive history</b>			
Primigravida	45 (40.2)	140 (43.9)	0.50
Nulliparous	67 (59.8)	183 (57.4)	0.65
Previous miscarriage	27 (24.1)	75 (23.5)	0.90
<b>Influenza vaccination history</b>			
Received influenza vaccine current season	57 (50.9)	286 (89.7)	<0.001
Received influenza vaccine prior season	33 (29.5)	205 (64.3)	<0.001

Note. EDD = estimated date of delivery. SD = standard deviation. EGA = estimated gestational age. Participants from the United States and Canada interviewed during the 2010–11 and 2012–13 influenza seasons.

<sup>a</sup> Chi-square or Fisher's exact test.

<sup>b</sup> Socioeconomic status calculated using the Hollingshead four factor index (Hollingshead, 1975) (N = 427).

**Table 2**  
Logistic regression model of variables related to likelihood of influenza vaccination while breastfeeding (N = 427).

Variable	Adjusted OR (95% CI)
SES <sup>a</sup>	
High	Ref.
Medium	0.46 (0.22–0.95)
Low	0.75 (0.31–1.82)
Number of concerns reported	
None (ref)	Ref.
1–2	0.16 (0.09–0.28)
3 or more	0.07 (0.02–0.22)
Prior year influenza vaccination	3.38 (2.01–5.69)

Note: Model adjusted for all variables shown in the table. Participants from the United States and Canada interviewed during the 2010–11 and 2012–13 influenza seasons.

<sup>a</sup> Socioeconomic status calculated using the Hollingshead four factor index (Hollingshead, 1975).

(60%), and had received an influenza vaccination for the current (80%) and prior (55%) influenza seasons (Table 1). Compared to other participants in the VAMPSS cohort study, those who completed the additional survey were more likely to be white (non-Hispanic), nulliparous, and to report having a high socioeconomic status (all with  $p < 0.05$ ). There were no differences across other demographic, risk behavior, or reproductive history characteristics presented in Table 1. Differences in factors assessed only at the time of the additional survey, including influenza vaccination status, prior year vaccination, and gestational age at the time of the survey, cannot be determined.

#### Likelihood of influenza vaccination while breastfeeding

When asked to imagine that they were now breastfeeding, 112 (26%) reported that they would be unlikely and 319 (74%) reported that they would be likely to be vaccinated. Those who were likely to be vaccinated had higher socioeconomic status ( $p < 0.01$ ), and more likely to have received an influenza vaccine in both the current and prior seasons ( $p < 0.001$ ) (Table 1).

In the logistic regression model, those who had an influenza vaccination in the prior flu season (OR = 3.38, 95% CI 2.01–5.69) had greater odds of being likely to vaccinate. Those reporting medium, as compared to high socioeconomic status (OR = 0.46, 95% CI 0.22–0.95) had lower odds of vaccination, as did those reporting one to two concerns (OR = 0.16, 95% CI 0.09–0.28) and those reporting three or more concerns (OR = 0.07, 95% CI 0.02–0.22) (Table 2).

#### Concerns about vaccination while breastfeeding

About half of participants (n = 218, 51%) reported having no concerns, 196 (45%) reported one or two concerns, and 16 (4%) reported

having three or more concerns about influenza vaccination while breastfeeding. The most common concerns reported were: vaccine safety and unknown risks of vaccination while breastfeeding (15%), potential harm to baby's physical health, such as fever or illness (14%), and worry about potential harm to the baby because of the vaccine passing through breast milk (12%). The proportion who identified each concern was significantly different across the likelihood groups, with the exception of those identifying concerns about developmental problems, information needs about safety, and potential harm from the vaccine passing through breast milk, where differences between groups were not significant (Table 3).

#### Discussion

Even in this high uptake study cohort, where 80% had received an influenza vaccination during pregnancy, half of women expressed at least one concern about influenza vaccination while breastfeeding. These concerns represent barriers to vaccination, as those with a greater number of concerns reported that they would be less likely to be vaccinated while breastfeeding. Our findings indicate that pregnant women, particularly those who do not regularly receive influenza vaccinations and those with lower socioeconomic status, need more information about safety and recommendations regarding vaccination while breastfeeding.

Healthcare providers play an important role in educating and reminding pregnant women about influenza vaccination recommendations and safety (Ahluwalia et al., 2010; Ding et al., 2014; Goldfarb et al., 2011; Gorman et al., 2012; Lynch et al., 2012). In this study, women expressed the greatest number of concerns about unknown safety and potential risks to the baby's health. Prenatal and postpartum visits are ideal times for providers to address these concerns. However, given the current limitations in evidence on benefits and risks, breastfeeding mothers may remain concerned about safety and could be less likely to have a vaccination. While influenza vaccination during breastfeeding is recommended, further research on child health outcomes may provide greater reassurance for those who remain concerned. The larger cohort study from which the present study sample was drawn provides new evidence regarding the safety of vaccination during pregnancy (Chambers et al., 2013; Schatz et al., 2011). The study design would allow for data to be collected on the safety of vaccination for infants of mothers who have an influenza vaccination while breastfeeding.

This study is the first to specifically evaluate pregnant women's anticipated concerns about having an influenza vaccination while breastfeeding, and how these concerns relate to their intentions regarding vaccination during that time. However, it does have several limitations. First, this cross-sectional survey is not sufficient to assess whether intentions lead to future behavior, as it does not include a follow-up assessment of vaccination behavior while breastfeeding. This preliminary work needs to be confirmed with evaluation of the

**Table 3**  
Concerns identified by those not likely and likely to have an influenza vaccination (N = 428).

Type of concern reported	n (%)	Not likely (n = 112)	Likely (n = 316)	p <sup>a</sup>
No concerns	224 (50.7)	20 (17.9)	196 (62.0)	<0.001
Safety of the vaccine or unknown risks	66 (15.4)	35 (31.3)	31 (9.8)	<0.001
Mercury (or thimerosal) or other ingredients in the vaccine	28 (6.5)	14 (12.5)	14 (4.4)	0.003
Might harm my baby's physical health (including fever, illness, flu symptoms)	60 (14.0)	25 (22.3)	35 (11.1)	0.003
Might cause developmental problems in my baby (including learning disabilities, autism, ADD, delays)	25 (5.8)	8 (7.1)	17 (5.4)	0.49
Might harm my health	13 (3.0)	11 (9.8)	2 (0.6)	<0.001
In general, I am opposed to vaccination	13 (3.0)	10 (8.9)	3 (0.9)	<0.001
I need more information about safety and recommendations (N = 427)	32 (7.5)	10 (9.0)	22 (7.0)	0.48
Worried about vaccine passing through breast milk and potential harm	50 (11.7)	18 (16.1)	32 (10.1)	0.092
Not necessary or beneficial	9 (2.1)	7 (6.3)	2 (0.6)	0.002
Other concerns	11 (2.6)	9 (8.0)	2 (0.6)	<0.001

Note: Includes participants reporting on both variables. Participants from the United States and Canada interviewed during the 2010–11 and 2012–13 influenza seasons.

<sup>a</sup> Chi-square or Fisher's exact test.

influenza vaccination concerns and vaccination uptake rates among currently breastfeeding women. Study participants represent a convenience sample drawn from a larger study of influenza vaccination during pregnancy, so participants are not representative of the general population of pregnant women and we cannot determine if this sample is representative of the VAMPSS cohort across all characteristics. Because not all potential participants were asked to complete a survey, we are also unable to determine if participant characteristics were related to study participation. Because a higher proportion of participants (80%) than in the United States (52%) had an influenza vaccination during pregnancy (Ding et al., 2014), this study may underrepresent the concerns and potential impact on vaccination uptake. Finally, we did not ask about the intensity of each concern, so a numerical count may not represent the magnitude of concern equally across participants.

## Conclusion

The results of this study indicate a need to provide additional information about the recommendations for influenza vaccination while breastfeeding, with a focus on the safety and risks for the baby. Additional research is needed to clearly identify both the benefits and risks of influenza vaccination choices for breastfeeding women and their babies so that women can make informed decisions. Prenatal and postpartum visits provide ideal education opportunities. This is particularly critical during influenza season and for mothers with infants who are too young to have an influenza vaccination, and could have significant public health benefits.

## Conflict of interest statement

The authors declare that there are no conflicts of interests.

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