

Can the vaccine adverse event reporting system be used to increase vaccine acceptance and trust?



Laura D. Scherer^{a,*}, Victoria A. Shaffer^{a,b}, Niraj Patel^a, Brian J. Zikmund-Fisher^{c,d}

^a Department of Psychological Sciences, University of Missouri, USA

^b Department of Health Sciences, University of Missouri, USA

^c Department of Health Behavior and Health Education, University of Michigan, USA

^d Department of Internal Medicine, University of Michigan, USA

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ABSTRACT

Vaccine refusal has an impact on public health, and the human papillomavirus (HPV) vaccine is particularly underutilized. Research suggests that it may be difficult to change vaccine-related attitudes, and there is currently no good evidence to recommend any particular intervention strategy. One reason for vaccine hesitancy is lack of trust that vaccine harms are adequately documented and reported, yet few communication strategies have explicitly attempted to improve this trust. This study tested the possibility that data from the vaccine adverse event reporting system (VAERS) can be used to increase trust that vaccine harms are adequately researched and that potential harms are disclosed to the public, and thereby improve perceptions of vaccines. In the study, participants were randomly assigned to one of three communication interventions. All participants read the Centers for Disease Control (CDC) vaccine information statement (VIS) for the HPV vaccine. Two other groups were exposed to additional information about VAERS, either summary data or full detailed reports of serious adverse events from 2013. Results showed that the CDC's VIS alone significantly increased perceptions of vaccine benefits and decreased perceived risks. Participants who were also educated about VAERS and given summary data about the serious adverse events displayed more trust in the CDC and greater HPV vaccine acceptance relative to the VIS alone. However, exposure to the detailed VAERS reports significantly reduced trust in the CDC and vaccine acceptance. Hence, general information about the VAERS data slightly increased trust in the CDC and improved vaccine acceptance, but the specific VAERS reports negatively influenced both trust and acceptance. Implications for communicating about vaccines are discussed.

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Attitudes toward vaccines are largely positive in the USA, [1] but a clinically significant proportion of American children are unvaccinated [2]. Research has tested communication strategies aimed at improving vaccination acceptance, but altering vaccine attitudes has proven to be particularly difficult. Two recent studies attempted to increase vaccine acceptance using numerous strategies, including increasing knowledge about vaccine preventable diseases, using dramatic narratives and pictures to communicate disease risk, and correcting misconceptions and myths about vaccines [3,4]. However, none of these intervention strategies influ-

enced vaccine acceptance. Although there have been some recent successes in improving vaccine acceptance [5–7], a recent review of published reviews on this topic concluded that more research is needed to determine whether any particular approach is consistently effective at persuading vaccine-hesitant individuals [8].

Numerous studies have indicated that one of the primary reasons why parents refuse vaccines is distrust [9–11], and yet few studies have attempted to address distrust in communication interventions [12]. Vaccine-hesitant individuals appear to be concerned that vaccine harms have not been thoroughly researched and disclosed by experts, and that information about vaccine harms is missing or unreliable [13]. A perception that vaccine harms are under-researched or ignored could explain why parents remain unconvinced by the information they do have. In this study, we were particularly interested in developing an intervention that could increase trust that vaccine harms are thoroughly researched and faithfully communicated to the public.

Abbreviations: VAERS, Vaccine Adverse Event Reporting System; CDC, Centers for Disease Control; HPV, Human Papillomavirus.

* Corresponding author at: University of Missouri Department of Psychological Sciences, McAlester Hall, Columbia, MO, USA. Tel.: +1 573 882 1803.

E-mail address: schererl@missouri.edu (L.D. Scherer).

The Centers for Disease Control (CDC) have extended considerable effort to document possible vaccine-related adverse events using the vaccine adverse event reporting system (VAERS). VAERS is a passive vaccine event reporting system that is mandated by law: Anyone can report anything to VAERS for any reason, making it a potentially rich source of data about possible vaccine harms. Moreover, VAERS reports are made available on the internet to the public [14]. The objective of VAERS is not to assess causal relationships between vaccines and adverse events, but instead to detect and monitor rare adverse events in the population, which can be further explored in studies designed to assess causality [14,15]. Hence, the VAERS database offers an opportunity to communicate real-world data that could demonstrate to individuals that 1) every effort is being made to collect information about potential vaccine harms, 2) in spite of this, very few events are reported, 3) even these few reported events are not necessarily caused by the vaccine and 4) this information is available for anyone to view and evaluate. Communicating about the VAERS reports in a transparent and complete way might alleviate concerns about undisclosed information.

In this study, we tested the possibility that open communication about VAERS—how it works, what it is for, and what the database contains—could improve trust in the accuracy and honesty of the CDC's conclusions about vaccine safety and increase vaccine acceptance by concretely illustrating how few adverse events occur compared to the number of vaccinations given, as well as highlighting the CDC's efforts to monitor and document possible harms.

1. Methods

1.1. Participants and setting

A total of 1259 adults located in the USA participated in this study in exchange for \$1 or \$1.50, depending on whether they received the long or short form of the survey. Participants were recruited using Amazon's Mechanical Turk (Mturk), which is a population of adults who are willing to take surveys in exchange for a small amount of money. As of 2010, the Mturk population included over 500,000 individuals, with 39% located in the USA [16]. Research on this population has shown that it is more educated than the general US population, over-represents whites and contains highly conscientious survey-takers [17]. This study was declared exempt by the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board.

Participant demographics are displayed in Table 1. Almost half of the sample reported being parents or guardians (45.7%, $N = 575$). As we describe below, analyses explored the influence of participant age and parental status as interaction terms and as covariates. No interactions involving participant age or parental status were observed, and including these variables as covariates did not influence the effect of the interventions. As a result, the entire sample was included in the analyses reported below.

1.1.1. Design

Participants were asked to evaluate the human papillomavirus (HPV) vaccine, which was chosen because CDC data indicates that this vaccine has been particularly underutilized and therefore is an important target for interventions (<http://www.cdc.gov/vaccines/who/teens/vaccination-coverage.html>). This was a 3-arm study in which participants were randomly assigned to conditions in which they received either 1) the standard two-page CDC vaccine information statement (VIS) for patients [VIS only condition], 2) the VIS plus summary data from the VAERS 2013 HPV reports [VIS + VAERS summary data condition] or 3) all of the aforementioned information plus the actual reports of serious adverse events listed as related to HPV vaccination in 2013 [VIS + VAERS summary + detailed reports

Table 1

Participant characteristics.

Characteristic	
Participant age range	18–70
Participant mean age (SD)	34.93 (11.37)
Gender	
Men	39.3% (495)
Women	58.1% (732)
Not reported	2.5% (32)
Race	
White/European American	81.2% (1022)
Black/African American	6.8% (85)
American Indian or Alaska native	1.1% (14)
Asian or Asian American	4.6% (58)
Native Hawaiian or Other Pacific Islander	0.2% (2)
Other/Mixed race	3.7% (46)
Not reported	2.5% (32)
Ethnicity	
Hispanic or Latino/a	6.4% (81)
Middle Eastern	1.8% (23)
Education	
Less than high school	1.1% (13)
High school only	8.8% (111)
Some college/trade school	28.2% (355)
Bachelor's/	46.2% (577)
Master's degree or more	13.8% (174)
Not reported	2.3% (29)
Work in medical field	6.2% (78)
Vaccine harmed you or someone you know	5.7% (70)

condition]. The information presented in these three conditions is described in detail below.

1.1.2. Pre-measures

At the start of the survey participants indicated whether they agreed or disagreed that 'The HPV vaccine is beneficial' and 'The HPV vaccine is risky' using 0–100 slider scales with endpoints labeled "Strongly Disagree" and "Strongly Agree."

1.1.3. Experimental interventions

Next, participants were randomly assigned to one of three experimental interventions. In the **VIS only condition**, participants read the two-page patient CDC VIS for the HPV Gardasil vaccine (<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil.pdf>) and then responded to the outcome measures.

In the **VIS + VAERS summary data condition**, participants first read the CDC VIS and then were given a description of the VAERS database that communicated the goals of VAERS [14] in non-technical language:

VAERS is a safety surveillance system. In VAERS, anyone can report any event for any reason. The purpose of VAERS is to make sure that any negative event following any vaccine can be recorded. Health experts think that it is important to make a record of ALL negative events that have even the tiniest chance of being related to vaccines, just to be as safe as possible.

Next participants read the *Guide To Interpreting VAERS Case Report Information* from the CDC website (<https://vaers.hhs.gov/data/index>) that describes the limitations of the VAERS data. Specifically, this information explained that VAERS is a passive reporting system and that it may contain events that are not causally related to vaccines. Finally, participants were shown summary data of all of the deaths and permanent disabilities that were reported in VAERS for the HPV vaccine in 2013 (Fig. 1). The total number of doses was estimated using HPV vaccine coverage rates in 2013 (<http://www.cdc.gov/vaccines/who/teens/vaccination-coverage.html>) and US population estimates for the relevant age group in 2013. Although far fewer participants received the Gardasil vaccine specifically, the Gardasil VIS was used for the sake of simplifying the study materials.

SUMMARY:	
POSSIBLE SERIOUS ADVERSE EVENTS:	
Deaths reported in VAERS in 2013	
as possibly related to HPV vaccine.....	7
Permanent disabilities reported in VAERS in 2013	
as possibly related to HPV vaccine.....	24
TOTAL VACCINES GIVEN:	
Total Doses of HPV vaccine given in 2013:.....	Approximately 10,000,000

Fig. 1. VAERS summary data, displayed for all participants receiving information about VAERS.

In the third **VIS + VAERS summary + detailed reports condition**, participants read all of the aforementioned information and then were additionally presented with the actual reports from VAERS. These detailed reports included all of the reported deaths ($N=7$) and permanent disabilities ($N=24$) reported in VAERS in 2013 from the publicly available WONDER site (<http://wonder.cdc.gov/>). The year 2013 was chosen because the study was designed in late 2014 and the aim was to provide comprehensive data from the most recent year available. To facilitate comprehension, the research team wrote brief summaries that presented the report in a format that was easier to understand, including defining medical terms and describing events in chronological order. Participants could also view the entire original report in a popup window by clicking on a large, prominently displayed button icon labeled “Click here to view full report”. The purpose of this intervention was to provide complete disclosure of all of the relevant VAERS reports.

1.1.4. Outcome measures

After receiving all of the information relevant to their randomly assigned condition, participants indicated their HPV vaccine acceptance (*If you had a 12 year old child, would you have your child get the HPV vaccine?*). Next, two questions assessed trust (*Do you trust the CDC's conclusions that the HPV vaccine is safe? Do you believe that the CDC is faithfully reporting the risks of the HPV vaccine?*). These questions were answered on 6-point Likert scales with labeled endpoints (e.g. 1 = Not at all, 6 = Very much so). Finally, participants answered questions that were identical to the pretest measures of perceived risks and benefits of the HPV vaccine, and these items were answered on 0–100 slider scales (identical to the pre-measures).

VAERS reports do not require proof that the vaccine caused the adverse event, and as a result, the reports are ambiguous with regard to the vaccine's causal role. Hence, one question is how participants *subjectively interpreted* the vaccine's causal role when they were exposed to the full reports. To answer this question, participants who saw the VAERS detailed reports indicated their subjective beliefs about whether the vaccine caused each reported death using a 6-point Likert scale (1= death was NOT caused by the vaccine, 6= death WAS caused by the vaccine). For the permanent disability reports, participants reported their subjective beliefs using a 5-point scale (0–4 reports were caused by the vaccine, 5–9, 10–14, 15–20, 20–24).

1.1.5. Analyses

The two trust questions were highly correlated ($\alpha=0.89$) and so a single trust outcome was created by computing the average of the two responses. OLS linear regression models using dummy coded condition variables were used to determine whether the interventions predicted vaccine acceptance and trust and whether there were any interactions between the interventions and participant age, parental status, and preexisting beliefs about the vaccine's risks and benefits. No interactions were significant, and therefore we report OLS regression models that utilized the entire sample

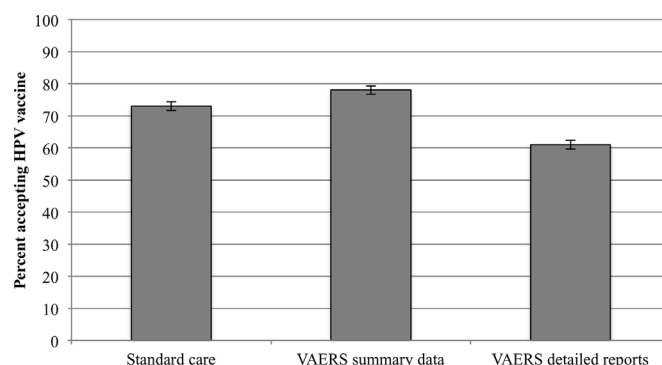


Fig. 2. Percentage of participants accepting the HPV vaccine, by experimental intervention.

and that tested the effects of the interventions with participant age and parental status as controls. These regressions were performed on 4 outcome measures: 1) Vaccine acceptance, 2) trust in the CDC, 3) change in perceived HPV benefit pre vs. post intervention and 4) change in perceived HPV risk pre vs. post intervention. Change scores were calculated such that higher scores indicated higher risk/benefit judgments on post-measure relative to the pre-measure.

Participants who read the VAERS detailed reports were also asked to provide their subjective judgment about whether each of the 7 reported deaths were caused by the vaccine or not. Responses on the “yes” side of the scale [4–6] were coded as ‘1’ and responses on the “no” side of the scale [1–3] were coded as ‘0’. Then all 7 responses were summed, resulting in a 0–7 scale with 0 = no deaths attributed to the vaccine and 7 = all deaths attributed to the vaccine. Ordinal regressions were used to determine the factors predictive of causal judgments about the deaths and permanent disabilities.

2. Results

2.1. Influence of interventions on vaccine acceptance and trust

Pre-measures of perceived vaccine risks and benefits indicated that 8.5% of participants reported low perceived benefits of the HPV vaccine (responded 0–50 on 100-point scale), and 31.7% reported high perceived risks (responded 50–100 on 100-point scale). This indicates that the sample had fairly positive evaluations of the vaccine's benefits, although a sizeable proportion of the sample held negative beliefs pertaining to vaccine risks.

Fig. 2 shows that in the VIS only condition 73% of participants indicated that they would give a 12-year-old child the HPV vaccine (i.e. responded 4, 5 or 6 on the 1–6 scale), compared to 78% in the VAERS summary data group and 61% in the VAERS detailed reports group. Hence, contrary to our desired result, exposure to the detailed VAERS reports *reduced* vaccine acceptance.

Linear regression coefficients displayed in Table 2 indicate that the VAERS summary data significantly increased vaccine acceptance relative to the VIS only group, whereas the VAERS detailed reports reduced vaccine acceptance relative to the VIS only group. The same pattern emerged for participants' trust in the CDC (Table 2): The VAERS summary data increased trust relative to the VIS only, but the VAERS detailed reports greatly decreased trust. The pattern of results described was similar regardless of preexisting beliefs about vaccine risks and benefits.

2.2. Vaccine risk and benefit judgments, pre vs. post intervention

Judgments about HPV vaccine risks and benefits were measured both before and after the experimental interventions, allowing us

Table 2

Each column represents regression results for each of the four primary outcome measures. Values are unstandardized regression coefficients with 95% confidence interval in parentheses. Participant age, parental status and knowing someone harmed by a vaccine served as control variables. Results for each intervention group are displayed in the bottom rows, in addition to R^2 .

	Vaccine acceptance	Trust in CDC	Pre-post difference in HPV benefit	Pre-post difference in HPV risk
Model constant	4.45 (4.12, 4.78)	4.86 (4.62, 5.10)	2.13 (−1.42, 5.69)	−0.42 (−5.31, 4.46)
Participant age (higher numbers = older age)	0.00 (0.00, 0.02)	0.00 (0.00, 0.01)	0.07 (−0.01, 0.17)	−0.15 (−0.28, −0.02)
Parental status (coded 0 = non-parent, 1 = parent)	−0.47*** (−0.67, −0.27)	−0.27*** (−0.41, −0.12)	−0.53 (−2.67, 1.61)	−2.59 (−5.54, .35)
Know someone harmed by vaccine (coded 0 = no, 1 = yes)	−2.18*** (−2.58, −1.77)	−1.97*** (−2.26, −1.67)	−2.73 (−7.08, 1.62)	3.92 (−2.06, 9.90)
Experimental conditions:				
VIS + VAERS summary data vs. VIS only	0.25* (0.02, 0.48)	0.17* (0.00, 0.33)	−1.08 (−3.52, 1.36)	−2.29 (−5.64, 1.05)
VIS + VAERS summary + detailed reports vs. VIS only	−0.45*** (−0.68, −0.22)	−0.26** (−0.42, −0.09)	−7.41*** (−9.86, −4.95)	6.82*** (3.45, 10.20)
R^2	0.12	0.15	0.03	0.03

* $p < .05$.** $p < .01$.*** $p < .001$.

to conduct tests of belief change within individuals. Table 2 shows that compared to the VIS only group, the detailed VAERS reports decreased perceptions of benefits from pre- to post-measure, and increased perceptions of risk. By contrast, the VIS only and the VAERS summary data groups had similar effects on judgments of benefits and risks from pre- to post-measure. The mean change scores displayed in Table 3 show that both the VIS only and VIS + VAERS data summary interventions increased perceptions of vaccine benefits from pre-to-post (both $p < .001$), and decreased perception of vaccine risks from pre-to-post, both $p < .05$. By contrast, the VAERS detailed reports *reduced* perceptions of benefit from pre-to-post ($p < .01$), and did not influence perceptions of risk from pre-to-post, $p = .96$ (Table 3).

2.3. Participants' subjective interpretations of causality

When participants read the detailed reports, most believed that the vaccines caused very few of the deaths and permanent disabilities. The modal response ($N = 167$, or 40.5%) was that none of the 7 deaths were due to the vaccine, and only 2.2% of participants who read the detailed reports ($N = 9$) believed that the vaccine caused all 7 deaths. Similarly, most participants believed that the vaccine caused between 0 and 4 of the 24 reported permanent disability events ($N = 152$, or 37.6%) and only 1.0% ($N = 4$) thought that the vaccine caused 20–24 of the disabilities. This is striking, because exposure to the detailed VAERS reports decreased vaccine acceptance even though the majority of these participants believed that the vaccine caused even fewer adverse events than what was indicated by the numbers alone. Further, these data allowed an opportunity to determine what factors predicted these subjective causal inferences. Table 4 shows two consistent predictors: Participants who had higher preexisting perceptions of vaccine risk were

more likely to believe that the vaccine caused the adverse event, as were participants with lower education.

3. Discussion

The purpose of this study was to test an intervention that was intended to increase vaccine acceptance and trust by communicating that the CDC diligently records possible vaccine harms and disseminates this information to the public. The intervention was based on findings indicating that some individuals distrust the research and reporting about vaccine harms, and therefore we tested the possibility that open communication about VAERS would increase trust. Results showed that information about VAERS in summary form slightly increased vaccine acceptance and trust in the CDC, but additionally providing participants with the VAERS detailed reports greatly reduced vaccine acceptance and trust in the CDC. This indicates that the reports themselves have the capacity to harm vaccine attitudes, even while the aggregate data that can be extracted from VAERS can possibly improve vaccine attitudes.

Furthermore, both the VIS-only and the VIS + VAERS summary data interventions significantly decreased perceived vaccine risks, and increased perceived vaccine benefits, as compared to baseline judgments. Hence, this study not only demonstrated the pitfalls of communicating the detailed VAERS reports, but also demonstrated the effectiveness of the CDC's VIS in *improving* perceptions of vaccine risks and benefits. This is the first study, to our knowledge, that has demonstrated that the CDC's VIS actually improves HPV vaccine perceptions in addition to providing vaccine information.

Moreover, this study provided information about how participants interpreted the VAERS detailed reports. Most participants believed that the vaccine caused few or even none of the adverse events, but even so, exposure to the detailed reports reduce vaccine acceptance. Participants who were more likely to attribute

Table 3

Means and standard deviations for each outcome by experimental intervention. Vaccine acceptance and trust in CDC utilized 1–6 Likert scales with higher scores indicating more trust and acceptance. Benefit and risk judgments utilized 0–100 sliding scales, and change scores were calculated as post measure–pre measure; positive change scores indicate higher benefit/risk perceptions at post measure relative to pre measure.

	Vaccine acceptance	Trust in CDC	HPV benefit change from pre to post	HPV risk change from pre to post
Vaccine information statement (VIS only)	4.41 (1.76)	4.76 (1.27)	4.41 (17.56)	−6.78 (21.77)
VIS + VAERS summary data	4.67 (1.64)	4.95 (1.18)	3.29 (15.04)	−9.05 (25.11)
VIS + VAERS summary + detailed reports	3.94 (1.84)	4.50 (1.44)	−3.00 (20.57)	0.06 (26.83)

Table 4
Regression coefficients (confidence intervals) for ordinal regression models predicting number of deaths and permanent disabilities that participants attributed to the vaccine. Results are separately displayed for participants' attributions for the seven deaths and 24 disabilities.

	Deaths believed to be caused by vaccine	Permanent disabilities believed to be caused by vaccine
Increased participant education	−0.18** (−0.30, −0.06)	−0.12* (−0.24, 0.00)
Increased participant age	−0.02* (−0.04, −0.01)	−0.01 (−0.02, 0.01)
Parental status (coded 0 = non-parent, 1 = parent)	−0.47* (−0.84, −0.04)	−0.14 (−0.54, 0.25)
Harmed by vaccine (coded 0 = no, 1 = yes)	0.48 (−0.31, 1.28)	−0.21 (−1.01, 0.59)
Higher pre-measured HPV risk perceptions	0.03*** (0.02, 0.04)	0.01* (0.00, 0.02)
Higher pre-measured HPV benefit perceptions	−0.01 (−0.01, −0.00)	−0.02*** (−0.03, −0.01)
Cox & Snell pseudo R^2	0.28	0.15

* $p < .05$.

** $p < .01$.

*** $p < .001$.

the adverse event to the vaccine were individuals who were more negative toward vaccines at the outset, and who had less education.

One important question is why the VAERS reports had a more negative effect on vaccine attitudes relative to the summary data alone. One possibility is that the individual reports allowed participants to 'see what they want to see,' interpreting the reports in a way that bolstered their preexisting beliefs [18]. However, if this were the case then the effect of the intervention would have been moderated by preexisting vaccine beliefs. Another possibility is that the reports increased the vividness of adverse events, making participants more vaccine-averse even when they judged that the vaccine did not cause the events [19]. A third possibility is that the presence of medical jargon and terminology in the reports reduced participants' level of certainty regarding vaccine decisions, making them less accepting [20].

3.1. Limitations and conclusions

This research was limited by the fact that real vaccination behavior was not measured. However, outcomes like trust in the CDC are not hypothetical, and reflect meaningful feelings in response to the information provided. Moreover, the information that participants responded to was completely real and taken directly from the VAERS database, and this is the first test (to our knowledge) of the influence of this information on vaccine attitudes. Furthermore, when conducting initial tests of a possible health intervention, ethical considerations suggest that the best approach is to test the intervention in hypothetical decisions first. These findings illustrate the importance of this approach, insofar as communicating about the detailed VAERS reports was harmful to vaccine attitudes.

This research was also limited by the fact that the sample was not restricted to parents making a vaccination decision for their child. However, given the observed results, we believed that it would be unwise and perhaps even unethical to replicate this study in a sample of parents making vaccine decisions for their child. Furthermore, about half of the sample reported being parents, and although parental status was associated with vaccine acceptance, the results involving the experimental intervention were neither mediated nor moderated by parental status or participant age. The lack of significant demographic moderators and the large sample powered to detect such effects indicates that the detailed VAERS reports similarly influence many different groups of people, including parents. Moreover, one of the primary outcome measures in this study was trust in the CDC, and results indicated that the detailed VAERS reports significantly reduced trust. Public trust in

government institutions is important regardless of one's parental status, age, or whether there is a discrete decision to be made.

The aim of this research was to test a novel approach to communicating about vaccines, with the hope that this would influence vaccine attitudes and increase trust. Although this study failed to identify a strongly effective new intervention, it did provide an important test of the influence of publicly available data on attitudes toward the HPV vaccine and trust in the CDC. We hope that this research will inform future research that seeks to improve vaccine acceptance.

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Contributors' statement

Dr Scherer conceptualized and designed the study, conducted the data analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Drs. Shaffer, Patel and Zikmund-Fisher conceptualized and designed the study, reviewed and revised the manuscript, and approved the final manuscript as submitted.

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