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Vaccine promotion trial mechanisms

# Exploring Mechanisms of a Web-Based Values-Tailored Childhood Vaccine Promotion Intervention Trial: Effects on Parental Vaccination Values, Attitudes, and Intentions


## Abstract

### Background

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 hypothesized mechanisms for two vaccine promotion educational websites (one tailored to parental values, beliefs, and intentions; one untailored) compared to usual care.

### Method

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 ($\leq$ 2 mos) 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.

### Results

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.

Conclusions

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

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, Jadad, Ross, & Wilson, 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; Kempe et al., 2015) and improving attitudes towards childhood vaccination (Chow, Danchin, Willaby, Pemberton, & Leask, 2017) is messaging tailored to personal parental values, concerns, and barriers to vaccination (Dempsey et al., 2020; Dempsey 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, Moyers, McAnally, & McKinley, 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 (that is, 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, Bryan, & Yeager, 2020; Willke, Zheng, Subedi, Althin, & Mullins, 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 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 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 non-tailored 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 sub-analysis of vaccine hesitant parents, on-time vaccination was worse in the tailored arm compared to 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 vs non-hesitant 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 hypothesized to be stable individual differences (Schwartz, 2012). Second, tailored vs untailored interventions were hypothesized to differentially influence changes in attitudes and intentions to vaccinate. And third, across interventions, changes in attitudes and intentions were hypothesized 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 BLINDED 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 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 BLINDED FOR REVIEW and is registered on clinicaltrials.gov (NCT02665013).

**Setting and Population**

The setting was BLINDED FOR REVIEW, a nonprofit, integrated healthcare system in the BLINDED FOR REVIEW. Eligibility criteria were: Women ≥18 years of age who were enrolled in the BLINDED 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 in the pregnancy, or a high-risk maternal condition. The CONSORT diagram for the overall trial is shown in Supplemental File 1 Figure 1.

**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 "non-hesitant," as assessed by the Parent Attitudes and Childhood Vaccines 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 2. 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 Parent Attitudes and Childhood Vaccines short (PACV-short) screening assessment was used to assess hesitancy. The PACV-short assessment is a validated 5-item instrument that assesses vaccine hesitancy, e.g., "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 "non-hesitant" (Oladejo et al., 2016).

*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; α = 0.73), Universalism (valuing protecting one's community as a whole from the harm of infectious disease; α = 0.86), Self-Direction (valuing the process of gathering information to make an informed decision; α = 0.66), Conformity (valuing the recommendations of experts and authority; α = 0.62), and Tradition (valuing following the established norm in one's religion or family; α = 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 Supplemental File 1.

*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, Dormandy, & Michie, 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 vs. 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, Child, Group, & Practices, 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 minutes 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 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 random coefficient model, 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 was 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 vs other responses. Random coefficient models 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

824 participants were randomized to study arm and completed the baseline survey (274 Usual care, 274 Untailored, 276 Tailored); ~14% were classified as hesitant in each arm (14.6% Usual Care, 14.2% Untailored, 14.1% Tailored). Demographics are shown in Table 1. 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; 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.

**Stability in values over time**

Table 3 shows PVVS scores over time and results of random coefficient models 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). In contrast, security (disease prevention) values became more important over time (decreased numerically; $M_{diff} = -0.02, p = .049$). Values for self-direction

became less important (increased numerically; $M_{diff} = 0.23$, $p < .001$) between baseline and final follow-up. Those non-hesitant at baseline reported security (disease prevention) was an equally important value at both time points, whereas those hesitant at baseline reported security (disease prevention) became more important over time ($M_{diff}$ (non-hesitant) = -.01 vs $M_{diff}$ (hesitant) = -.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 non-hesitant ($M_{diff} = 0.20$, $p < .001$); this difference was small but statistically significant ($p = .049$). 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), $p = .12$). 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 vs non-hesitant (p = .17). However, there was a wide confidence interval around the effect of time for those hesitant (OR = 3.00 (0.85, 10.64), p = .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 = .04). There was no change in intentions over time in the usual care group (OR = 1.00 (0.61, 1.75), p = .91), while both tailored (OR = 2.21 (1.21, 4.04), p = .01) and untailored arms (OR = 1.90 (1.24, 2.9), p = .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 vs non-hesitant (OR = 2.48 (1.29, 4.77), p = .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 non-hesitant at baseline did not change intention over time (i.e., continued to intend to vaccinate; OR = 1.25 (0.91, 1.71), p = .17). There was no effect of study arm on the differences in changes in intentions for those hesitant vs non-hesitant (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 was 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 to 9 visits. Of the 276 tailored 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%; $p = .28$). 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; 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; $p = .13$).

## 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, Amlot, Weinman, Yiend, & Rubin, 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, Chapman, Rothman, Leask, & Kempe, 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, Schaffer, Barr, Ruffin, & Carlos, 2011; A. F. Dempsey, Maertens, Sevick, Jimenez-Zambrano, & Juarez-Colunga, 2019; Gerend, Shepherd, & Lustria, 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 non-significant 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 while 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 was not definitive regarding some stronger effects for hesitant vs non-hesitant parents. That is, there might have been ceiling effects for non-hesitant parents (Frew & Lutz, 2017), or hesitant parents may benefit from an audience segmentation approach, such as would be informed by social marketing (Nowak, Gellin, MacDonald, & Butler, 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 non-hesitant 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 (J. M. Glanz, Kraus, & Daley, 2015; Mossey, Hosman, Montgomery, & McCauley, 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 BLINDED 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. While the BLINDED population is demographically

representative of BLINDED and there were few exclusion criteria, such that nearly the entire cohort of pregnant people at BLINDED during the study period were eligible to participate, results may not generalize. While 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. While 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.

**Table 1 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) | | | | |
| Non-hesitant | 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) | | | | |
| < 40K | 7.2% (59) | 7.3% (20) | 6.6% (18) | 7.6% (21) |
| 40-80K | 26.9% (222) | 26.3% (72) | 24.1% (66) | 30.4% (84) |
| 81-120K | 36.3% (299) | 36.1% (99) | 38.3% (105) | 34.4% (95) |
| 121-150K | 10.1% (83) | 10.9% (30) | 9.9% (27) | 9.4% (26) |
| > 150K | 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) |

| *Characteristic* | *Total (n = 824)* | *Study arm* *Usual care (n = 274)* | *Untailored website (n = 274)* | *Tailored website (n = 276)* |
|---|---|---|---|---|
| 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) |

Table 2. Intervention exposures and measures by study administration time points

| Study Administration Time Points | | | |
|---|---|---|---|
| Baseline (T1): ≤2 mos of age, Time point 2 (T2): 4-6 mos, Time point 3 (T3): 10-12 mos | | | Time point 4 (T4): 15 mos of age |
| Pre-exposure Survey Measures | Intervention Exposure | Post-exposure Survey Measures | 15-month Follow-Up Survey Measures |
| • Intention to vaccinate<br>• ***Parental Vaccine Values<br>• **Vaccine Hesitancy<br>• *Respondent Demographics | Tailored Website<br>OR<br>Untailored Website<br>OR<br>Usual Care | Intention to Vaccinate<br>Vaccination Attitudes, Norms, and Perceived Behavioral Control | Parental Vaccine Beliefs<br>Vaccine Hesitancy<br>Website Satisfaction**** |

*Note.* *assessed only at baseline; **assessed at baseline and Time point 4; ***assessed only at baseline and Time point 3; ****administered to website arms only

Table 3 Descriptive Statistics for Parent Vaccine Values (PVV) Subscales and Stability Over Time

| *PVV subscales* | *Baseline M (SD)* | *Timepoint 3 M (SD)* | *Mdiff (CI)* | *RCM Change over time** | *Mdiff in change for hesitant vs non-hesitant (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) | $p = .053$ | -0.053 (-0.19, 0.084) | P = .45 |
| Security – Disease Prevention | 1.2 (0.35) | 1.2 (0.34) | -0.023 (-0.047, -0.0001 | $p = .049$ | -0.11 (-0.201, -0.018) | P = .02 |
| Security – Vaccine Risk | 2.3 (0.85) | 2.3 (0.87) | -0.026 (-0.08, 0.028) | $p = .34$ | 0.079 (-0.059, 0.22) | P = .26 |
| Tradition | 4.6 (1.2) | 4.7 (1.2) | 0.047 (-0.016, 0.11) | $p = .14$ | -0.0018 (-0.178, 0.182) | P = .98 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Self-Direction | | | 0.23 (0.15, 0.31) | $p < .001$ | 0.2 (0.0011, 0.4) | P = .049 |
| | 2.7 (1.1) | 2.9 (1.2) | | | | |
| Conformity | | | -0.0011 (-0.042, 0.04) | $p = .96$ | 0.022 (-0.12, 0.16) | P = 0.76 |
| | 2.7 (0.65) | 2.7 (0.73) | | | | |

*Controlling for study arm and baseline hesitancy

**Baseline and Time point 3 calculated based on composite scores for each PVVS subscale. Random Coefficient Models (RCM) conducted on item-level analysis.

**Figure Captions**

Figure 1. Conceptual Model of Intervention Strategies, Targets, and Theoretical Constructs for the BLINDED Intervention

Figure 2. Rate of late vaccination by baseline and follow-up intentions

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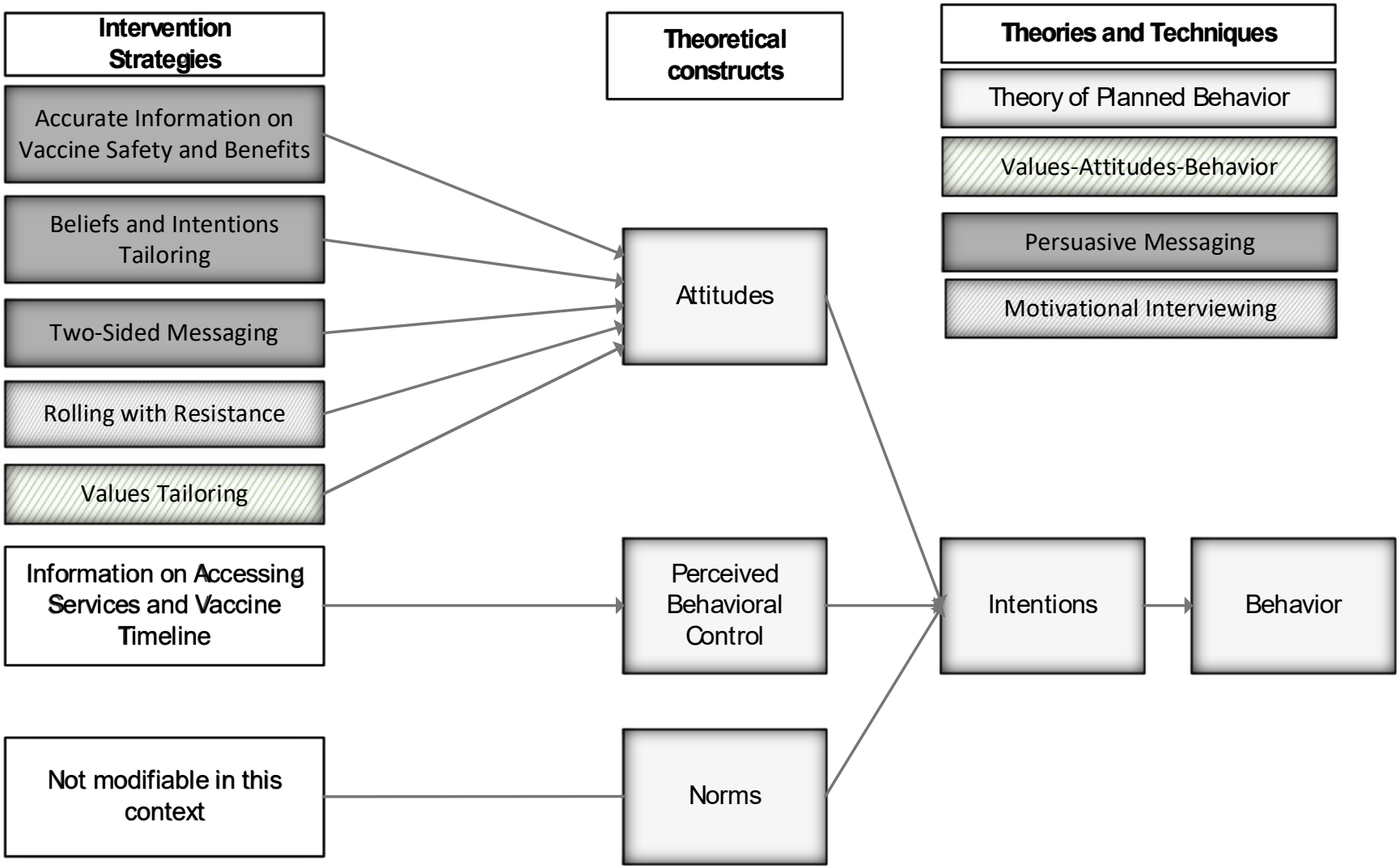


Figure 1

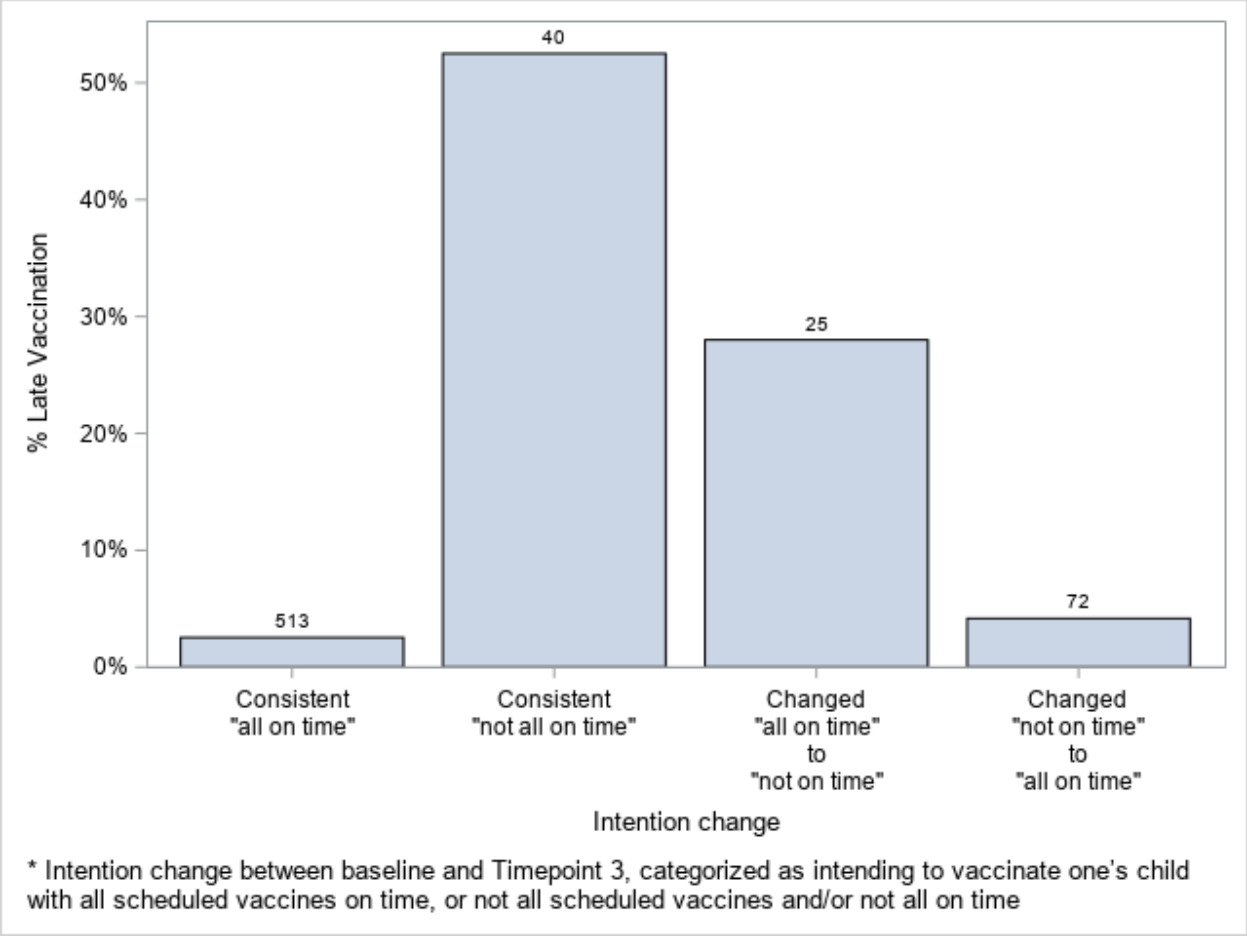


Figure 2