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Exploring mechanisms of a web-based values-tailored childhood vaccine promotion intervention trial: Effects on parental vaccination values, attitudes, and intentions

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Abstract

A recent childhood vaccine promotion intervention trial showed no effects on vaccination outcomes relative to usual care. The purpose of this paper was to test assumptions and theory-based relationships underlying hypothesised mechanisms for two vaccine promotion educational websites (one tailored to parental values, beliefs, and intentions; one untailored) compared with usual care. This is a secondary analysis of a three-arm randomized controlled trial. Parental vaccine values, hesitancy, attitudes, and intention to vaccinate surveys were administered at baseline (≤2 months) and at 4–6 and 10–12 months of age. Vaccination was assessed using electronic health records. Analyses included random coefficient models and risk differences with exact confidence limits. Parental vaccine values were mostly stable over time. Vaccine attitudes were generally positive, with no differences among study arms. Both tailored and untailored website arms showed similar increases in intention to vaccinate more than usual care. Positive changes in intentions were associated with lower rates of late vaccination.

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Although attitudes and intentions predicted vaccination behavior and the intervention increased intention to vaccinate all on time, the web-based education and values-tailored messaging approaches were not effective at increasing vaccination rates. Intentions are necessary but insufficient targets for vaccine promotion interventions.

KEYWORDS

attitudes, mechanisms, tailored messages, vaccination, values, web-based intervention

INTRODUCTION

The public health goal of ensuring broad population rates of childhood vaccination for preventable infectious disease continues to present a challenge to clinicians, public health agencies, and researchers. Many vaccine promotion interventions fail to have the desired effect on vaccination outcomes. Given vaccination decisions and behaviors are multifactorial—with factors ranging from psychosocial (i.e. negative attitudes towards vaccination due to fear of adverse effects of vaccines or distrust of pharmaceutical companies) to logistical (i.e. lack of access or awareness; Mills et al., 2005)—no one intervention is likely to be sufficient or universally appropriate for every setting or population (Kaufman et al., 2018). One proposed novel strategy for addressing the myriad-specific concerns and hesitations among parents (Kempe et al., 2011, 2015) and improving attitudes towards childhood vaccination (Chow et al., 2017) is messaging tailored to personal parental values, concerns, and barriers to vaccination (Dempsey et al., 2020; Dempsey, Wagner, et al., 2019). To improve access and reach of interventions, web-based approaches may complement individual counseling in clinical contexts.

Designing and testing novel behavior change interventions for health promotion should include both a theory-based approach and examination of the proposed mechanisms of change (Michie & Prestwich, 2010). Among the benefits of a theory-based approach is the ability to incorporate intervention features reflecting behavior change techniques known to influence intermediate factors (i.e. theoretical constructs such as attitudes) associated with the behavioral outcome (e.g. vaccination behavior). Measurement of such intermediate factors at key time points during the intervention trial (i.e. at baseline and at a specified follow-up time following exposure to the intervention but before assessment of outcomes) then facilitates testing whether the intervention worked as designed.

An exploration of underlying theory-based mechanisms (Hagger et al., 2020) can build the literature on both effective and ineffective behavior change strategies for influencing specific theoretical constructs, as well as inform which theories apply to which health behaviors (i.e. changes in the constructs predict changes in the behavioral outcome—i.e. proposed mediation). Furthermore, theory can inform the characteristics of people that may respond differently to different types of interventions (i.e. proposed moderation or heterogeneity of effects) (Tipton et al., 2020; Willke et al., 2012). Testing such effects can be particularly important for interventions that do not influence behavior change as expected (i.e. null trials).

Improving interventions tested in null trials can be guided by understanding of the source of the null effect (use of the wrong theory or the wrong approach, as in a poorly operationalized theory). Advancing understanding of which types of vaccination promotion interventions are effective under which circumstances - and for which types of participants - would benefit from such a theory-based approach.

The purpose of this paper was therefore to examine potential theory-based explanations for null effects of a web-based values-tailored vaccine promotion intervention trial (Dempsey, Wagner, et al., 2019; Glanz et al., 2020). In designing this trial, the conceptual model was based on a hybrid of the values–attitude–behavior (VAB) model (Dempsey et al., 2020) and the theory of planned behavior (TPB; Ajzen, 1991). According to the VAB model, personal values (which are presumed to be stable across time and context) influence attitudes and subsequent behavior—in this case, in the context of childhood vaccination. The TPB further specifies that attitudes—along with perceived norms and perceived behavioral control—influences intentions, which then directly affect behavior. Our preliminary work suggested that values and attitudes towards vaccination were intercorrelated and independently associated with vaccination behavior—thus indicating the values could be an appropriate tailoring variable in an intervention designed to influence vaccination attitudes (Cataldi et al., 2019). That is, by appealing to an individual's personal values—thought to serve as a stable, guiding force in personal choices and decisions (Schwartz, 2012)—we might influence attitudes and intentions to vaccinate. In turn, more positive intentions to vaccinate were expected to promote likelihood of a child receiving all recommended vaccines on time. To test this hypothesis, we compared a web-based values-tailored intervention arm to a web-based nontailored intervention arm, with a third no-contact control arm (i.e. usual care).

The primary analysis of the trial outcomes found no effects of the intervention on on-time vaccination rates, which were 91.44%, 92.86%, and 92.31% among tailored, untailored, and usual care arms, respectively (Glanz et al., 2020). In the subanalysis of vaccine hesitant parents, on-time vaccination was worse in the tailored arm compared with untailored. We explored several a priori-specified explanations for the null effect of the trial overall (and worse outcomes in tailored vs. untailored arms). We examined the extent to which an interactive educational website, with and without values-tailored messaging, was an engaging, effective approach to changing attitudes, intentions, and vaccination behavior in a general patient population, relative to usual care. Specifically, we examined several facets of the values-tailored, web-based intervention approach: (1) basic assumptions regarding the stability of values over time (and thus suitability as a tailoring variable), (2) changes over time and differences among study arms in changes in vaccine attitudes and intentions (the intended theory-based targets), (3) differential effects of the intervention on targets for those hesitant versus nonhesitant at baseline (suggesting the intervention may only be appropriate for certain people rather than a broad population-based approach), and (4) participant engagement and satisfaction with the web-based platform.

We tested the following a priori theory-based hypotheses: first, the basic assumption that must hold is that attitudes and intentions to vaccinate are modifiable and can change over time. Conversely, values are generally hypothesised to be stable individual differences (Schwartz, 2012). Second, tailored versus untailored interventions were hypothesised to differentially influence changes in attitudes and intentions to vaccinate. And third, across interventions, changes in attitudes and intentions were hypothesised to predict vaccination behavior. If all three hypotheses were supported, an alternative hypothesis was that the effect of the intervention was only evident among those hesitant at baseline—suggesting the null effect was a population/sample issue and the intervention was not targeted to the right group.

METHOD

Design and conceptual model

The Redivac study was a patient-level randomized controlled trial with three study arms. The study protocol, intervention development, and main outcomes are described in detail elsewhere (Cataldi et al., 2019; Dempsey et al., 2020; Dempsey, Wagner, et al., 2019; Glanz et al., 2020). The conceptual model reflecting the intervention strategies and target theoretical constructs is shown in Figure 1. For this paper, we focus on theory-based relationships among the intervention arms and attitudes, intentions, and vaccination behavior. Although norms and perceived behavioral control constructs from the TPB were measured, these constructs were not intentionally targeted by the intervention. The study was approved by the Kaiser Permanente Colorado Institutional Review Board and is registered on clinicaltrials.gov (NCT02665013).

Setting and population

The setting was Kaiser Permanente Colorado (KPCO), a nonprofit, integrated healthcare system in the Denver/Boulder region of Colorado. Eligibility criteria were the following: women ≥18 years of age who were enrolled in the KPCO health plan between April 2016 and October 2017, were in their third trimester of pregnancy or had a child ≤2 months of age, and spoke English. Exclusion criteria included diagnosis of fetal demise, miscarriage, congenital anomaly

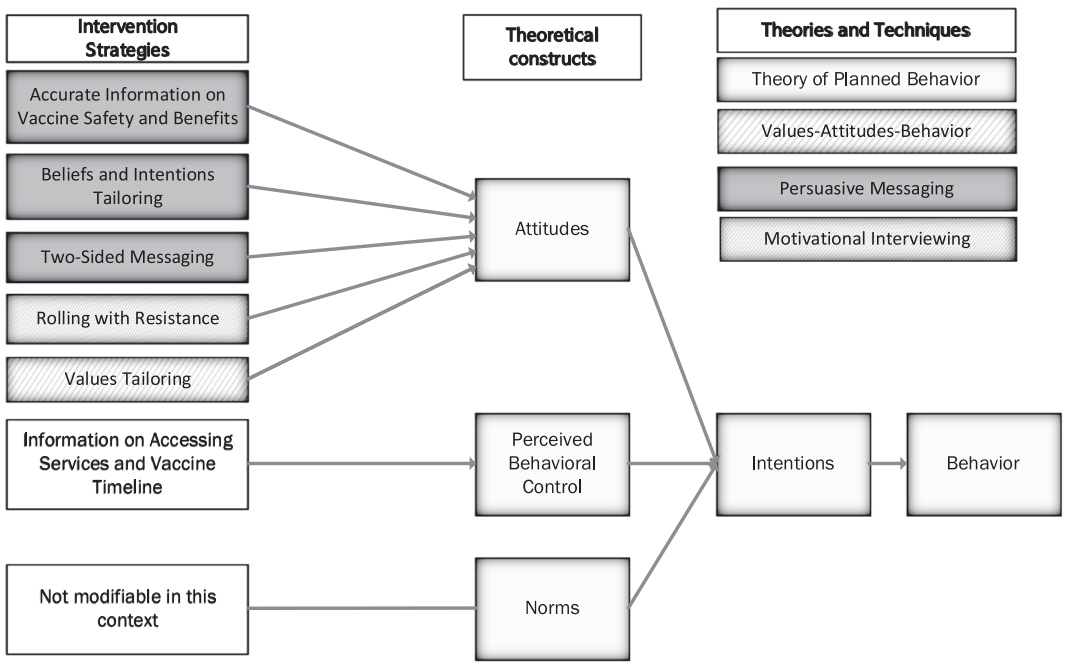

FIGURE 1 Conceptual model of intervention strategies, targets, and theoretical constructs for the Redivac intervention [Color figure can be viewed at wileyonlinelibrary.com]

in the pregnancy, or a high-risk maternal condition. The CONSORT diagram for the overall trial is shown in Figure S1.

Interventions

The interventions are described in detail elsewhere (Dempsey et al., 2020). Briefly, the untailored website included educational content designed to address common beliefs and concerns about childhood vaccines. The tailored website included the same content and provided introductory persuasive messages for each page tailored to the individual participant's stated baseline intention to vaccinate and their vaccination values. The untailored website did not reference the participant's baseline intentions or values. Those in the usual care condition did not view a website.

Procedures and timeline

After providing informed consent and completing a baseline survey, participants were randomized to one of three arms of the study, the tailored website, the untailored website, or the usual care study arm, using a random allocation ratio of 1:1:1. Randomization was conducted within two strata of vaccine hesitancy, "hesitant" and "nonhesitant," as assessed by the Parent Attitudes and Childhood Vaccines short (PACV-short) scale (Oladejo et al., 2016). Randomization was carried out using the SAS/STAT procedure Proc Plan (SAS Institute, Inc, Cary, NC).

Intervention exposures and data collection time points for outcomes and measures of interest for this analysis are shown in Table 1. Participants completed pre-exposure surveys at baseline (T1), when the infant was between 4 and 6 months (T2), when the infant was between 10 and 12 months (T3), and when the child was between 13 and 15 months of age (T4). Follow-up outreach included up to 10 email and phone contacts. Following survey completion at time points 1–3, participants assigned to either untailored or tailored website arms were exposed to the website. Post-exposure surveys were administered to all study arms via an automated email after logging out of the website with instructions to claim a $20 incentive for study participation and an invitation to take the post-exposure survey.

Outcomes and measures

Hesitancy

The PACV-short screening assessment was used to assess hesitancy. The PACV-short assessment is a validated 5-item instrument that assesses vaccine hesitancy, for example, "Overall, how hesitant about childhood vaccines would you consider yourself to be?" and "It is better for my child to develop immunity by getting sick than to get a vaccine." Each item on the PACV-short is scored on a 0–2 scale, with a summary score ranging between 0 and 10. Parents with PACV summary scores ≥ 5 are classified as vaccine "hesitant" and with scores <5 are classified as "nonhesitant" (Oladejo et al., 2016).

TABLE 1 Intervention exposures and measures by study administration time points

Study administration time points			
Baseline (T1): ≤2 mo of age, Time point 2 (T2): 4–6 mo, Time point 3 (T3): 10–12 mo,			Time point 4 (T4): 15 mo of age
Pre-exposure survey measures	**Intervention exposure**	**Post-exposure survey measures**	**15-mo follow-up survey measures**
• Intention to vaccinate • Parental vaccine values[c] • Vaccine hesitancy[b] • Respondent demographics[a]	• Tailored website OR • Untailored website OR • Usual care	• Intention to vaccinate • Vaccination attitudes, norms, and perceived behavioral control	• Parental vaccine beliefs • Vaccine hesitancy • Website satisfaction[d]

[a]Assessed only at baseline.
[b]Assessed at baseline and time point 4.
[c]Assessed only at baseline and time point 3.
[d]Administered to website arms only.

Values

The Parental Vaccine Values Scale (PVVS) is a valid and reliable 20-item scale with six subscales assessing values related to vaccination (Cataldi et al., 2019). Subscales include security-disease prevention (valuing protecting one's children from the harm of infectious disease; (Cronbach's alpha [α] = 0.74), security-vaccine risk (valuing protecting one's children from perceived harm of vaccines; $\alpha = 0.73$), universalism (valuing protecting one's community as a whole from the harm of infectious disease; $\alpha = 0.86$), self-direction (valuing the process of gathering information to make an informed decision; $\alpha = 0.66$), conformity (valuing the recommendations of experts and authority; $\alpha = 0.62$), and tradition (valuing following the established norm in one's religion or family; $\alpha = 0.79$). PVVS items are assessed with a 5-point Likert scale (1 = *very important* to 5 = *not at all important*), and each subscale is computed as an average of the corresponding items. Lower scores indicate greater importance of a value when making decisions about vaccination. The complete list of items in the PVVS is shown in Table S1.

Attitudes towards vaccination

Three items assessed participants' *attitudes* regarding vaccinating their newborn during the first year of life. These were modified from common attitude items identified in the literature (Marteau et al., 2001). One item assessed how beneficial or harmful it would be for their newborn to receive the eight vaccines in the infant series. The second item asked how important or unimportant it would be for their newborn to receive the eight vaccines in the infant series. The third item asked how good or bad it would be for their newborn to receive the eight vaccines in the infant series. Response options were all on a 5-point scale that ranged from 1 = *very beneficial* to 5 = *very harmful*, 1 = *very important* to 5 = *very unimportant*, and 1 = *very good* to 5 = *very bad*, respectively. A mean of these three items was calculated, with means close to 1 representing very positive attitudes.

Intentions

Intention items were asked of all participants at each time point and again after each exposure to the intervention. Two items developed for this study to reflect the complex nature of vaccine intentions (both which vaccines and when) assessed mothers' intention to vaccinate their newborn during the first year of life. One item assessed how many of the eight vaccines in the infant series a participant planned to have their infant receive the following options: "none of the vaccines," "some of the vaccines," and "all of the vaccines." The second item assessed when respondents intended to have their infant vaccinated: "all on-time as recommended by my baby's doctor" and "all or some later than my baby's doctor recommends" (often referred to as a "delayed scheduled" or an "alternative schedule"). Combining these two items and accommodating skewness in the data, respondents were categorized as intending to vaccinate all on time versus not all on time.

Vaccination behavior

Vaccination behavior was determined from electronic medical records and was defined as a binary indicator of "on time" or "late vaccination" based on the recommended Advisory Committee on Immunization Practices (ACIP) schedule (Glanz et al., 2013; Strikas et al., 2015).

Website use and satisfaction

Website usage was measured using backend server data with dates and time stamps for each webpage visited. Website analytics included the number of participants who visited the website at least once, the number of website visits per participant, and the number of pages viewed per participant. We defined visit as a series of page requests from the same participant with no more than 30 min between each page request. Participants using the tailored and untailored websites were invited to complete a 22-item satisfaction survey at time point 4. The research team adapted and expanded on questions from the team's prior work to assess participants' experience using the website and included understandability of the information, characterization of the website information in terms of trust and balance of information provided, usefulness of the information to the participant, and the technical reliability of the website. Given the tailored website was designed to enhance trust and perceived relevance of information, we report here on two of the satisfaction survey items related to trust and relevance (i.e. "In general, how much do you trust the information on the Vaccines and Your Baby website?"; "The information provided by the website was of personal relevance to me.").

Analysis

Descriptive statistics including means, standard deviations, and percentiles were calculated for numeric measures, and counts and percentages for categorical measures. Likert scale items were analyzed as both numeric and categorical. Reliability of the attitude items was analyzed by calculating Spearman correlations among the items as well as Cronbach's alpha.

Random coefficient models (RCMs) were used to examine basic assumptions of parental vaccine value stability over time (baseline to time point 3), estimated using a random intercept and slope for time and an unstructured correlation matrix. Fixed effects were included for study arm, time, and hesitancy status. Separate interaction models were developed to estimate differences between study arms and baseline hesitancy over time. Due to the nature of the RCM, individuals that were lost to follow-up were retained in the model. We modeled individual items rather than the composite score for each subscale, and thus the outcome of item response was treated as having a normal distribution. Denominator degrees of freedom, for F and t tests, were calculated using the between-within method.

Analysis of changes in theory-based intervention targets was limited to those with vaccination outcome data and at least one follow-up survey. All three follow-up surveys were used for all analyses. Differences in response rates to follow up surveys by study arm, hesitancy, and baseline intention were analyzed using logistic regression, adjusted for repeated measures with generalized estimating equations. Baseline measures were only included for the intention analysis, as attitudes were not measured at baseline. Due to skew in responses to attitude items, the responses were dichotomized as the most positive response versus other responses. RCMs were developed in the same way as for temporal stability, with the exceptions that the outcome was binary, the model for intention did not support a random slope for time, and while the attitude model supported a random slope, the correlation structure was variance components only. Finally, given small cell sizes, we calculated a risk difference using exact confidence limits as described by Chan and Zhang (1999) to examine effects of changing intentions from "not all on time" to "all on time" on vaccination behavior.

Data management and analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, North Carolina), with the exception of assessing temporal measurement invariance, which was done using R 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria) and the lavaan package (Rosseel, 2012).

RESULTS

Sample characteristics

Eight hundred and twenty-four participants were randomized to study arm and completed the baseline survey (274 usual care, 274 untailored, and 276 tailored); ∼14% were classified as hesitant in each arm (14.6% usual care, 14.2% untailored, and 14.1% tailored). Demographics are shown in Table 2. The analyses of measurement invariance and temporal stability of values included all 824 participants who completed the baseline the survey. Of the 824 initial participants, for the pre-exposure surveys that assessed intention, values, and hesitancy, 96% responded to pre-exposure survey 2, 88% responded to pre-exposure survey 3, and 82.6% had vaccination data (17.4% considered lost to follow up for the main outcomes analysis). Among 681 participants with vaccination data, there were 597 (88%) with sufficient post-exposure survey data for analysis of intervention targets. Post-exposure survey completion rates were 73% at time 1 (77% of those hesitant at baseline, 73% of those not hesitant at baseline), 52% at time 2 (42% of those hesitant at baseline, 53% of those not hesitant at baseline), and 46% at time 3 (45% of those hesitant at baseline, 46% of those not hesitant at baseline). No significant differences in rates of follow-up by study arm, hesitancy, or baseline intention were found.

TABLE 2 Sample characteristics overall and by study arm

Characteristic	Total ($n = 824$)	Study arm		
		Usual care ($n = 274$)	Untailored website ($n = 274$)	Tailored website ($n = 276$)
Baseline hesitancy: % (n)				
Nonhesitant	85.7% (706)	85.4% (234)	85.8% (235)	85.9% (237)
Hesitant	14.3% (118)	14.6% (40)	14.2% (39)	14.1% (39)
Race/ethnicity: % (n)				
White, non-Hispanic	81.1% (668)	83.2% (228)	82.1% (225)	77.9% (215)
Hispanic	12.1% (100)	10.9% (30)	11.3% (31)	14.1% (39)
Other	5.3% (44)	4.0% (11)	5.5% (15)	6.5% (18)
No response	1.5% (12)	1.8% (5)	1.1% (3)	1.4% (4)
Income: % (n)				
<40 K	7.2% (59)	7.3% (20)	6.6% (18)	7.6% (21)
40–80 K	26.9% (222)	26.3% (72)	24.1% (66)	30.4% (84)
81–120 K	36.3% (299)	36.1% (99)	38.3% (105)	34.4% (95)
121–150 K	10.1% (83)	10.9% (30)	9.9% (27)	9.4% (26)
>150 K	15.7% (129)	15.3% (42)	17.9% (49)	13.8% (38)
No response	3.9% (32)	4.0% (11)	3.3% (9)	4.3% (12)
Employment: % (n)				
Full time	68.8% (567)	70.1% (192)	68.2% (187)	68.1% (188)
Part time	13.6% (112)	11.3% (31)	14.6% (40)	14.9% (41)
Unemployed	1.6% (13)	1.5% (4)	0.7% (2)	2.5% (7)
Stay at home	14.9% (123)	16.8% (46)	15.3% (42)	12.7% (35)
Student	1.0% (8)	0.4% (1)	0.7% (2)	1.8% (5)
No response	0.1% (1)	0.0% (0)	0.4% (1)	0.0% (0)
Education: % (n)				
Grade school	0.7% (6)	1.1% (3)	0.7% (2)	0.4% (1)
High school	2.3% (19)	1.5% (4)	2.2% (6)	3.3% (9)
Some college	11.2% (92)	10.6% (29)	10.2% (28)	12.7% (35)
College	39.2% (323)	42.0% (115)	37.6% (103)	38.0% (105)
Grad school	46.1% (380)	44.2% (121)	48.9% (134)	45.3% (125)
No response	0.5% (4)	0.7% (2)	0.4% (1)	0.4% (1)
Age: M (SD)	32.0 (4.4)	31.8 (4.4)	32.2 (4.2)	32.0 (4.5)

Stability in values over time

Table 3 shows PVVS scores over time and results of RCMs with subject-level random effects examining stability over time. RCMs showed universalism, security (vaccine risk), tradition, and conformity values were stable over time overall and across study arms (all p-values > .05).

TABLE 3 Descriptive statistics for parent vaccine values (PVV) subscales and stability over time

PVV subscales	Baseline *M* (*SD*)	Time point 3 *M* (*SD*)	M_{diff} (CI)	RCM change over time[a]	M_{diff} in change for hesitant vs. nonhesitant (CI)	RCM effect of hesitancy on change over time diff in diff
Universalism	1.8 (0.63)	1.7 (0.66)	−0.041 (−.083, 0.00045)	$p = 0.053$	−0.053 (−0.19, 0.084)	0.45
Security-disease prevention	1.2 (0.35)	1.2 (0.34)	−0.023 (−0.047, −0.0001	$p = 0.049$	−0.11 (−0.201, −0.018)	0.02
Security-vaccine risk	2.3 (0.85)	2.3 (0.87)	−0.026 (−0.08, 0.028)	$p = 0.34$	0.079 (−0.059, 0.22)	0.26
Tradition	4.6 (1.2)	4.7 (1.2)	0.047 (−0.016, 0.11)	$p = 0.14$	−0.0018 (−0.178, 0.182)	0.98
Self-direction	2.7 (1.1)	2.9 (1.2)	0.23 (0.15, 0.31)	$p < .001$	0.2 (0.0011, 0.4)	0.049
Conformity	2.7 (0.65)	2.7 (0.73)	−0.0011 (−0.042, 0.04)	$p = 0.96$	0.022 (−0.12, 0.16)	0.76

Note: Baseline and time point 3 calculated based on composite scores for each PVVS subscale. RCM conducted on item-level analysis.

Abbreviations: RCM, random coefficient model; PVVS, Parental Vaccine Values Scale.

[a]Controlling for study arm and baseline hesitancy.

In contrast, security (disease prevention) values became more important over time (decreased numerically; $M_{diff} = -0.02$, $p = 0.049$). Values for self-direction became less important (increased numerically; $M_{diff} = 0.23$, $p < .001$) between baseline and final follow-up. Those nonhesitant at baseline reported security (disease prevention) were an equally important value at both time points, whereas those hesitant at baseline reported security (disease prevention) became more important over time (M_{diff} ;nonhesitant] $= -.01$ vs. M_{diff} [hesitant] $= -0.12$, $p = 0.02$). Similarly, there was a difference for self-direction, which became less important (increased numerically) more for those hesitant ($M_{diff} = 0.40$, $p < .001$) than for nonhesitant ($M_{diff} = 0.20$, $p < .001$); this difference was small but statistically significant ($p = 0.049$). While statistically significant, all changes in values were very small (less than 1/2 of a standard deviation). Collectively, results suggest some parental vaccine values do appear to change slightly prior to and after delivery (specifically, self-direction and security [disease prevention]), but others remained stable.

Changes in vaccination attitudes over time

Across all study arms, attitudes towards vaccination did not change over time (post-exposure surveys T1: $M = 1.27$, $SD = 0.53$; T2: $M = 1.21$, $SD = 0.51$; T3: $M = 1.25$, $SD = 0.58$). Most participants responding to the post-exposure surveys had strongly positive attitudes towards vaccination at all time points (1 = very positive attitudes). To address this extreme skew, attitudes were dichotomized as "1" or "not 1." Overall, there was no change over time in odds of responding "1" to all attitudes items (OR = 1.35 [0.93, 1.97], $p = 0.12$). There were no differences in attitudes between study arms at post-exposure T1 ($p = 0.96$), suggesting that there was no effect of the initial intervention exposure on attitudes. Furthermore, changes in attitudes over time were not significantly different between study arms (F[2, 559] $= 0.37$, $p = 0.69$). There were no differences in changes in attitudes for those hesitant versus nonhesitant ($p = 0.17$). However, there was a wide confidence interval around the effect of time for those hesitant (OR = 3.00 [0.85, 10.64], $p = 0.09$), suggesting additional data are needed to more precisely estimate changes in attitudes for those initially hesitant to vaccinate.

Changes in intentions to vaccinate over time

The percent of those who intended to vaccinate all on time increased significantly (pre-exposure T1: 82.4%; post-exposure T1: 79.9%; T2: 89.6%; T3: 88.0%) over time across all study arms, such that odds of intending to vaccinate all on time increased with each successive time point (OR = 1.61 [1.19, 2.16], $p = 0.002$). Tests of interactions between linear time and study arm using orthogonal contrasts showed the two website arms (tailored and untailored) were more effective at increasing intentions to vaccinate than usual care (OR = 1.98 [1.03, 3.81], $p = 0.04$). There was no change in intentions over time in the usual care group (OR = 1.00 [0.61, 1.75], $p = 0.91$), whereas both tailored (OR = 2.21 [1.21, 4.04], $p = 0.01$) and untailored arms (OR = 1.90 [1.24, 2.9], $p = 0.003$) showed an increase in those who intended to vaccinate all on time. There was not a significant difference in change in intentions between tailored and untailored arms (OR = 1.16 [0.57, 2.39], $p = 0.68$).

Across all three arms, there was a significant difference in changes in intentions over time for those hesitant versus nonhesitant (OR = 2.48 [1.29, 4.77], $p = 0.006$). There was a

significant increase in percent of those intending to vaccinate all on time among those who were hesitant at baseline (OR = 3.1 [1.72, 5.58], $p < .001$), whereas those nonhesitant at baseline did not change intention over time (i.e. continued to intend to vaccinate; OR = 1.25 [0.91, 1.71], $p = 0.17$). There was no effect of study arm on the differences in changes in intentions for those hesitant versus nonhesitant ($p = 0.51$); however, cell sizes were small.

Effects of changes in intentions on vaccination outcomes

Among those with complete data for intentions at both baseline and T3, there were 538 people who intended to vaccinate all on time at baseline and 112 who did not intend to vaccinate all on time at baseline. Of those intending to vaccinate all on time at baseline, 513 (95%) still intended to vaccinate all on time, and 25 (5%) changed their mind (decided not to vaccinate all on time). Across all study arms, of those not intending to vaccinate all on time at baseline, 72 (64%) changed their mind and decided to vaccinate all on time. As shown in Figure 2, rates of late vaccination were highest for those who consistently reported intending not to vaccinate all on time (52.5% late), and lowest for those consistently reporting intending to vaccinate all on time between baseline and T3 (2.5% late). Those changing from all on time to not all on time were late 28% of the time, whereas those changing from not all on time to all on time were late only 4.2% of the time. Thus, changing intentions from not all on time to all on time was highly protective for being late on vaccination (risk difference = −48% [−64%, −31%]). Tests of effects of study arm on relationship between changes in intentions and late vaccination were not possible due to small cell sizes.

Website use and satisfaction

Of the 550 participants in the tailored and untailored arms, 509 (92.55%) visited the website at least once, with a mean of 2.52 visits ($SD = 1.19$) and range of 1–9 visits. Of the 276 tailored

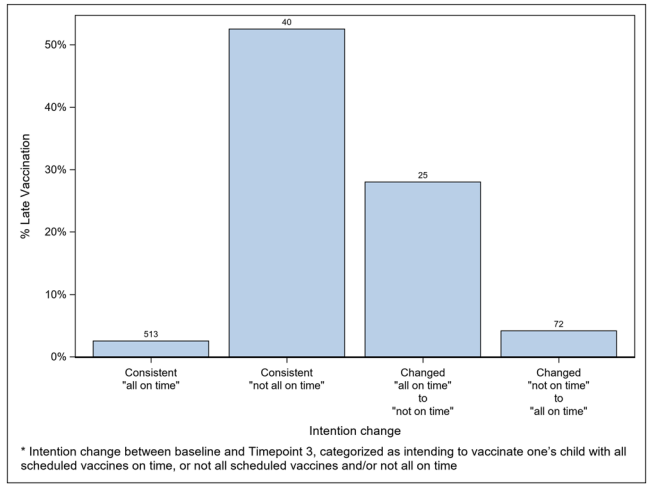

FIGURE 2 Rate of late vaccination by baseline and follow-up intentions [Color figure can be viewed at wileyonlinelibrary.com]

website participants, 259 (93.84%) visited the website at least once compared with 250 (91.24%) of the 274 untailored website participants. The mean number of visits for the tailored and untailored website participants was 2.62 ($SD = 1.20$) and 2.42 ($SD = 1.17$), respectively. The mean number of pages visited by the tailored and untailored participants was 14.42 ($SD = 18.04$) and 14.02 ($SD = 22.66$), respectively. Overall, among participants in the tailored and untailored website arms who completed the satisfaction survey ($n = 117$), 96 (82.1%) agreed/strongly agreed that the information provided by the website was personally relevant (83.0% of tailored website, 81.0% of untailored website; $p = 0.81$). Those hesitant to vaccinate at baseline ($n = 14$) found the websites somewhat but not significantly less relevant than those not hesitant at baseline (71.4% vs. 83.5%; $p = 0.28$). Two thirds of satisfaction survey participants reported they did not completely trust the information on the website (32.5% completely trust, 47.0% mostly trust, 15.4% somewhat trust, and 5.1% trust a little). Those in the tailored arm were slightly but not significantly more likely to report completely trusting the information than those in the untailored arm (39.0% completely trust vs. 25.9% completely trust; $p = 0.13$).

DISCUSSION

The results of this investigation partially supported several mechanistic hypotheses, based on the conceptual framework, that the educational website arms (both tailored and untailored) would increase intention to vaccinate all on time (relative to usual care) and that increased intention to vaccinate all on time would predict decreased rates of late vaccination. These findings are consistent with past studies examining the relationship between vaccination intention and behavior (Smith et al., 2017), though our study is one of only handful to examine this relationship in the context of providing education via the web (Esposito et al., 2018; Kim et al., 2020; O'Leary et al., 2019; Salmon et al., 2019). However, contrary to the hypotheses, there were no differences in changes in attitudes over time or differentially by study arms. There were also no effects of the intervention on other theory-based constructs shown in the conceptual model (norms and perceived behavioral control) that were not specifically targeted by the intervention (results not shown for brevity). It is an unfortunate but well-known phenomenon that changing how people think and feel about vaccination is quite challenging (Brewer et al., 2017)—and the values-based, tailored web-based approach does not appear to have been more successful than previous attempts. It is unclear why changes in intentions between study arms did not yield a direct effect of the intervention on late vaccination in the overall trial analysis, even though change in intention was associated with less late vaccination. This finding may suggest that changing intentions is necessary but not sufficient to change vaccination behavior—a well-established, known phenomenon in behavior change (Schwarzer, 2008; Webb & Sheeran, 2006). Thus, it appears that at least part of the explanation for the null effect of the trial is an incomplete or inadequate theory underlying the mechanism of change. Those designing vaccine promotion interventions may consider moving beyond techniques designed to enhance intentions (i.e. enhancing motivation) to also including intervention strategies that focus on volition (i.e. following through on intentions). Several health behavior change theories such as the health action process approach (HAPA; Schwarzer & Hamilton, 2020) consider volitional phases of change during the intervention development process. Application of the HAPA model to influenza vaccination for people with chronic obstructive pulmonary disease (COPD) has shown that targeting both the

motivational and volitional phases of change yielded positive effects (Vayisoglu & Zincir, 2019). Future research in childhood vaccination may also consider application of the HAPA model.

This analysis further suggests no added benefit of tailored messaging over an untailored interactive website in terms of either perceived personal relevance or promoting intention to vaccinate. Of the few studies that have been done examining tailored messaging for improving vaccination, most have focused on human papillomavirus vaccination, and effects on vaccination have been mixed (Bennett et al., 2015; Dempsey et al., 2011; Dempsey, Maertens, et al., 2019; Gerend et al., 2013; Salmon et al., 2019). Why might this be? First, participants might have experience reactance to perceived attempts at manipulation through values tailoring. However, there was a small, but nonsignificant signal that the tailored website garnered more trust than the untailored website. Second, the decision to tailor on baseline values was based on an incorrect assumption that values would be stable over time. Results showed self-direction values became less important after delivery whereas universalism and protection from disease became more important after delivery. As a result, tailored messaging may have been less relevant to participants at later exposure time points than at earlier time points. This finding is in contrast to the general principle that global personal values are stable over time (Schwartz, 2012); domain-specific values may be more likely to shift over time.

An important and potentially viable explanation for the overall trial null effect may be that the effectiveness of a web-based, tailored messaging intervention approach for increasing vaccination rates would be more evident in a sample of parents who are all vaccine hesitant. The results from this secondary analysis suggested but were not definitive regarding some stronger effects for hesitant versus nonhesitant parents. That is, there might have been ceiling effects for nonhesitant parents (Frew & Lutz, 2017) or hesitant parents may benefit from an audience segmentation approach, such as would be informed by social marketing (Nowak et al., 2015). This is worth investigating in future research.

We also explored whether the null effects may have stemmed from lack of participant engagement and satisfaction with the website. Our satisfaction survey, while representative of only about a fifth of study participants, suggested it is a struggle to garner the trust of parents when presenting scientific information about vaccination safety and benefits. Several studies have shown trust to be a key factor promoting parents vaccine acceptance (Rosso et al., 2019). Conversely, parents with significant vaccine hesitancy often have decreased levels of trust in information provided about vaccines, and in the intentions of their child's medical provider, than nonhesitant parents (Peretti-Watel et al., 2019; Romijnders et al., 2019). Thus, the failure of both our tailored and untailored websites to induce high levels of trust might have contributed to the lack of effect of these interventions on vaccine uptake.

With the plethora of information available, it can be extremely difficult for parents to understand which information sources are trustworthy or not (MacDonald & Dube, 2020), and little is known about how to convince parents that the vaccination information being provided is trustworthy. Past research among vaccine hesitant parents suggested that providing balanced messages that acknowledge both “pros” and “cons” to vaccination (as opposed to focusing on pros only) would help make the information be perceived as more trustworthy (Glanz et al., 2015; Mossey et al., 2019). This supposition was supported by earlier work in which we engaged vaccine hesitant parents representing our study population in selecting the message content of our intervention websites (Dempsey et al., 2020). Despite this extra

attention, perceived lack of trust in the information provided remained an issue for some participants.

Limitations and future directions

The primary limitations were declining response rates to follow-up surveys, potential lack of generalizability beyond the KPCO population and the limited sample of vaccine hesitant parents. Those who did not complete the later follow-up surveys might have demonstrated systematically different attitudes and intentions to vaccinate at the later time points, which might have influenced the findings. However, follow-up rates were unrelated to study arm, baseline hesitancy, or baseline intention to vaccinate. Although the KPCO population is demographically representative of KPCO and there were few exclusion criteria, such that nearly the entire cohort of pregnant people at KPCO during the study period were eligible to participate, results may not generalize. Although there were study arm differences in changes in intentions, this was not enough to yield study arm differences in vaccination behavior. It may be that intentions were subject to social desirability—such that participants in the intervention arms inflated reports of intentions to vaccinate perceiving this to be the desire of researchers. However, given changes in intentions were associated with vaccination behavior in general across the sample, it is unlikely this was the case. Finally, some evidence suggested findings may vary among vaccine hesitant parents. A future study should consider effects within a larger set of vaccine hesitant parents.

CONCLUSION

We explored several theory-based explanations for null results from a vaccine promotion intervention trial. Elements of several explanations were evident. Use of parental vaccine values to tailor persuasive messaging was not an effective approach; this may be partially due to some values lacking stability over time, an important assumption underlying use as a tailoring variable. Although positive changes in intentions to vaccinate were associated with more on-time vaccination, and the educational website arms (tailored and untailored) enhanced intentions relative to usual care, these effects did not extend to an observable effect of the intervention on on-time vaccination. Finally, there is some suggestion that intervention effects may be more demonstrable at improving vaccination rates among vaccine hesitant parents; this should be investigated in a larger sample of vaccine hesitant parents.

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CONFLICT OF INTEREST

Dr. Amanda Dempsey serves on the Advisory Boards for Merck, Sanofi, and Pfizer and has worked as a consultant for Pfizer. None of these companies played a role in this research and she does not receive research funding from these groups. All other authors have no conflicts to declare.

ETHICS STATEMENT

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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