

Randomized Quality Improvement Trial of Opting-In Versus Opting-Out to Increase Influenza Vaccination Rates during Pregnancy

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Abstract

Introduction Despite strong recommendations, only 40.6% of pregnant women attending two prenatal clinics were vaccinated against influenza during the 2009 pandemic. We tested whether an opting-out approach would improve vaccine uptake. **Methods** We conducted a randomized quality improvement (QI) trial to compare opting-out with conventional opting-in consent for influenza immunization. Women age ≥ 18 years attending the University of Texas Health Science Center at Houston (UTHealth) or UT-Medical Branch (UTMB) prenatal clinics during the 2010–2011 influenza season, were eligible.

Results We enrolled 280 women (140 UTHealth, 140 UTMB). Both groups had similar mean age (26.0 ± 5.5 years), mean gestational age (19.4 ± 9.5 weeks), and percent with underlying health conditions (20.7%). Vaccination rates with opting-in and opting-out were similar among all (83 vs. 84%), UTHealth (87 vs. 93%), and UTMB patients (79 vs. 76%) ($p > 0.05$). In subsamples of patients assessed, consent strategy did not significantly affect maternal recall of information provided.

Conclusion While prenatal influenza vaccination uptake doubled from the 2009–2010 influenza season, opting-out did not perform better than opting-in, a conclusion opposite that we would have reached had this been a nonconcurrent trial. Vaccination rates dropped posttrial; hence, continued research is needed to increase the prenatal influenza immunizations.

Keywords

- ▶ pregnancy
- ▶ influenza vaccines
- ▶ vaccines
- ▶ immunization
- ▶ consent forms

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Pregnancy increases the risk for serious complications from influenza infection. Despite strong recommendations for universal influenza vaccination of pregnant women,^{1–4} fewer than 55% of eligible pregnant women in the U.S. are vaccinated.² Women who are uninsured, unemployed, and are of low socioeconomic status have the lowest influenza vaccine rates (14.6–47.2%), nationally.² Furthermore, only 67.3% of eligible pregnant women report to have received a recommendation and offer for influenza vaccine.²

Vaccination during pregnancy reduces not only preterm delivery among mothers but also influenza,^{3,5–7} treatment with antibiotics, and hospitalizations of their infants.^{5,8–11} Younger infants are particularly at risk as the influenza vaccine is not approved for infants before the age of 6 months.^{12,13} National vaccination rates, during pregnancy, remain far below the 80% goal of the Healthy People 2020 goal.^{4,14,15} Reasons include failure of obstetricians to provide influenza vaccination in their office, maternal ignorance of the importance of vaccination during pregnancy, and undue maternal concern about vaccine safety.^{16–18}

As in other states, written consent for vaccination is not legally required in Texas, only verbal consent.¹⁹ The usual practice of requiring written consent appears to be an attempt to reduce any litigation risks rather than to meet patients' needs or wants. In our society, written consent is generally required when extra risk, responsibility, liability or cost are incurred. In this context, requiring written consent can be viewed as inherently misleading for immunizations that reduce risk, impose no extra responsibility or liability, and entail minimal cost.^{20–25} The process of requiring a signature to refuse vaccination (“opting-out”) may decrease unwarranted fears about vaccine safety and lower refusal rates in comparison to requiring a signature to receive vaccination (“opting-in”).²⁰ Opting-out has been found in other circumstances to increase the understanding of information provided in seeking consent,²³ increased consent rates, and avoid selection biases.^{26–28}

In response to consent rates of only 15 to 28% during the 2009 influenza A (H1N1) pandemic in the U.S.,⁴ we conducted a randomized quality improvement (QI) trial²⁹ in 2 centers serving a largely minority population to compare opting-in with opting-out consent for influenza immunization among pregnant women during the 2010–2011 influenza season. We hypothesized that the use of an opting-out approach would increase influenza vaccination rates. We also assessed whether there were major differences in maternal recall of the information provided in seeking consent.

Methods

Populations

Women, 18 years old or older, followed up in prenatal clinics of the University of Texas Health Science Center at Houston (UTHealth) or UT-Medical Branch (UTMB) clinics during the October 2010–March 2011 influenza season were eligible for enrollment, irrespective of pregnancy complication. Women with a contraindication to influenza vaccination, a small percentage of our population, were excluded. The majority

of the women, served by these clinics have Medicaid or government insurance, are of low socioeconomic status and unemployed. All women services, including obstetrical services, are provided at both sites. Vaccination, delivery at the clinics, is a nurse-driven process. Nurses document maternal vaccination status, obtain written consent, provide a current copy of the Centers for Disease Control and Prevention (CDC) Vaccination Information Statement (VIS) to eligible mothers, prior to vaccination, and administer the vaccine.

Randomization and Consent Procedure for Immunization

As allowed under federal regulations,³⁰ Institutional Review Board (IRB) approval was obtained to waive consent for randomization with the stipulations noted below for this QI trial (#HSC MS 10–0557). Patients were randomized using consecutively numbered, opaque, sealed envelopes prepared using random.org by project personnel with no patient contact. Randomization occurred at each site. Before approaching the patient, a research nurse (UTHealth) or clinic nurse (UTMB) opened the envelope which contained either an opt-in or an opt-out consent form (see **Appendix A** and **B**). Both forms provide the same written information for the patient to read about influenza infection and vaccination. Each patient was also read a standard script by the nurse based on information taken from the CDC VIS. Patients randomized to the opting-in approach, signed the form if they accepted immunization; those randomized to opt-out, signed the form if they refused vaccination. The nurse recorded whether the vaccine was administered and the reasons stated by any patient who refused the vaccine. At the conclusion of the visit, the nurse read the patient an IRB-approved statement indicating that the patient was enrolled in a randomized trial of consent strategies for immunization.

Assessment of Maternal Recall of Information Provided

After disclosing randomization, the nurse sought if the patient would be interested in participating in the evaluation described below. As required by our IRB, participating mothers signed a separate consent and Health Insurance Portability and Accountability Act (HIPAA) form. To explore whether there were major differences between groups in recall of the information provided about influenza and vaccination, research nurses at each site, called the first 25 patients who consented. Five attempts (2 attempts between 9 a.m. and 5 p. m., 2 attempts between 5 and 9 p.m., and one attempt during the weekend) were made starting 2 days after the clinic visit.

Power and Statistical Analysis

We retrospectively reviewed vaccination rates for the 2009–2010 influenza season (the year prior to our trial) to confirm baseline rates. During December 2009, 61.4% (216 of 352) of eligible pregnant women seen at UTHealth were vaccinated against influenza and 37.4% (842 of 2,250) women at UTMB clinics; combined 40.6% (1,058 of 2,602) were vaccinated. To achieve 90% power to detect an increase to 60% with an opting-out approach (two-sided α error = 0.05), we calculated that 140 patients would be needed in each group.

Data were uploaded to an electronic database for analysis (Microsoft Access 2010, Redmond, WA). SAS was used for analysis (SAS version 9.4, Cary, NC). Descriptive characteristics were analyzed using χ^2 and Fisher's exact. Nonparametric Wilcoxon's tests and median values were used to compare and characterize data failing to meet parametric assumptions; p -values ≤ 0.05 were considered statistically significant. All data were kept in a locked file cabinet and electronic files were password protected. The trial was registered on ClinicalTrials.gov (NCT01233804).

Results

We enrolled 280 women, 140 from UTHealth and 140 from UTMB. The two consent groups were similar at baseline (see **Table 1**). Among all enrollees, mean age was 26.0 years (± 5.5 , range 13.8–42.6) and mean gestational age was 19.4

weeks (± 9.5 , range 4–40). Most patients were Hispanic ($n = 148$ [52.9%]); 58 (20.7%) had underlying conditions. The majority of patients were enrolled during January 1, 2011 to March 30, 2011 (209 [74.6%]) (late in influenza season).

Vaccination Rates

The rates were substantially higher among eligible women than expected in both groups, with no significant difference between opting-in and opting-out groups, among all patients (83 [116/140] vs. 84% [118/140], $p = 0.87$) or those at either UTHealth (87 vs. 93%, $p = 0.40$) and UTMB (79 vs. 76%, $p = 0.84$) (**Fig. 1**). A considerable percentage of women in their third trimester (17 [20%] of 86) and those with underlying conditions (7 [12%] of 58) did not get vaccinated. The most common reason given for refusal was worry about side effects (25 [51%]). The second was a belief that they were not at risk for influenza (11 [22.4%]).

Table 1 Baseline maternal characteristics by consent strategy ($n = 280$)

	Opt-In ($n = 140$)	Opt-Out ($n = 140$)
Age, y, mean (standard deviation [SD]), range	26.5 (5.5), 17.9–42.6	25.5 (5.4), 13.8–42.3
Gestational age, wk, mean, (SD), range	18.8 (9.7), 5–40	19.9 (9.2), 4–39
	n (%)	n (%)
Ethnicity		
Hispanic	71 (50.7)	77 (55)
African American	52 (37.1)	45 (32.1)
Caucasian	17 (12.1)	16 (11.4)
Other ethnicity	0	2 (1.4)
Trimester ^a		
First	50 (36.0)	37 (26.4)
Second	47 (33.8)	59 (42.1)
Third	42 (30.2)	44 (31.4)
Underlying health conditions ^b	29 (20.7)	29 (20.7)
Diabetes mellitus	13 (9.3)	6 (4.3)
Asthma	9 (6.4)	11 (7.9)
Hypertension	9 (6.4)	8 (5.7)
Pulmonary	1 (0.7)	0
Cardiac	1 (0.7)	2 (1.4)
Hepatic	1 (0.7)	2 (1.4)
Immunocompromised	0	3 (2.1)
Renal	0 (0.0)	0
Enrolled ^c		
January–March 2011	105 (75.0)	104 (74.8)
November–December 2010	35 (25.0)	35 (25.2)

^aOpt-In/Trimester $n = 139$ due to missing data.

^bSubcategories can be multiple responses.

^cOpt-out/Enrolled $n = 139$ due to missing data.

Maternal Recall

Among 51 mothers assessed, 45 (36 vaccinated, 9 unvaccinated) women were reached as 6 did not answer after five attempts. While power was limited, we found no evidence that consent strategy had a large effect on maternal recall of information provided in the consent. Twenty one (88%) of 24 in the opting-in group versus 20 (95%) of 21 in the opting-out group ($p = 0.61$) could name at least one symptom of influenza. Sixteen (67%) of 24 in the opting-in group versus 11 (53%) of 21 in the opting-out group ($p = 0.37$) could name one side effect of influenza vaccine.

Discussion

In this study, we compared two strategies of consenting pregnant women (opting-in vs. opting-out) on influenza vaccination uptake in a parallel, randomized quality improvement trial. The unexpected high vaccination rates in both groups (83–84%) in our trial is likely due to strong support from departmental leaders at the time (i.e., 1 year after an epidemic season in 2009–2010), monitoring of vaccination rates, and increased attention to the immunization status. A possible second contributing factor could be ethnicity as over half of our patient population was Hispanic (52.9%). During the 2016–2017 influenza season in the U.S., eligible pregnant women who were Hispanic had the highest rates (61.2%) for getting the vaccine when compared with other races and ethnicity.²

Note that, the influenza vaccination rates at UTHealth dropped after our trial to 52.9%. Contributing factors to this decline could have been the Hawthorne effect, when individuals modify or improve an aspect of their behavior in response to their awareness of being observed.³¹ Additionally, the intense media coverage of the 2009–2010 influenza season, which contributed to a heightened perception of risk among communities and increased in proactive measures, such as getting an influenza vaccination, waned.^{32,33} Similar to our trial results, national influenza vaccination rates also dropped in the U.S. after the 2009–2010 influenza season.^{34,35}

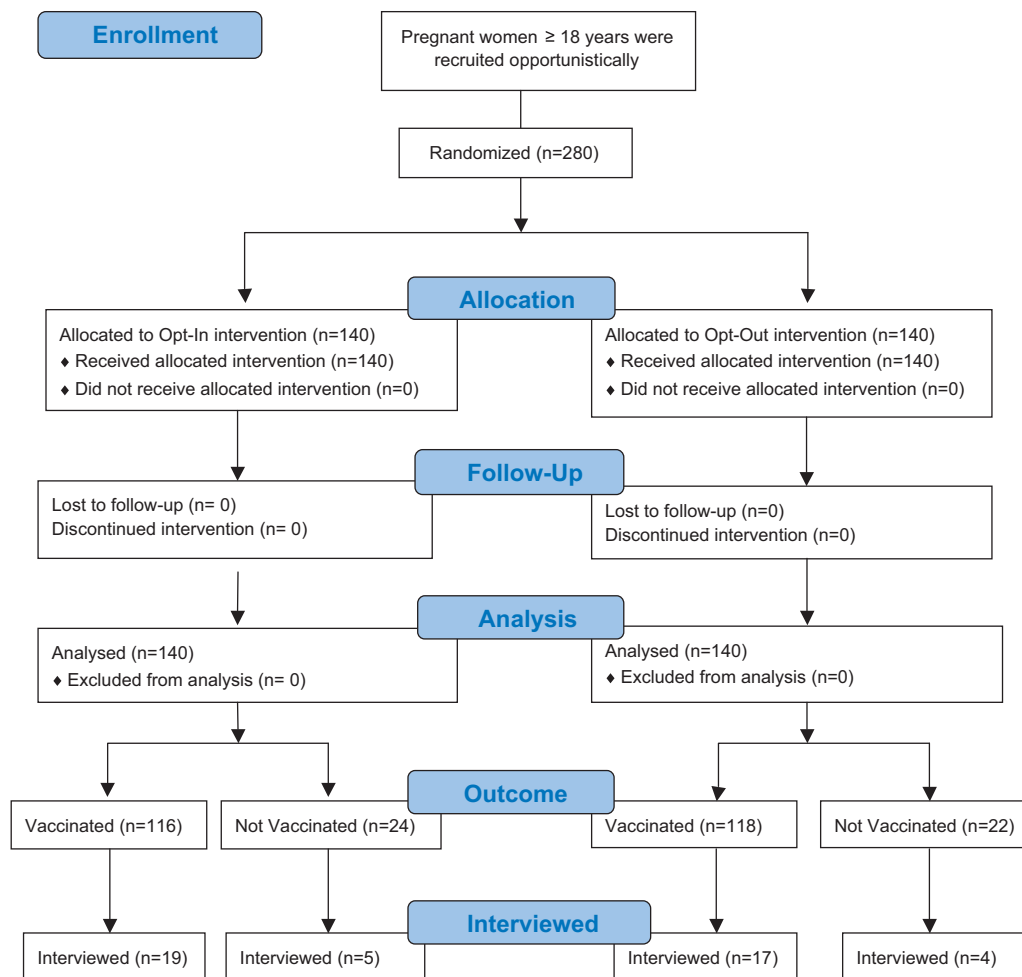


Fig. 1 Flow diagram of progress through phases of trial.

This study has important implications for clinicians. First, even our relatively high rates, left a sizable percentage of women at risk, particularly among those with underlying conditions. One fifth (20%) of women in their third trimester and one in tenth (12%) with underlying conditions did not get vaccinated. Such patients are at particularly increased risk of influenza morbidity and should be specifically targeted for vaccination.^{3,36} To date, a healthcare provider recommendation remains one of the strongest predictors of influenza vaccination among women.³⁷

Our findings are also relevant for policy makers, who involved in clinical research, such as IRB members. Opting-out strategies improve recruitment, reduce selection bias, and increase patient understanding, recall, and satisfaction in clinical research that involves minimal risk.^{23,28} This approach however remains controversial, as IRB generally require conventional opting-in consent for participants in research. For studies; however, where risks from research are not increased or even reduced, such as minimal-risk comparative effectiveness or quality improvement trials, an opting-out consent strategy is increasingly seen as acceptable.^{27,38–43} Additionally, our trial design, which included randomization, avoided common biases associated with typical observation QI studies.⁴⁴ In particular, a pre-post

design would have erroneously concluded that our intervention had an effect.⁴⁵

Despite continued suboptimal maternal vaccination rates in the U.S. (37.4% during 2016–2017),² few interventions to increase maternal agreement to influenza vaccination have been well tested.^{46–48} An important strength of this trial, is that it was an innovative strategy, utilizing and assessing the role of consent, on influenza vaccine uptake rates among pregnant women. Opt-out consents are already used in clinical practice and have led to clear improvements in healthcare and immunization rates in nonpregnant persons.^{20,21,25} Creative strategies addressing patient and healthcare provider barriers to vaccination, such as why obstetricians do not routinely recommend vaccination during pregnancy, are needed especially in states such as Texas where maternal mortality continues to rise.^{49–52}

Our trial had several limitations. First, only 2 centers were included. Both were academic centers and both offered vaccinations on site which could limit the generalizability of our findings to other centers. Second, the majority of our patients were enrolled during the second half of influenza season (January to March, 2011) which could have increased the number of opportunities for women to have been vaccinated. Finally, we attempted to standardize vaccination

information presented to patients in both groups by using a script. Again, this strategy could have impacted vaccination rates as compared with usual practice.

Conclusion

Our trial serves as a unique example of a randomized QI trial to test a strategy to augment the delivery of a proven medical intervention. Our data indicate that with undue effort to optimize influenza immunization rates during pregnancy, rates exceeding 80% can be achieved, even in populations that tend to have low immunization rates. Unfortunately, a sizable proportion of high-risk patients continued to decline vaccination, and most women who declined vaccination were unduly afraid of side effects. With this relatively high rate of immunization, the use of opting-out did not increase immunizations over that with opting-in. However, as for immunization, as for other procedures or therapies, the use of opting-out might help to increase immunizations in settings with low rates that are associated with conventional opting-in approaches. Continued research is needed to identify and implement methods to increase influenza immunizations during pregnancy.^{51,53}

Conflict of Interest

The authors report no conflict of interest.

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Appendix A Opt-In Consent (version 1.0)



Influenza Virus Vaccine

Please read this carefully

All people, age 6 months or older, are recommended to receive annual influenza vaccine. Pregnant women are at risk for serious complications of influenza infection. Women who are pregnant during the influenza season are recommended to receive influenza vaccine.

I have read the Vaccine Information Statement about influenza vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks.

I agree to receive the influenza vaccine today.

Patient (print): _____
 Patient (signature): _____
 Date (mm/dd/yy): _____ Time: _____
 Witness (print): _____
 Witness (signature): _____
 Date (mm/dd/yy): _____ Time: _____

Appendix B Opt-Out Consent (version 1.0)



Please read this carefully

I understand that my healthcare provider has recommended that I receive the influenza vaccine.

I have read the Vaccine Information Statement about the influenza vaccine and the disease it prevents. I have had a chance to discuss this with my healthcare provider who has answered all of my questions about the influenza vaccine.

I understand that the American Academy of Pediatrics, the Centers for Disease Control and Prevention, the American College of Obstetrics and Gynecology, and the Advisory Committee on Immunization Practices have all recommended that I receive the influenza vaccine.

Nevertheless, I have decided to decline the influenza vaccination.

I know that failure to follow the recommendations about vaccination may endanger my health or life and others with whom I have contact.

I know that I may readdress this issue with my healthcare provider at any time and that I may change my mind and accept the influenza vaccination in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Signature: _____ Date: _____
 Witness: _____ Date: _____

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