Vaccine xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Cancer-salient messaging for Human Papillomavirus vaccine uptake: A randomized controlled trial

Rachael M. Porter [a,b,*], Avnika B. Amin [a,b], Robert A. Bednarczyk [a,b,c], Saad B. Omer [a,b,c,d]

[a] Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA, United States
[b] Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA, United States
[c] Emory Vaccine Center, Emory University, Atlanta, GA, United States
[d] Department of Pediatrics, School of Medicine, Emory University, Atlanta, GA, United States

ARTICLE INFO

Article history:
Received 29 August 2017
Received in revised form 12 January 2018
Accepted 15 January 2018
Available online xxxx

ABSTRACT

Background and objectives: Vaccination with Human Papillomavirus (HPV) vaccine is recommended for 11–12 years-old, but uptake is suboptimal. Current messaging focuses on HPV infection transmission and prevention. Parents and providers are often uncomfortable discussing sexual practices of adolescents, contributing to the delay/refusal of vaccine. We created a cervical cancer-salient message encouraging HPV vaccination, emphasizing disease salience and disease threat, while promoting self-efficacy. We hypothesized this message would have greater effects on vaccine confidence and intent to vaccinate compared to Centers for Disease Control and Prevention (CDC) and non-vaccine control messages.
Methods: A 3-arm randomized trial was conducted. Parents of girls aged 9–17 were eligible for the study. We measured participants' vaccine confidence and intent to vaccinate at baseline and post intervention message. Recruitment and surveys were administered online through Amazon Mechanical Turk.
Results: 762 participants completed both surveys. We saw modest increases in vaccine confidence when comparing cervical cancer arm and control arm, and CDC arm and control arm; estimates were not statistically significant. The odds of reporting intent to vaccinate among the cervical cancer message arm were 1.13 times the odds of reporting intent to vaccinate in the control arm (95% CI: 0.30. 4.29). Intent to vaccinate was also not statistically significantly different between CDC message arm and control arm (OR = 1.25, 95%CI: 0.66, 2.37).
Conclusion: Neither message had effect on intent to vaccinate, highlighting need for research to identify successful messaging strategies for HPV. Exploratory analyses suggest among parents with 'Low' vaccine confidence at baseline, the cervical cancer framed message may be more effective in changing intention than the CDC message or non-vaccine control. Future work should target groups with 'Low' or 'Medium' vaccine confidence at baseline - they may be more amenable to change, and more receptive to disease-salient messaging.
Clinical Trial Registration: Clinicaltrials.gov, Reference #: NCT03002324.

1. Introduction

Human Papillomavirus (HPV) is the most common sexually transmitted infection in the United States [1]. Persistent HPV infection can lead to cancer, with cervical cancer being the most common cancer caused by HPV among women [2]. Across genders, incidence and prevalence of HPV-related oropharyngeal cancer (OPC) have increased, making the oropharynx most common site of HPV-related cancers [2,3]. There is no cure for HPV, but HPV infections are preventable through vaccination. Three HPV vaccines are currently licensed for use in the United States, and are given in 2 or 3 dose series depending on age at vaccination [4]. Despite being recommended for more than a decade, HPV vaccine uptake remains suboptimal [5,6]. Among adolescents aged 13–17 years old, uptake of at least 1 dose of HPV vaccine was 60.4%, while uptake of 3 doses was only 37.1%. For parents, an important factor for HPV vaccine uptake is provider recommendation [7–9]; however, provider discomfort when discussing child sexuality with parents is a significant barrier for providers in recommending HPV vaccination [10–12]. Additionally, parents may deem the vaccine unnecessary

Abbreviations: HPV, Human Papillomavirus; CDC, Centers for Disease Control; VIS, Vaccine Information Statement; VCS, Vaccine Confidence Scale; PACV, Parent Attitudes about Childhood Vaccines; CI, Confidence Interval.

* Corresponding author at: 1518 Clifton Road, Atlanta, GA 30322, United States.
E-mail address: rmp413@gmail.com (R.M. Porter).

https://doi.org/10.1016/j.vaccine.2018.01.040
0264-410X/

as their child is not sexually active [7]. However, this reasoning highlights the lack of parental appreciation of the HPV vaccine, as they miss the fundamental goal of vaccination as a prevention strategy provided prior to exposure [7,13].

Parental decisions to vaccinate their children, specifically with the HPV vaccine, can be tied to multiple behavioral constructs. These include perceived susceptibility of HPV infection (is my child at risk of infection), perceived benefit, and perceived severity (of disease, and of vaccine related adverse events) [14,15]. This would suggest that messaging surrounding the HPV vaccine should be highly salient within these constructs. However, messages currently being used - including messages from the CDC - are not focused on perceived susceptibility of cervical cancer, or perceived severity of cervical cancer; even though these factors have been identified as predictive to vaccination status among adolescents [16]. For example, the CDC's Vaccine Information Statement (VIS) has direct reference to HPV as a sexually transmitted disease, despite literature suggesting sexual reference is a factor contributing to vaccine refusal and delay [7,11,12]. Additionally, current CDC and other messages are not disease salient in regard to cervical cancer.

We sought to create a message to promote HPV vaccination, framing HPV vaccination as protection against cervical cancer. We designed a message to emphasize disease salience and disease threat, and promote self-efficacy. We hypothesized that a cervical cancer targeted message would have an equal or stronger effect on intent to vaccinate than currently available messages from the CDC, compared to a control message.

2. Methods

We conducted a 3-arm randomized trial, comparing three messages - a CDC HPV message, a cervical cancer-salient message, and a non-vaccine control message - on attitudes towards adolescent vaccines and intent to vaccinate adolescents with the HPV vaccine. This study was conducted among parents of females 9–17 years old. Study participants were recruited online through Amazon Mechanical Turk, and followed for 2 weeks to assess attitudes toward vaccination, vaccine confidence and intent to vaccinate before and after message delivery. The Emory University Institutional Review Board approved all study activities (Study #00087211). This trial is registered on ClinicalTrials.gov, under reference number NCT03002324.

Eligibility criteria for our study included: men and women who were over 18 years at the time of recruitment, who had at least one daughter aged 9–17 years, who currently lived in the United States, and had heard of HPV. Recruitment was conducted through Amazon Mechanical Turk web services, and screening and survey administration were conducted using SurveyMonkey. Participants, regardless of eligibility, were given $0.05 for successfully completing the screening questions. Participants eligible to enroll in the study who finished the baseline survey were rewarded $0.95, to a total of $1.00. Participants who returned 2 weeks later to complete the follow-up survey were rewarded an additional $2.00, for a total $3.00 in compensation for all counted in the final sample.

Participants randomized to the non-vaccine related control arm read a passage about bird feeding, which was used as a control in similar trials [17,18]. Participants randomized to the CDC message arm read a message taken almost directly from the CDC VIS on HPV [19] that was minimally altered for length and clarity. Participants randomized to the cervical cancer-salient messaging arm read a message developed by the study team. All messages fell between 8.7 and 9.1, inclusively, on the Flesh-Kincaid grade level reading scale. This range was used to keep our messages' reading level consistent and comparable to the CDC message, which has a reading level of 9.1.

There were two co-primary outcome measures in this study: (1) vaccine confidence, quantified by change in score on the Vaccine Confidence Scale (VCS) [20,21], and (2) intent to vaccinate daughters with the HPV vaccine, measured through questions constructed by the study team. The VCS is an 8-point questionnaire built on constructs of 'benefits', 'harms' and 'trust'. Four questions on the scale contribute to the 'benefits' factor, and are related to safety and advantages of vaccinating your teenager. Two questions on the scale correspond to the 'harms' factor, and touch on perceived negative effects of vaccinating your teenager, including adverse events. The final two questions of the scale focus on the parent and healthcare provider relationship, which correspond to the 'trust' factor [20]. The response to each of these eight statements is a scaled response from 0 to 10, with higher score relating to positive attitudes towards vaccines [20]. Overall VCS scores were calculated by averaging the numeric answers to the eight questions, while reverse coding the responses for the two 'harms' related questions. We assessed participant's scores on the VCS prior to message delivery, with comparison to scores after they received one of the randomized messages.

The baseline survey assessed participants' attitudes towards vaccines, quantified hesitancy toward vaccines, knowledge of HPV, and sociodemographic characteristics. Key sociodemographic data collected included the eligible child's age, parent age, race/ethnicity of parent, gender of parent, number of children in household, average income of household, marital status of participant and participants' education level. Questions used to assess participants' attitudes, knowledge, and beliefs during this study were adapted directly from the Vaccine Confidence Scale and the Parent Attitudes about Childhood Vaccines (PACV) short scales [20–23]. Participants were asked if their child has received at least one dose of HPV vaccine (yes/no/I don't know), and if they intend to complete the series (if yes) or their intent to vaccinate their child (if no or I don't know). In analysis, these questions were combined to create one value for intention. The post intervention questionnaire included Vaccine Confidence Scale and PACV short scale questions, as well as six questions about overall engagement in the messages. Participants were again asked about their intent to complete the vaccine series or intent to vaccinate their child with the HPV vaccine, dependent on their child's vaccine status.

Sample size calculations were completed using PASS (version 11, NCSS LLC, Kaysvile, Utah) using the one-way ANOVA procedure. A mean score of 8.19 (standard deviation = 3.0) on the Vaccine Confidence Scale was used as the baseline, based on the work of Gilkey et al. on the Vaccine Confidence Scale [20]. Given these parameters, the proposed number of study participants was 699, with 233 participants in each study arm, to yield 90% power to detect a 0.5-point change in VCS. We assumed 50% of participants would return for the second survey, and thus aimed to enroll 1450 participants at baseline.

Descriptive statistics were used to summarize participant sociodemographic characteristics. Bivariate analyses were conducted to assess randomization of sociodemographic characteristics by intervention arm using chi-square and t tests. Differences between post-intervention and baseline VCS scores were computed and used as a primary outcome. Mean differences in VCS scores were compared between each intervention arm and the control arm using unpaired t tests with unequal variance assumptions.

For all regression analyses, the sample was restricted to allow for comparisons between one intervention arm and the control arm, with independent comparisons between the CDC message and control arms, and the cervical cancer-salient message and the control arms. Logistic regression models were used to compare

Please cite this article in press as: Porter RM et al. Cancer-salient messaging for Human Papillomavirus vaccine uptake: A randomized controlled trial. Vaccine (2018), https://doi.org/10.1016/j.vaccine.2018.01.040