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Immunization effects of a communication intervention to promote preteen HPV vaccination in primary care practices

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ABSTRACT

Objectives: HPV vaccination at the recommended ages of 11–12 is highly effective yet has stalled well below the goal of 80% of the population. We evaluated a statewide practice-based communication intervention (tools: brochures, posters, online training for providers and resources for parents, video game for preteens) to persuade parents, preteens and providers to vaccinate against HPV. The 9-month intervention started May 1, 2015.
Methods: We compared vaccine initiation and completion rates over three 9-month periods (baseline, intervention, post-intervention) between practices enrolled in the intervention and a comparable comparison group. All practices reported to the North Carolina Immunization Registry (NCIR) and had at least 100 11- and 12-year-olds who had not completed the HPV vaccine series. Of 175 eligible practices, the 14 intervention practices included 19,398 individuals and the 161 comparison practices included 127,896 individuals. An extended Cox model was used to test the intervention effect.
Results: The intervention had a significant effect on both initiation and completion during the intervention and post-intervention periods; the estimated hazard ratio (HR) for initiation was 1.17 ($p = .004$) during the intervention and 1.11 ($p = .005$) post-intervention. Likewise, completion during the intervention period was 17% higher in intervention practices, after controlling for baseline differences. This effect increased in the post-intervention period to 30% higher ($p = .03$).
Conclusions: Individuals in the intervention practices were 17% more likely to initiate and complete HPV vaccination than in the comparison practices during the intervention period and the effect was sustained post-intervention. This intervention is promising for increasing rates of HPV vaccination at ages 11–12.

1. Introduction

A vaccine to prevent the acquisition of human papillomavirus (HPV) types that cause genital warts and cancers was recommended by the Advisory Committee on Immunization Practices (ACIP) for routine use in females in 2006 and in males in 2011 [1,2]. More than ten years later, uptake of the vaccine has stalled well below the goal of 80% of the population [3], with only 50% of females and 38% of males ages 13–17 in the United States having completed the 3-dose series in 2016 [4]. In October 2016, ACIP recommended a 2-dose series if the HPV vaccine was initiated before the age of 15 [5]. Preteens can receive HPV vaccine at the same clinical visit as Tdap and meningococcal vaccines yet often do not [4]. The result is that a highly effective medical innovation to prevent HPV-related disease goes unused in a large segment of the population [3].

Many parents may not consent to HPV vaccination because of concern about safety, side effects and possibly encouraging early sexual activity [6]. Many providers do not stress early vaccination as most effective [7–9] Other clinical care setting interventions to promote HPV vaccination have focused on (1) stressing cancer prevention [10], (2) bundling recommendation of HPV vaccination with other adolescent vaccinations (Tdap and meningococcal) [11], (3) training providers to issue a strong, presumptive recommendation [9], (4) assessing the effect of "an announcement" vs a "conversation" with parents [12], and (5) helping with quality control efforts in the clinic through medical record searches and reminders, text messages and training [13].

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With extensive input from parents, preteens and providers [14,15], we developed tools to encourage communication and persuade parents and providers to choose HPV vaccination at the routine recommended ages of 11–12. These tools include print and online materials discussing the risk of HPV infection and more immediate consequences of HPV-related disease (e.g., genital warts) and involving the preteen in the decision making process [16–18], a strength of this particular intervention and a gap in previous interventions. To evaluate our main intervention outcome, we analyzed data from the North Carolina Immunization Registry (NCIR) to compare pre-intervention immunization initiation and completion of 11–12 year olds with post-intervention immunizations.

2. Methods

2.1. Study design

The *Protect Them* study tests the effectiveness of a practice-based communication intervention to promote preteen vaccination against HPV. Intermediate outcomes include reported discussion about HPV and HPV vaccination among provider, parent and preteen. Vaccination outcomes include initiation and completion of the HPV series.

To ensure statistical power, we recruited practices that reported to the NCIR and had at least 100 11- and 12-year-olds who had not yet completed the HPV series. Practices were enrolled through recruitment in random order with a goal, based on statistical power, of 16 practices per study wave. Eligible practices that declined or who were not contacted served as a comparison group. The study was approved by the University's Institutional Review Board.

2.2. Setting

We divided North Carolina into three approximately equal geographic regions and conducted the study in three waves from 2015 to 2017. Multiple waves allowed for adjustment due to secular trends, e.g., change in vaccination recommendations to 2 doses before the age of 15 and Food and Drug Administration (FDA) license of a 9-valent vaccine. This paper describes the results of Wave 1 and includes eligible practices in the central region of NC.

2.3. Intervention description

The *Protect Them* study fosters conversations about HPV vaccination and the prevention of STIs and cancer; the focal groups are providers, parents and preteens and the setting is the clinic. Research staff recruited the practices in random order by first sending a fax about the study, then following up by phone for a response. We approached 62 practices to enroll a sample of 14 practices for Wave 1. We asked practices to 1) commit 50% of their providers to online training about vaccine epidemiology, communicating with parents and preteens about HPV and HPV vaccine, and systems level supports; 2) display posters and brochures in English and Spanish with the headline "1 in 2 people will get HPV, which causes genital warts and cancer" for 9 months in their clinics; and 3) screen parent/preteen dyads for a smaller nested study (data not reported here) to test the acceptability and efficacy of an original video game, *Land of Secret Gardens*. The game uses growing a healthy garden as a metaphor for a healthy body protected against HPV. The intervention lasted 9 months to allow time for vaccination initiation and completion of the series by at least a portion of preteens. Incentives included $2000 (practice), $100 (provider) and $100 in gift cards (dyads in the nested study) to complete pre and post surveys and use the materials. Process and outcome evaluations of these components on intermediate outcomes (e.g., changes in knowledge, beliefs, attitudes, communication) are ongoing.

2.4. Sample

There were 175 eligible practices for inclusion in Wave 1. From February 2015 to May 2015, sixty-two practices were contacted to yield 14 practices for the study (enrollment rate of 22%). The other 161 practices served as a comparison group. We contacted 24 practices at least once, 32 at least two or more times and visited six in person. Most frequent reasons given for not enrolling were: no time, practice undergoing change and understaffed.

In the intervention group, data collection included surveys of practices and providers pre and post intervention (not reported here). For both the intervention and comparison groups, NCIR vaccination data were collected over a 27-month period (9-months pre-intervention, 9-months during intervention, and 9-months post-intervention, from Aug 1, 2014-Oct 31, 2016) and were provided in a de-identified dataset to the study team from the state health department.

Individuals were included in this analysis if they had not completed the three-dose HPV series before the start of the study period. For the majority of our statistical models, we included participants who were 11–13 years old (our targeted age range for vaccination) any time during the study period. Because of the length of the study, this captured a set of individuals who ranged in age from 9 to 14 years old at the start of the 9-month intervention. In a follow-up analysis of whether the intervention had a differential effect according to age, we expanded the sample to include all participants who were 9–14 at the start of the intervention, regardless of whether they were 11–13 at any time during the study period.

2.5. Statistical analysis

The NCIR registers child and adolescent vaccines given in North Carolina and tracks each child and adolescent with a unique ID number that translates across practices. The registry includes information about vaccines given in NC (date, vaccine type, and provider) as well as historical vaccine information from medical records. In addition, the registry includes child and adolescent date of birth and race/ethnicity. The NCIR also contains limited information about the socioeconomic status of each child by indicating whether the child is eligible for a publicly funded vaccine (Medicaid, Uninsured, Underinsured, or membership, e.g., Indian Health Service). We use the eligibility and race/ethnicity variables in our analyses as a way of capturing differences among practices.

As we did in a previous study using NCIR data [17], we built time-to-event models with time-varying predictors to account for intervention status. The two vaccination outcomes of interest were initiation of the HPV series and completion of the three-dose HPV series. For each outcome, we used the Cox models to test whether intervention practices experienced increased vaccination during the 9-month intervention period and whether there were sustained improvements during the 9-month post-intervention period.

The model is an extended Cox model with both time-independent and time-varying predictors [19]. The model includes a time-independent indicator of whether an individual is in an intervention practice, X_1. The first time-varying predictor, $X_2(t)$, captures the start of a practice's participation in the intervention. An additional time-varying covariate, $X_3(t)$, is used to model the incremental effect of the post-intervention period. The model predictors control for a systematic baseline difference in vaccination hazard. The model parameters are β_1, β_2, and β_3 for X_1, $X_2(t)$, and $X_3(t)$ respectively. The parameter β_1 control for baseline