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RESEARCH PAPER

A randomized trial of maternal influenza immunization decision-making: A test of persuasive messaging models

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ABSTRACT

Objective: We sought to examine the effectiveness of persuasive communication interventions on influenza vaccination uptake among black/African American pregnant women in Atlanta, Georgia. Methods: We recruited black/African American pregnant women ages 18 to 50 y from Atlanta, GA to participate in a prospective, randomized controlled trial of influenza immunization messaging conducted from January to April 2013. Eligible participants were randomized to 3 study arms. We conducted follow-up questionnaires on influenza immunization at 30-days post-partum with all groups. Chi-square and *t* tests evaluated group differences, and outcome intention-to-treat assessment utilized log-binomial regression models. Results: Of the 106 enrolled, 95 women completed the study (90% retention), of which 31 were randomly assigned to affective messaging intervention ("Pregnant Pause" video), 30 to cognitive messaging intervention ("Vaccines for a Healthy Pregnancy" video), and 34 to a comparison condition (receipt of the Influenza Vaccine Information Statement). The three groups were balanced on baseline demographic characteristics and reported health behaviors. At baseline, most women (63%, n = 60) reported no receipt of seasonal influenza immunization during the previous 5 y. They expressed a low likelihood (2.1 ± 2.8 on 0-10 scale) of obtaining influenza immunization during their current pregnancy. At 30-days postpartum follow-up, influenza immunization was low among all participants (7-13%) demonstrating no effect after a single exposure to either affective messaging (RR = 1.10; 95% CI: 0.30-4.01) or cognitive messaging interventions (RR = 0.57; 95% CI: 0.11-2.88). Women cited various reasons for not obtaining maternal influenza immunizations. These included concern about vaccine harm (47%, n = 40), low perceived influenza infection risk (31%, n = 26), and a history of immunization nonreceipt (24%, n = 20). Conclusion: The findings reflect the limitations associated with a single exposure to varying maternal influenza immunization message approaches on vaccine behavior. For this population, repeated influenza immunization exposures may be warranted with alterations in message format, content, and relevance for coverage improvement.

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Introduction

Influenza-related infections are a significant contributor to population morbidity and mortality on a global and national scale, particularly among immunocompromised populations including pregnant women.[1-4] The American College of Obstetricians and Gynecologists (ACOG) and the Advisory Committee on Immunization Practices (ACIP) recommend that pregnant women (and women who expect to be pregnant during the influenza season) receive the trivalent inactivated influenza vaccination.[1,2] Yet, vaccination rates among racially and ethnically diverse pregnant women are significantly lower than those of whites despite persistently higher rates of morbidity, mortality, and hospitalizations due to influenza.[3-11]

Even with a substantial body of scientific evidence documenting the safety of the influenza vaccine for pregnant women, and the corresponding risk of severe influenza-related complications including low infant birth weight and preterm birth outcomes, vaccination among pregnant women remains suboptimal to Healthy People 2020 goals.[12] For example, prior to our undertaking this study, an Internet panel survey conducted by the Centers for Disease Control and Prevention (CDC) during the 2010-2011 influenza season with women who were pregnant during the 2010 influenza season (N = 1,457), found that only 32% of pregnant women received the influenza vaccine during pregnancy.[13] The most cited reason for not receiving the influenza vaccine was concern about the safety of the vaccine.[12-14]

Overall female adult influenza vaccination rates have remained historically low, particularly within minority communities. During the 2011-2012 influenza season, only 40% of pregnant non-Hispanic black women received an influenza vaccine compared to 49% of pregnant Hispanic women and 48% of pregnant non-Hispanic white women.[15] Low uptake of

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the influenza vaccine in these populations may be due to negative vaccine attitudes, poor experiences with healthcare providers, and general concerns about vaccine safety and effectiveness.[16]

Improvements in cost and access barriers (e.g. free prenatal care, free vaccines) have not eliminated racial and ethnic disparities in immunization rates among pregnant women. Evidence suggests that misperceptions of influenza illness and immunization significantly influence the decision to vaccinate during pregnancy. An array of factors, ranging from individual issues such as previous immunization behavior and attitudes toward vaccination, to patient-provider vaccine communication, and social network influences may impact maternal vaccination decisions.[17-21]

Immunization message framing

Various forms of persuasion theory have been applied to immunization decision-making and have therefore informed message framing strategies for pregnant women.[22] One of these frameworks, the Elaboration Likelihood Model (ELM), posits that individuals tend to engage in 2 types of information processing depending on the extent of risk associated with a behavior.[23] For example, many "low risk" decisions do not require extensive issue-relevant considerations (e.g., buying distilled water) and thus these types of decisions are motivated by heuristic or peripheral cues (i.e., a brand logo). Yet, many health decisions require careful consideration that invokes higher cognitive processing (or central-route) functioning.[24,25]

ELM suggests that influenza vaccination attitudes and beliefs are influenced by the interplay of variables as the recipient evaluates a message (i.e., "get immunized") and the message source (i.e., government, clinic, and/or physician recommending vaccine).[26,27] Application of the model would suggest that those who consider immunization would face a risk-taking decision, and therefore may engage in careful thinking about immunization information. This high degree of cognitive engagement (i.e., "high involvement" processing) would theoretically sustain counterpersuasion efforts (e.g., friends and family's negative reactions) and would result in temporal persistence and predicted behavioral outcomes (e.g., influenza immunization).[28,29] Yet, strong affective evaluations of information may also occur with emotional responses invoked especially due to the incongruence such action poses to strongly held vaccine beliefs (i.e., cognitive dissonance) among racial and ethnic minorities.[26]

Given the challenges associated with improving maternal immunization coverage among this vulnerable population, this study sought to test 2 forms of targeted persuasive messaging models in comparison to generic influenza Vaccine Information Statements (VIS) developed by the CDC. Thus, the study fills an important gap in our understanding of how to effectively persuade pregnant women to accept influenza immunization.

Results

Baseline characteristics and vaccine attitudes of study participants

Of the 95 who completed follow-up assessment that we were able to include in this analysis, 31 were randomly assigned to Arm 2 affective messaging intervention ("Pregnant Pause" video), 30 to Arm 3 cognitive messaging intervention ("Vaccines for a Healthy Pregnancy" video), and 34 to the control group (VIS). The three groups were well balanced in terms of baseline demographic characteristics (Table 1). Overall, participants' mean age was around 26 years, many had achieved a high school education or less (60%, n = 57), and most had some form of health insurance (92%, n = 87).

Response rates were calculated by (number enrolled and followed-up)/(number screened and eligible). Our results indicate that the response range was very close across all 4 sites (78% to 83%); thus, the potential for response bias resulting from variance in clinic population was likely minimal. Among 407 patients approached at Urban 1, 270 (66%) agreed to be screened for study eligibility, and 50 of these (19%) were eligible; 39 enrolled and

Table 1. Participant sociodemographic characteristics (N = 95).

	Overall (n = 95)	Arm 1 Comparison Group (n = 34)	Arm 2 (Pregnant Pause movie) (n = 31)	Arm 3 (Vaccines for a Healthy Pregnancy) (n = 30)	p-value
Mean age at baseline (years)	26.1 ± 5.5	25.3 ± 6.0	25.8 ± 5.1	27.4 ± 5.1	
Education					
Less than high school	12 (13%)	5 (15%)	4 (13%)	3 (10%)	0.925
High school graduate or equivalent (GED)	45 (47%)	17 (50%)	15 (48%)	13 (43%)	
Technical/vocational or associates	29 (31%)	9 (26%)	10 (32%)	10 (33%)	
Bachelor degree	8 (8%)	3 (9%)	2 (6%)	3 (10%)	
Graduate degree	1 (1%)	0 (0%)	0 (0%)	1 (3%)	
Ethnicity					
African American/Black	94 (99%)	34 (100%)	31 (100%)	29 (97%)	0.335
Other, specify	1 (1%)	0 (0%)	0 (0%)	1 (3%)	
Children (not including current pregnancy)	1.2 ± 1.4	1.0 ± 1.3	1.5 ± 1.5	1.2 ± 1.4	
Currently has health insurance					
Yes	87 (92%)	31 (91%)	30 (97%)	26 (87%)	0.107
Practice					
Urban 1	39 (41%)	14 (41%)	14 (45%)	11 (37%)	0.733
Urban 2	5 (5%)	3 (9%)	1 (3%)	1 (3%)	
Suburban 1	18 (19%)	8 (24%)	4 (13%)	6 (20%)	
Suburban 2	33 (35%)	9 (26%)	12 (39%)	12 (40%)	

GED General Education Diploma

Table 2. Participants' baseline health-seeking behavior and health knowledge.

	Overall (n = 95)	Arm 1 Comparison Group (n = 34)	Arm 2 (Pregnant Pause movie) (n = 31)	Arm 3 (Vaccines for a Healthy Pregnancy) (n = 30)	p-value[a]
Considers OB/GYN to be primary care doctor[b]					
Yes	74 (80%)	27 (79%)	25 (83%)	22 (76%)	0.736
No	19 (20%)	7 (21%)	5 (17%)	7 (24%)	
Number of times been treated for an illness or condition by a health care provider in past year					
0	38 (40%)	12 (35%)	14 (45%)	12 (40%)	0.708
1-4	49 (52%)	20 (59%)	15 (48%)	14 (47%)	
5-9	2 (2%)	0 (0%)	1 (3%)	1 (3%)	
10 times or more	4 (4%)	1 (3%)	1 (3%)	2 (7%)	
Don't know	2 (2%)	1 (3%)	0 (0%)	1 (3%)	
How many seasonal influenza vaccines received in past 5 years					
5 (every year)	1 (1%)	0 (0%)	0 (0%)	1 (3%)	0.135
2-4	9 (9%)	4 (12%)	5 (16%)	0 (0%)	
1	14 (15%)	6 (18%)	6 (19%)	2 (7%)	
0	60 (63%)	21 (62%)	16 (52%)	23 (77%)	
Don't know	11 (12%)	3 (9%)	4 (13%)	4 (13%)	
Respondents who have ever gotten an influenza vaccine: Where did you get your last flu shot?					
Primary care doctor's office	7 (19%)	2 (17%)	2 (12%)	3 (38%)	0.721
Ob/Gyn doctor's office	2 (5%)	0 (0%)	2 (12%)	0 (0%)	
Community/public health clinic	5 (14%)	2 (17%)	2 (12%)	1 (13%)	
Storefront clinic	2 (5%)	0 (0%)	2 (12%)	0 (0%)	
Hospital	6 (16%)	3 (25%)	2 (12%)	1 (13%)	
School health clinic	3 (8%)	1 (8%)	2 (12%)	0 (0%)	
Worksite health clinic	2 (5%)	1 (8%)	1 (6%)	0 (0%)	
Other	1 (3%)	1 (8%)	0 (0%)	0 (0%)	
Don't know	9 (24%)	2 (17%)	4 (24%)	3 (38%)	
Baseline likelihood of getting influenza vaccine during current pregnancy (range 0-10)	2.1 ± 2.8	1.8 ± 2.8	2.6 ± 2.9	1.9 ± 2.9	0.877
Baseline hesitancy about getting recommended vaccines (range 0-10)	4.5 ± 3.1	4.8 ± 3.2	4.7 ± 3.1	3.8 ± 3.1	0.215
I feel knowledgeable about the vaccines my new baby will begin getting after (s)he is born					
Strongly agree	27 (29%)	9 (26%)	8 (26%)	10 (34%)	0.653
Agree	32 (34%)	11 (32%)	11 (35%)	10 (34%)	
Not sure	23 (24%)	8 (24%)	8 (26%)	7 (24%)	
Disagree	7 (7%)	4 (12%)	1 (3%)	2 (7%)	
Strongly disagree	5 (5%)	2 (6%)	3 (10%)	0 (0%)	

[a]In relation to comparison group

completed follow-up. Of the 54 patients approached at Urban 2, 49 (91%) agreed to be screened for study eligibility, and 6 of these (12%) were eligible; 5 enrolled and completed follow-up. At Suburban clinic 1, 126 patients were approached, 82 (65%) agreed to be screened for study eligibility, and 23 of these (28%) were eligible; 18 completed follow-up. Among 154 patients approached at Suburban 2, 116 (75%) agreed to be screened for study eligibility, and 41 of these (35%) were eligible; 33 enrolled and completed follow-up.

Overall, the majority of participants (80%, n = 74) considered their OB/GYN physician to be their primary care doctor. Most women (63%, n = 60) reported no receipt of seasonal influenza vaccine in the past 5 y. Only one person received influenza vaccine routinely during the past 5 y with an additional 10% (n = 9) of participants reported getting an influenza vaccine at least 2 of the last 5 y. Of these participants who reported ever receiving an influenza vaccine, they were also asked to report where they last got their shot administered. Responses varied greatly with primary care doctor's office being the most commonly cited place for getting vaccinated for seasonal influenza (19%, n = 7), followed closely by hospital (16%, n = 6) and health clinic (14%, n = 5). Two women (5%) reported that they received influenza vaccination at their OB/GYN practice.

At baseline, there was no significant difference in health behaviors and knowledge by randomization group. On a scale of 0-10 (definitely no - definitely yes), the mean baseline likelihood of getting influenza vaccine during the current pregnancy was only 2.1 (Table 2). Women were moderately hesitant about getting vaccines recommended by a doctor during their pregnancy (4.5/10.0 scale). Women were much more likely to report intention to vaccinate their newborn with all recommended childhood vaccines than themselves (8.2/10.0 scale). Notably, a majority of women felt that they were knowledgeable about the infant and childhood immunizations (63%, n = 59).

Vaccine education intervention and influenza vaccine practices and attitudes

At 30 d postpartum, women reported very low acceptance of influenza vaccines during their pregnancy (≤13%) (Table 3). Neither intervention format (Arm 2 or Arm 3) resulted in significant influenza immunization increases during pregnancy as measured at 30-days postpartum. Thus, no effect was observed after a single exposure to either Arm 2 affective messaging (RR = 1.10; 95% CI: 0.30-4.01) or Arm 3 cognitive messaging interventions (RR = 0.57; 95% CI: 0.11-2.88). Additionally, the log-binomial regression models showed that there was no

Table 3. Associations between vaccine education interventions and influenza vaccination during pregnancy.

Outcome	Arm 1 Comparison Group No. (%)	Arm 2 (Pregnant Pause movie)[a]			Arm 3 (Vaccines for a Healthy Pregnancy ibook)[a]		
		No. (%)	Risk Ratio (95% CI)	P-value	No. (%)	Risk Ratio (95% CI)	P-value
Influenza vaccine administered during pregnancy	4 (12%)	4 (13%)	1.10 (0.30-4.01)	0.889	2 (7%)	0.57 (0.11-2.88)	0.493
Mother's intention to be vaccinated with influenza vaccine in future pregnancies (scale 0-10)							
Low likelihood (0-3)	13 (38%)	12 (39%)	Ref		8 (27%)	Ref	
Medium likelihood (4-6)	9 (26%)	7 (23%)	0.90 (0.42-1.95)	0.791	12 (40%)	1.47 (0.79-2.72)	0.224
High likelihood (7-10)	12 (35%)	12 (39%)	1.04 (0.59-1.84)	0.889	10 (33%)	1.16 (0.65-2.07)	0.622

[a]Referent is comparison group.

association in intention to receive the influenza vaccine during future pregnancies based on any arm exposure condition.

Table 4 presents risk ratios of reasons for not getting vaccinated with the influenza vaccine during their pregnancy between study groups. Regardless of study group, women most commonly reported that the main reason for not receiving the influenza vaccine was due to vaccine safety concerns (47%, n = 40), followed by low perceived risk of influenza virus infection (31%, n = 26). No significant associations between vaccine education interventions and reasons for not getting the influenza vaccine during their pregnancy were observed.

Discussion

Although maternal influenza immunization has the dual effect of protecting mothers and infants during the first 3 months of life,[30] vaccine uptake has remained suboptimal among pregnant black/African American women.[22] In recent years, CDC, ACOG, and ACIP have made directed considerable attention and resources toward the promotion of maternal influenza immunization to address vaccine-preventable morbidity and mortality.[31-35] Despite these efforts, the results from this study underscore findings from a body of scientific literature that points toward considerable influenza vaccine refusal and hesitancy among pregnant women.[36-40]

As this study was informed by ELM, our overall messaging strategies were likely ineffective in a single-dose exposure as they did not invoke cognitive appraisal resulting in immunization as an outcome.[41,42] Yet, it is important to recognize that ELM is a persuasive model which argues for a temporal orientation toward its effects; in other words, for behavioral change to take effect especially when negative or neutral attitudes have previously formed, repeated messaging is warranted over time.[43,44] Thus, even "higher involvement" cognitive strategies utilized in this study such as interactive "Q&A" formatting of vaccine concerns (which theoretically should invoke active information processing), a null effect on behavior is highly likely in the short term especially in light of social-normative beliefs.[22,45]

Indeed, this study presents findings that suggest deeply held beliefs in the community about influenza vaccine pose considerable communication challenges not likely surmounted with any single type of vaccine promotion message exposure.[22] The fact that ≤13% of the women in our cohort were vaccinated during pregnancy, and that ≤39% of our sample reported that they intended to be vaccinated with influenza vaccine in future pregnancies is reflective of an ingrained (anti)immunization continuum.[46,47] These findings are mirrored in other studies that have examined challenges with vaccine uptake among racially and ethnically diverse minority communities.[48,49] Our findings reinforce the notion that maternal immunization is not likely to shift without effective, repeated messaging that normalizes vaccination as a women's and infant health protection issue.[50]

With 80% of our sample expressing that they consider their OB/GYN to be their primary care physician, yet only 5% of them ever having received a vaccine from their OB/GYN, there is a unique opportunity presented to shift the targeted

Table 4. Associations between vaccine education interventions and women's reported reasons for not getting vaccinated with influenza vaccine, among women who did not receive the influenza vaccine during pregnancy (n = 85).

	Overall No. (%)	Arm 1 Comparison Group No. (%)	Arm 2 (Pregnant Pause movie)[a]			Arm 3 (Vaccines for a Healthy Pregnancy ibook)[a]		
			No. (%)	Risk Ratio (95% CI)	P-value	No. (%)	Risk Ratio (95% CI)	P-value
I was worried the vaccine would cause me or my baby harm	40 (47%)	12 (40%)	12 (44%)	1.11 (0.60–2.04)	0.734	16 (57%)	1.43 (0.83–2.46)	0.198
I didn't think I was at risk for influenza	26 (31%)	11 (37%)	5 (19%)	0.51 (0.20–1.27)	0.146	10 (36%)	0.97 (0.49–1.93)	0.940
I don't take vaccines	20 (24%)	6 (20%)	5 (19%)	0.93 (0.32–2.69)	0.888	9 (32%)	1.61 (0.66–3.94)	0.299
The vaccine was not recommended to me by my doctor	15 (18%)	7 (23%)	2 (7%)	0.32 (0.07–1.40)	0.129	6 (21%)	0.92 (0.35–2.40)	0.862
I don't think the vaccine works or works well	13 (15%)	3 (10%)	4 (15%)	1.48 (0.36–6.03)	0.583	6 (21%)	2.14 (0.59–7.76)	0.246
I didn't think influenza was that dangerous for me	7 (8%)	3 (10%)	1 (4%)	0.37 (0.04–3.35)	0.377	3 (11%)	1.07 (0.24–4.88)	0.929
I am afraid of needles	6 (7%)	3 (10%)	3 (11%)	1.11 (0.24–5.05)	0.892	0 (0%)	NA	NA
I was concerned that the vaccine would weaken my immune system	5 (6%)	2 (7%)	3 (11%)	1.67 (0.30–9.23)	0.559	0 (0%)	NA	NA

[a]Referent is comparison group.

technologically driven messages delivered by our intervention toward more tailored practice-based messaging strategies in the future.[51] This is especially relevant as merely 18% of our sample indicated "vaccine was not recommended to me by my doctor" which suggests that OB/GYN physicians in particular may also lack necessary communication skills to address vaccine reluctance as it has not been a component of their formal or continuing education training.[52-54] Thus, with provision of CME/CEU training for OB/GYNs and midlevel nursing staff on vaccine concerns cited by this population (i.e., potential vaccine-related harm, low perceived influenza risk, and overall adult vaccine refusal), practices and providers may be better equipped to address an immunization service gap in women's healthcare, deliver more persuasive vaccine messages, and therefore normalize vaccination in the context of routine clinical care.[55-57] In addition, successful promotion of maternal immunization is linked to availability of vaccine within the clinic.[58] Thus, our findings highlight the need for maintenance of maternal immunization supply and onsite vaccination for patients to act upon the messages and recommendations they may be receiving prior to and within clinical encounters.

The findings from this study will inform the development of future integrated interventions. Specifically, this study points to the need for physician/provider training in vaccine communication and factors contributing to pregnant women's varying immunization decisions. By understanding the informational needs and concerns of pregnant women, in addition to their previous vaccination history, more effective messages may be developed and targeted to each group's unique needs. Such an approach to tailored messaging, combined with provider recommendation and ease of access, may ultimately lead to greater acceptance and uptake of immunization during pregnancy.

Limitations

We recognize the limitations associated with the self-report nature of the data, as our protocol did not allow for us to verify stated vaccine histories with medical records or vaccine registry data. Any recall bias, which may have been introduced, is assumed to have been non-differential with respect to characteristics likely to be associated with intention to receive antenatal influenza vaccine. We acknowledge an important limitation of including a practice that did not offer onsite vaccination to its patients. By including a practice that did not offer influenza vaccine, we may have missed an important opportunity to assess our intervention among certain minorities or women of lower socioeconomic status for whom immunization access may have served as a key barrier.[59-61] Additionally, among those practices serving women who do not typically obtain influenza vaccine, providers may also be less inclined to stock vaccine as vaccine purchase prices may not fully offset actual provider reimbursement.[59,62] In addition, the peak of the 2012-2013 influenza season in the US was in late December; thus, we may have missed opportunity to capture many women who were vaccine acceptors before this event occurred. The study timing was also suboptimal as data was collected after the peak influenza season, which was around late December for the 2012-2013 flu season.[63]

Methods

Study design and data collection

We conducted a prospective randomized controlled trial with baseline and follow-up measurement of message framing effects collected $\geq$ 30-days postpartum, allowing for up to 60 d thereafter to qualify as within the window for follow-up. We recruited women from January through April 2013, a period that corresponded with active seasonal influenza patterns observed on surveillance reports.[64] We obtained permission from 4 antenatal practices located in urban and suburban Atlanta, Georgia to recruit participants in waiting room areas at designated times convenient for the office. This strategy was most conducive for recruitment as our consent process, time to view or work with the interventions, and completion of baseline measures occurred within 30-minute blocks per participant. We selected the clinics for this study as they served racially and socioeconomically diverse pregnant populations representative of the metro Atlanta area. As we had previous study experiences recruiting pregnant women at some practices, we had established relationships with some practices included in this study. In addition, we added those who agreed to allow us to recruit in their waiting areas.

We documented the general vaccine guidelines for each clinic to capture the fact that practices followed these recommendations. Thus, we did not think it was necessary to have personal communication with each provider to know if/when they were recommending the vaccines. We considered clinic recommendations when analyzing participants' responses to how likely they were to follow their provider's advice in the questionnaire at baseline and follow-up.

Even though some women were seen by the clinician following consent, they were able to complete the study procedures prior to leaving the office. In addition, only one woman signed the consent and received the vaccine during the visit, prior to completing the baseline procedures, and thus was withdrawn from the study to ensure results were not affected. Thus, our participant data collection strategy did not impose any disruption to the clinical flow.

Participants

We screened and enrolled black/African American women, between the ages of 18 and 50 years, who confirmed that they were pregnant at the time of enrollment with an expected delivery date no later than July 2013. Women were excluded from the study if they had already received the 2012-2013 seasonal influenza vaccine during their current pregnancy or were under the age of 18 y. All women who agreed to participate assented to be randomized to one of 3 conditions, and complete in-person baseline and 30-day postpartum telephone follow-up assessments.

Study procedures

Research staff recruited potential participants as they entered the antenatal clinics by following a recruitment script and completing a screening checklist. Written informed consent was obtained from all eligible women prior to baseline assessment

and randomization. Following consent, participants were asked to complete a baseline, paper-based questionnaire comprised of 24 items to assess their vaccination attitudes, knowledge, normative influences, and beliefs. This assessment took approximately 15 minutes to complete.

Randomization to interventional formats

Following questionnaire completion, participants were then randomly assigned to one of the 2 vaccine education interventions or the comparison condition (2012-2013 influenza VIS). Those assigned to the VIS arm were given the material to read in the presence of a study team member. Following review of the material presented based on arm assignment, all participants were provided with a $35 gift card for completion of the baseline questionnaire and review of the material at this session.

Women assigned to the first intervention, a short film entitled "Pregnant Pause," were instructed to watch the 9-minute film viewed on a study iPad. This story centered on a black/African American pregnant woman's dilemma to get an influenza vaccine at 2 of her routine obstetrical visits. With normative and persuasive influences featured in the storyline, the film depicted physician-actors giving the woman their recommendation to obtain the influenza immunization while acknowledging and discussing her concerns, including those of her mother whose anti-vaccination beliefs ran counter to the recommendation (i.e., cognitive dissonance). Thus, the film utilized affective ELM cueing techniques (e.g., reliance on physician credibility for vaccine decision-making and addressing normative beliefs).

The second intervention was also delivered on a study iPad entitled "Vaccines for a Healthy Pregnancy." This format encouraged women to watch short videos of actual physicians providing detailed, question-and-answer information on influenza vaccines. This information-dense format contained short modules covering topics such as the importance of these vaccines for both the mother and child, the severity of the diseases, how the vaccines work to protect pregnant women and their newborns, vaccine safety information, and information on the current ACIP recommendations. Thus, this interactive educational tutorial enabled women to choose the topic(s) that they were most interested in and enabled them to complete each tutorial separately. Such a strategy is consistent with ELM "central route" processing that promotes issue-relevant thinking, evaluation of argument strength, and emphasizes the personal relevance of the topic.

Randomization was done at the patient level for each practice across all clinics on all days in the field. There was no concern regarding cross-contamination as the waiting rooms were typically very busy and large. We assigned headphones to each participant to listen to the material delivered via iPads, thus reducing potential for interaction among participants and/or others nearby. In addition, we assigned a team member to observe waiting room conditions to evaluate any potential for contamination of which none was recorded. We also had the participants complete the intervention in a quiet area of the waiting room whenever possible. There were also not enough eligible participants, relative to the number screened each day, for there to be a concern regarding discussions between participants randomized to each arm.

At 30-days postpartum, participants were contacted by study team staff by phone or email for a single vaccination outcome-oriented follow-up questionnaire. Participants were contacted per our study protocol up to 3 times before we determined that they were unreachable. Subsequently, questionnaires were conducted by telephone during which participants were asked to describe general health of the mother and newborn child(ren), influenza immunization status during pregnancy, future vaccination intentions, and attitudes and beliefs regarding vaccination. Participants were compensated with a mailed grocery store gift card ($50 value) after completion of their follow-up questionnaire.

Measurement and statistical analysis

The primary outcome for this study was uptake of influenza vaccine during pregnancy. Three of the 4 practices offered influenza vaccination as a clinical service. Secondary outcomes included mother's intention to be vaccinated with influenza vaccine in a future pregnancy. Participants who reported not getting vaccinated with influenza vaccine were also asked to report reasons for not receiving the vaccine during pregnancy.

Study population demographic data were compared among intervention groups and control using descriptive analysis. We assessed the success of randomization with respect to maternal age, education, gravidity, health insurance, health seeking behavior, pregnancy complications, and recommendation of influenza vaccine by Ob/Gyn. Chi-square tests and t-tests were used to test for differences in proportions and means between the intervention groups. Risk ratios (RRs) were calculated for the study outcomes with the use of log-binomial regression models (i.e., binomial generalized linear models using the log link function). All analyses were based on intention-to-treat.

Based on power calculations made before the study, we planned to enroll 162 women, or 54 women in each study arm, in order to have 80% power to detect a 20 percentage point increase in influenza vaccine coverage in each of the intervention arms compared to the control arm. However, 106 women were ultimately enrolled and completed baseline assessments. Of the 106 enrolled, we were able to complete 95 follow-up assessments at 30-days postpartum to evaluate vaccination outcomes reported herein. Thus, our retention rate was 90% for this cohort. All analyses were conducted using SAS version 9.4 (SAS Institute, Inc., Cary, NC).

Conclusion

The findings reflect the limitations associated with single exposure to maternal influenza immunization persuasive messaging approaches on vaccine behavior. Given the low historical acceptance of influenza vaccination among black/African Americans resulting in potential cognitive dissonance for this type of vaccine behavior, repeated influenza immunization exposures may be warranted with alterations in message format, content, and relevance for coverage improvement.

Disclosure of potential conflicts of interest

The authors report no conflict of interest.

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