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RESEARCH ARTICLE

Efficacy of a Web-Based Intervention to Increase Uptake of Maternal Vaccines: An RCT

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Introduction: Tetanus, diphtheria, and acellular pertussis (Tdap) and influenza vaccines are recommended for pregnant women in each pregnancy, yet uptake is suboptimal. This study tested the efficacy of an online vaccine resource in increasing uptake of Tdap and influenza vaccines among pregnant women.

Study design: RCT.

Setting/participants: This study was conducted among women in the third trimester of pregnancy in an integrated healthcare system in Colorado in September 2013−July 2016, with data analysis in 2017−2018.

Intervention: Women were randomly assigned to 1 of 3 arms: website with vaccine information and interactive social media components, website with vaccine information only, or usual care. Participants in the website with vaccine information and interactive social media components and website with vaccine information only arms had access to the same base vaccine content. The website with vaccine information and interactive social media components also included a blog, discussion forum, and "Ask a Question" portal.

Main outcome measures: Tdap and influenza vaccination. These outcomes were analyzed separately.

Results: For influenza (n=289), women in both the website with vaccine information and interactive social media components (OR=2.19, 95% CI=1.06, 4.53) and website with vaccine information only (OR=2.20, 95% CI=1.03, 4.69) arms had higher vaccine uptake than the usual care arm. The proportions of women receiving the influenza vaccine were 57%, 55%, and 36% in the website with vaccine information and interactive social media components, website with vaccine information only, and usual care arms, respectively. For Tdap (n=173), there were no significant differences in vaccine uptake between study arms. The proportions of women receiving Tdap were 71%, 69%, and 68% in the website with vaccine information and interactive social media components, website with vaccine information only, and usual care arms, respectively.

Conclusions: Web-based vaccination information sent to pregnant women can positively influence maternal influenza vaccine uptake. Because of potential scalability, the impact of robust vaccination information websites should be studied in other settings.

Trial registration: This study is registered at www.clinicaltrials.gov NCT01873040.

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INTRODUCTION

Pregnant women are at increased risk for severe disease from influenza,[1–5] and newborns are at high risk of morbidity and mortality from both influenza[6–8] and pertussis.[9,10] For these reasons, influenza and tetanus, diphtheria, and acellular pertussis (Tdap) vaccination have been recommended routinely for all pregnant women since 2004 and 2011, respectively.[11,12] Substantial evidence exists on both the effectiveness[13–20] and safety[21–27] of these vaccines in pregnancy.

Despite the benefits of these vaccines for pregnant women and newborns, several barriers contribute to suboptimal uptake.[28–31] In addition to lack of provider recommendation,[32] women have expressed concerns about the need for vaccination and vaccine safety in pregnancy.[33] Data from the 2011–2012 influenza season found that among pregnant women who received a recommendation from a healthcare provider and were offered influenza vaccine but refused, the 3 most common concerns were that the vaccine would cause influenza, safety risk to the baby, and not believing the vaccination was effective.[32] Another important barrier is lack of obstetric provider time to adequately explain the risk and benefits of vaccination,[34] suggesting that providers need resources to convey vaccine information without adding time to the visit.

Vaccine information websites offer a potential resource for obstetric providers to promote vaccination without adding time to the patient encounter. However, vaccine content available on the Internet ranges from carefully presented factual information to anti-vaccine content that perpetuates myths and uses social media to disseminate misinformation.[35,36] Pregnant women seeking information may have difficulty finding accurate information, and exposure to anti-vaccine messages may lower their intention to vaccinate.[37,38] A factually accurate website promoted by their obstetric provider could offer an alternative to these anti-vaccine websites. Further, an interactive social media website could appeal to women who prefer this type of web-based interaction to more traditional, static websites.[39,40] There are no known interventions to increase uptake of maternal vaccines when women resist vaccination. This paper describes the results of a substudy within the Colorado Vaccine Social Media study,[41] an RCT designed to increase childhood vaccination. The objective for this substudy was to evaluate the efficacy of web-based vaccine information and social media interventions to increase maternal vaccine acceptance.

METHODS

Between September 2013 and July 2016, a single-center RCT of vaccine information and social media interventions designed to reduce undervaccination among infants was conducted. Participants were individually randomized to 1 of 3 groups: website with vaccine information and interactive social media components (vaccine social media [VSM]), website with vaccine information only (vaccine information [VI]), or usual care only (UC).

As part of that study, maternal vaccination concerns were also addressed. The primary outcomes for this study were receipt of influenza and Tdap vaccines among eligible pregnant women. The hypothesis was that women exposed to the interventions during pregnancy would have higher vaccination rates than UC. The Kaiser Permanente Colorado (KPCO) IRB approved this study.

Study Population

All participants were members of the KPCO health plan, a nonprofit MCO providing health care to approximately 628,000 individuals. Approximately 5,000 pregnant women and 130,000 children receive care at KPCO clinics yearly. Recruitment was conducted between September 2013 and October 2015 as previously described.[41] For recruitment to the overall study focused on infant vaccines, electronic health record data were used to identify pregnant women in the third trimester of pregnancy (6–13 weeks from delivery). Women were eligible for the study if they were aged ≥18 years, spoke English, had Internet access, and had health insurance through KPCO. Pregnant women were ineligible for enrollment if they had a diagnosis for fetal death, miscarriage, or congenital anomaly. Informed consent was obtained online using a secure encryption program.

For this substudy, there were separate analytic cohorts for Tdap and influenza vaccination. Inclusion in 1 of the cohorts did not preclude inclusion in the other. Women were eligible for each analysis if they had not already received the respective vaccine before enrollment in the study and had delivered at least 2 weeks after enrollment to allow adequate time for viewing the intervention and receipt of the vaccine before delivery. For influenza, the analysis was limited to members enrolled during the influenza season or with an estimated date of delivery during influenza season (October 1–March 31). Participants were excluded from analyses if they disenrolled from KPCO, requested removal from the study, or experienced a fetal demise (as the authors immediately ceased any further study contact with these women).

Consented participants were administered a baseline survey to assess demographics (including age, number of children, race, income, and education) and Internet use.[42] Participants were also administered the Parent Attitudes and Childhood vaccines survey—a validated, 15-item instrument that assesses vaccine hesitancy on a scale from 0 to 100.[43] Participants scoring ≥50 were classified as vaccine hesitant, whereas participants with scores <50 were nonhesitant. Because most website visitors do not actively engage in social media activities,[44,45] for the overall study, a randomization allocation ratio of 3:2:1 was used across the VSM:VI:UC arms to facilitate interaction in the VSM arm. The SAS/STAT PROC PLAN procedure (SAS 9.4) was used to generate the random allocation sequence lists. Vaccination data were extracted from the electronic health record.[46]

Measures

The intervention was designed through focus groups, individual interviews, surveys, and usability testing with parents and pregnant women.[47] Details of this process have been described previously.[48] Though most of the website was devoted to childhood

immunizations, the website also contained information specifically related to maternal vaccinations and concerns. This information included national vaccine recommendations during pregnancy (Tdap and influenza), details on each recommended vaccine including safety information and ingredients, a description of the diseases the vaccines prevent (tetanus, diphtheria, pertussis, and influenza), and answers to common vaccine concerns during pregnancy. Information was arranged into short, easy-to-read sections, using best practices in risk communication and website design.[49–52] Sources of information were thoroughly referenced with web links to help convey transparency and credibility.[53,54] Participants in the VSM and VI arms had access to the same base vaccine content, which they accessed through a link sent to their e-mail address.

Participants in the VSM arm also had access to interactive components including a blog, discussion forum, chat room, and an "Ask a Question" portal through which participants could ask experts questions about vaccination. All interactive components were moderated to prevent bullying and disclosure of personal health information.

Participants enrolled in the UC arm received routine obstetric care but did not have access to the website intervention. Usage and interaction for the overall study are described in the primary outcomes manuscript.[41] Overall, 35% of participants in the VSM and VI arms visited the websites at least once, with a mean of 1.8 visits (median=1.0) and range of 1 to 15 visits.

Statistical Analysis

As recruitment for the overall study was powered on infant vaccination status, power calculations for maternal vaccination outcomes were not performed for this substudy. Separate analyses for Tdap and influenza vaccines were conducted. The primary outcome was vaccine receipt before delivery. Follow-up was from the date of enrollment through delivery. The primary outcome was dichotomized to vaccinated or unvaccinated. Women who had received the vaccine of interest before delivery were counted as vaccinated for each analysis. The associations between the interventions and vaccination status were assessed using logistic regression to estimate ORs and associated 95% CIs.[55] Models were adjusted for baseline vaccine hesitancy status (a dichotomous variable as described above) and for variables that were significantly different across the 3 arms on univariable analysis. Data were analyzed in 2017–2018.

RESULTS

There were 1,093 members enrolled in the overall study and randomized (Figure 1). In the overall study population, of 1,093 enrolled pregnant women, 94% received the Tdap vaccine and 74% received the influenza vaccine. Of the 952 women enrolled into the overall study at least 2 weeks before their estimated due date who were followed through the birth of their children, 82% had received Tdap before enrollment, resulting in a total of 173 who met criteria for the Tdap analysis (i.e., unvaccinated at enrollment). Among the 657 participants enrolled during the influenza season, 56% had received their influenza vaccine before enrollment, leaving 289 participants for the influenza vaccine analysis.

Tables 1 and 2 show baseline characteristics of the maternal Tdap and influenza study populations, respectively, by study arm. Using the Parent Attitudes and Childhood vaccines screener, 25% and 21% of women were classified as vaccine hesitant in the Tdap and influenza analyses, respectively. Baseline vaccine hesitancy status was higher in the UC arm than the VSM and VI arms in both the Tdap and influenza analyses, although these differences were not statistically significant. In the influenza analysis, for race, the VI arm had a statistically higher proportion of women classified as nonwhite.

Of the eligible pregnant women, 54% overall received the influenza vaccine before delivery (155/289). Both intervention arms (VSM and VI) achieved higher influenza vaccination rates than UC (Table 3). Women receiving any intervention were more likely to receive the influenza vaccine than UC (57% vs 36%, p=0.01). In the VSM arm, 57% received the influenza vaccine, 56% in the VI arm, and 36% in the UC arm. Of the 289 pregnant women in this analysis, 21% were classified as vaccine hesitant. Of these, 27% received the influenza vaccine compared with 61% of nonhesitant women. Odds of influenza vaccine receipt were twice as high in the VSM arm than the UC arm (OR=2.19, 95% CI=1.06, 4.53) and the VI arm versus the UC arm (OR=2.20, 95% CI=1.03, 4.69). There was no difference between the intervention arms.

Of the eligible pregnant women, 70% overall received Tdap vaccine before delivery (121/173). There were no significant differences in Tdap vaccination uptake by study arm (Table 3). For the VSM arm, 71% of women received Tdap; for the VI arm, 69%; and for the UC arm, 68%. Of the 173 pregnant women in this analysis, 25% were classified as vaccine hesitant. Of these, 35% received the vaccine compared with 82% of those classified as nonhesitant. None of the ORs reached statistical significance.

DISCUSSION

In this study, women receiving a web-based intervention designed to address concerns about vaccines were more likely to receive the influenza vaccine than women receiving UC, although the addition of social media components did not appear to impact uptake beyond provision of the web-based information. These results suggest that web-based vaccine information sent to pregnant women can have a positive impact on maternal vaccine uptake.

There have been relatively few intervention trials to address suboptimal uptake of vaccines in pregnancy. A

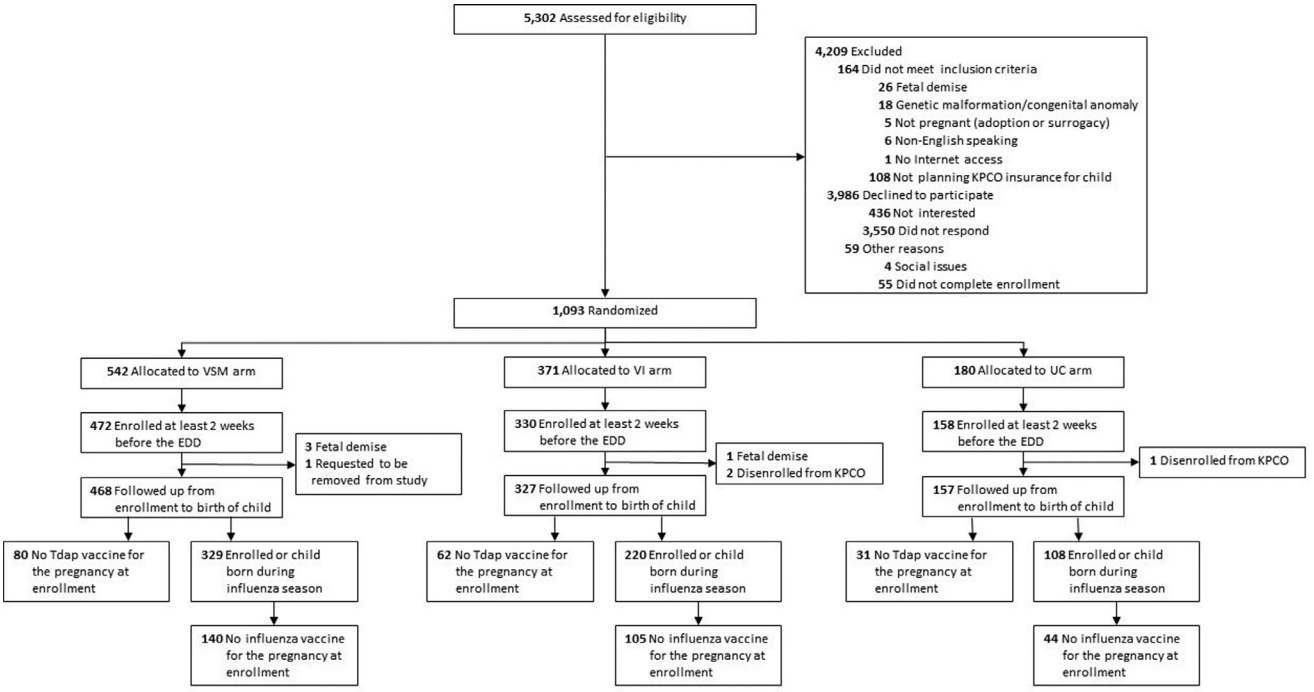

Figure 1. Flow diagram for identifying eligible populations for Tdap and influenza vaccine analyses.
EDD, expected date of delivery; KPCO, Kaiser Permanente Colorado; Tdap, tetanus-diphtheria-acellular pertussis; UC, usual care; VI, vaccine information; VSM, vaccine social media.

Table 1. Baseline Characteristics of Enrolled Members for Tdap Vaccine Analysis, by Study Arm

Characteristic	Total, *n* (%) (*n*=173)	Vaccine social media, *n* (%) (*n*=80)	Vaccine information, *n* (%) (*n*=62)	Usual care, *n* (%) (*n*=31)	*p*-value
Hesitancy by PACV[a,b]	43 (24.9)	17 (21.3)	15 (24.2)	11 (35.5)	0.29
Mother's age at enrollment, years					0.94
Mean (SD)	32.0 (4.5)	31.9 (4.7)	32.1 (4.4)	32.1 (4.2)	
Number of children[b,c]					0.81
Pregnant with first child	81 (46.8)	38 (47.5)	30 (48.4)	13 (41.9)	
Have previous child/children	91 (52.6)	42 (52.5)	31 (50.0)	18 (58.1)	
Race[b]					0.14
White	148 (85.6)	67 (83.8)	51 (82.3)	30 (96.8)	
Other[d]	25 (14.5)	13 (16.3)	11 (17.7)	1 (3.2)	
Household income[b,c]					0.47
≤$80,000	76 (43.9)	33 (41.3)	27 (43.6)	16 (51.6)	
>$80,000	89 (51.5)	45 (56.3)	30 (48.4)	14 (45.2)	
Education[b,c]					0.23
Some college or less	34 (19.7)	16 (20.0)	15 (24.2)	3 (9.7)	
College and higher	138 (79.8)	64 (80.0)	46 (74.2)	28 (90.3)	
Use of Internet for health[b,c]					0.98
Less than every week	64 (37.0)	30 (37.5)	23 (37.1)	11 (35.5)	
Every week or more	108 (62.4)	50 (62.5)	38 (61.3)	20 (64.5)	

Note: [a]Assessed using the PACV screening survey. Participants scoring 50 or higher on a scale of 0 to 100 were classified as vaccine hesitant.
[b]Percentages represent column percentages.
[c]Numbers do not equal column total because of missing data.
[d]Includes African American, American Indian, Asian, and Mixed.
PACV, Parent Attitudes and Childhood Vaccines; Tdap, Tetanus-diphtheria-acellular pertussis.

Table 2. Baseline Characteristics of Enrolled Members for Influenza Vaccine Analysis, by Study Arm

Characteristic	Total, *n* (%) (*n*=289)	Vaccine social media, *n* (%) (*n*=140)	Vaccine information, *n* (%) (*n*=105)	Usual care, *n* (%) (*n*=44)	*p*-value
Hesitancy by PACV[a,b]	60 (20.8)	25 (17.9)	23 (21.9)	12 (27.3)	0.38
Mother's age at enrollment, years					
Mean (SD)	31.3 (4.2)	31.5 (4.4)	31.2 (4.0)	31.0 (4.3)	0.81
Number of children[b]					0.22
Pregnant with first child	165 (57.1)	75 (53.6)	67 (63.8)	23 (52.3)	
Have previous child/children	124 (42.9)	65 (46.4)	38 (36.2)	21 (47.7)	
Race[b]					0.01[c]
White	255 (88.2)	130 (92.9)	85 (81.0)	40 (90.9)	
Other[d]	34 (11.8)	10 (7.1)	20 (19.0)	4 (9.1)	
Household income[b,e]					0.94
≤$80,000	116 (40.1)	54 (38.6)	44 (41.9)	18 (40.9)	
>$80,000	162 (56.1)	80 (57.1)	58 (55.2)	24 (54.6)	
Education[b]					0.20
Some college or less	46 (15.9)	19 (13.6)	22 (21.0)	5 (11.4)	
College and higher	243 (84.1)	121 (86.4)	83 (79.1)	39 (88.6)	
Use of Internet for health[b]					0.92
Less than every week	104 (36.0)	50 (35.7)	37 (35.2)	17 (38.6)	
Every week or more	185 (64.0)	90 (64.3)	68 (64.8)	27 (61.4)	

Note: [a]Assessed using the PACV screening survey. Participants scoring 50 or higher on a scale of 0 to 100 were classified as vaccine hesitant.
[b]Percentages represent column percentages.
[c]Vaccine social media arm and vaccine information arm statistically different at α=0.05.
[d]Includes African American, American Indian, Asian, and Mixed.
[e]Numbers do not equal column total because of missing data.
PACV, Parent Attitudes and Childhood Vaccines.

study from Hong Kong tested the effectiveness of a 10-minute, in-person educational intervention on influenza vaccination, with 21% of those in the intervention arm being vaccinated compared with 10% in the control arm.[56] Such studies, however, present generalizability and feasibility problems, as in-person education requires having an individual trained in patient education at each clinic and has the potential to interrupt clinical flow. In another in-clinic intervention, Kriss et al.[57] compared a video intervention with an iBook and UC among pregnant African American women in Georgia to increase uptake of Tdap and showed increased uptake of Tdap in the iBook group compared with UC (RR=2.83, 95% CI=1.26, 6.37). Similar to the previous study, though, this in-clinic intervention required study staff to deliver the intervention. A separate multimodal intervention in Georgia to increase vaccination uptake with interventions at the practice, provider, and patient levels, which included an iPad-based patient education module, did not show a positive impact on either influenza or Tdap vaccination.[58]

Table 3. Proportion of Pregnant Women Who Received Vaccine After Enrollment in the Study and OR Estimates for Receiving Vaccine Between Study Arms

Study arm	Received influenza vaccine *n* (%)	Study arm comparisons	OR for receiving influenza vaccine[a] (95% CI)	*p*-value
Influenza vaccine (*n*=289)				
VSM (*n*=140)	80 (57.14)	VSM vs UC	2.19 (1.06, 4.53)	0.03
VI (*n*=105)	59 (56.19)	VI vs UC	2.20 (1.03, 4.69)	0.04
UC (*n*=44)	16 (36.36)	VSM vs VI	1.00 (0.58, 1.71)	0.99
Tdap vaccine (*n*=173)				
VSM (*n*=80)	57 (71.25)	VSM vs UC	0.83 (0.30, 2.30)	0.72
VI (*n*=62)	43 (69.35)	VI vs UC	0.81 (0.28, 2.31)	0.69
UC (*n*=31)	21 (67.74)	VSM vs VI	1.03 (0.46, 2.31)	0.94

Note: [a]Model adjusted for baseline vaccine hesitancy and race.
Tdap, tetanus-diphtheria-acellular pertussis; UC, usual care; VI, vaccine information; VSM, vaccine social media.

Text messaging intervention trials to increase maternal vaccine uptake can avoid the problem of in-clinic intervention delivery, but results have been mixed. A study performed in New York City using a series of 5 educational text messages showed a modest impact on influenza vaccine uptake (49% in the intervention arm versus 47% in the control arm).[59] A study in Pittsburgh testing preventive health messages with or without vaccine educational information showed no impact on influenza vaccine uptake.[60] Although text messaging interventions have the advantage of potential scalability, they may be difficult to implement because they require patients to opt in to text messages, and practices may not have the technical capabilities to implement them. In the context of these studies, the positive finding regarding increased uptake of influenza vaccine in this study is hopeful, as a web-based intervention introduced by e-mail is more easily scalable than in-clinic interventions and may offer more detailed information than text messaging interventions.

Vaccination rates for the overall study population (from the primary outcomes study[41]) were 94% and 74% for Tdap and influenza vaccines, respectively, much higher than those in the populations eligible for this study (70% and 54%, respectively), suggesting that at least some portion of the population eligible for this substudy had previously refused vaccination. This is supported by the finding that more women were classified as vaccine hesitant by the Parent Attitudes and Childhood vaccines screener in both the influenza- and Tdap-eligible populations than in the overall study population (25% for Tdap and 21% for influenza, compared with 14% for the overall population).[41] As many of the trial participants were excluded from these analyses owing to receiving vaccines before trial enrollment, future work should explore whether web-based vaccine information interventions may be more effective if introduced earlier in pregnancy. This may also be beneficial as it can promote Tdap vaccination in the preferred earlier side of the 27–36-week window.[61] However, it may be preferable to focus such interventions on more vaccine hesitant populations, and introduce them only after pregnant women refuse a vaccine. Most pregnant women are accepting of vaccination and trust their obstetric provider recommendations.[62] Evidence-based strategies such as standing orders[63] and presumptive recommendations[64] (also known as "announcements")[65] are likely the best way to introduce vaccination for most pregnant women. Offering web-based vaccine interventions early in pregnancy, when women are already inundated with information about other aspects of pregnancy, may be confusing and has the potential to raise questions or concerns for women who are already accepting of vaccination. It may be best to implement such interventions only after women have questioned an initial standing order or provider recommendation.

Web-based interventions have the potential to make obstetric visits more efficient for obstetric providers. After refusing a "first pass" of a standing order or provider recommendation, referring patients to a website with an assurance that they can revisit the discussion at the next visit may save time and be more effective than engaging in a lengthy discussion. This approach has some important requirements, however. First, most web-based resources have not been developed with the same approach as this study, and very few have been tested for effectiveness. Instead, these resources are primarily based on the Information Deficit Model,[66] which assumes that misperceptions are because of a lack of knowledge, and that the solution is to provide more information. Yet there is robust literature across disciplines to suggest that simply providing information often does not lead to people changing their views and may even be counterproductive.[67] Indeed, attempts to debunk myths can counterintuitively reinforce the myths.[38,68] Carefully constructing responses to myths and creating a website that pays close attention to tone and wording, though, as was done in this study, may mitigate the impact of this "backfire effect."[69,70]

Another feature of this intervention that may at least in part explain its effectiveness at increasing influenza vaccine uptake was that links to the website were actively sent to participants by e-mail, which is different than the typical approach of simply recommending a website verbally or in a written handout or having resources available on a practice website. To be effective in other settings, such as private obstetric practices, it may be necessary to develop systems for actively sending patients electronic materials.

Limitations

This study has some limitations. First, this was a substudy of a larger study with childhood vaccination as the primary outcome. If this study been designed specifically to address maternal immunization, the size and makeup of the study population and the timing of the intervention may have been different, and thus results may have also been different. Although there was no effect with Tdap, that may be because of the population for this study, and using different timing or populations may show an impact. There also may have been unmeasured bias not mitigated by randomization. For example, the hesitancy rate in the UC arm was higher than in the

other arms. However, even when controlling for hesitancy, the influenza analysis showed an effect. In addition, the study was conducted in a single, integrated healthcare system in Colorado, in a population that is likely different than the U.S. population, potentially limiting generalizability. Moreover, only English speakers were included in the intervention. Finally, the use of Internet-based health information is a rapidly evolving area, and attitudes and practices of pregnant women and parents that were used to design the intervention may have changed in the intervening years since the website was developed.

CONCLUSIONS

Web-based interventions, with and without social media components, designed to increase uptake of childhood vaccines by focusing on women during pregnancy showed higher uptake of influenza vaccine in pregnant women receiving the intervention, which is notable as very few interventions have been shown to be effective at addressing vaccine hesitancy in any population, including pregnant women. These results suggest there is potential for such interventions to increase uptake of maternal vaccines. Web-based interventions have the advantage of scalability and offer a low-cost approach to deliver vaccine-related information.[71,72] Implementing such interventions has particular potential in health systems, including MCOs, insurance companies, large hospital-affiliated systems, and accountable care organizations. If proven effective in other settings, the use of online resources to promote maternal vaccination is a highly scalable intervention that will not take away from time-limited obstetric visits. Further exploration is needed to determine the optimal timing and populations for administration of online interventions to increase Tdap and influenza vaccine uptake in pregnancy.

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STO'L conceptualized and designed the study, contributed to the website design and moderation, and drafted the initial and final manuscript; KJN, SBO, JMG, NMW, and CRK assisted in study design and development and moderation of the vaccine website; KJN contributed to the study design, carried out the initial and further analyses, and reviewed and revised the manuscript; NMW and CRK coordinated and supervised all data collection, and reviewed and revised the manuscript; all authors approved the final manuscript as submitted.

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SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at https://doi.org/10.1016/j.amepre.2019.05.018.

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