Does a Customized Website Affect HPV Vaccine Use among Latino Adolescents and Young Adults?

Amanda F Dempsey, MD, PhD, MPH, Julie Maertens, PhD, Andrea Jimenez-Zambrano, MPH, Carter Sevick, MS**

**All authors are members of the Adult and Child Consortium for Outcomes Research and Dissemination Science (ACCORDS) Program at the University of Colorado Denver.

Original Project Title: A Randomized Controlled Trial of a Web-based Educational Intervention for Latino Young Adults and Parents of Adolescents to Minimize Disparities in HPV Vaccination

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Abstract

Background: Human papillomavirus (HPV) causes a number of cancers and other diseases, several of which disproportionately affect Latinos. Unfortunately, Latinos also have poor uptake of HPV vaccines, which prevent HPV-associated diseases. There is a paucity of research on interventions to increase HPV vaccination among Latinos, which our work sought to address.

Objectives: The objectives of the project were to (1) use community input to create a web-based educational intervention for Latino young adults (aged 18-26) and parents of Latino adolescents (aged 9-17) that provided individually and culturally tailored information about HPV for Latinos; (2) compare the impact of the intervention versus an untailored web-based educational intervention based on the HPV Vaccine Information Sheet from the Centers for Disease Control and Prevention, versus usual care (individualized physician discussion of the vaccine and/or receipt of a paper version of the on HPV Vaccine Information Sheet) on vaccine use among young adults and adolescents.

Methods: In phase I, community input representing end-users of our intervention created the intervention for Latinos. In phase II, we evaluated this new intervention, called CHICOs (Combatting HPV Infection and Cancers), in a 3-armed, randomized controlled trial conducted in the waiting rooms of 5 family medicine practices serving mainly Latinos. We assessed the relative efficacy of CHICOs versus an untailored intervention, both of which were delivered via iPad, versus usual care for their impact on HPV vaccine uptake among adolescent and young adult Latinos. Eligible participants were English- or Spanish-speaking young adult patients (aged 18-26) or parents of Latino adolescents (aged 9-17) who reported not yet completing the 3-dose HPV vaccine series (i.e., 0, 1, or 2 doses). Data on the primary outcomes—6 different measures of HPV vaccine uptake—came from the clinics’ medical records and the statewide immunization registry. The primary analyses were 2-way comparisons between arms (i.e., tailored versus untailored, tailored versus control, untailored versus control), stratified by adolescent versus young adult vaccination. We used multiple imputation to account for missing data and analyzed data using an intent-to-treat (ITT) approach. Secondary outcomes included
changes in vaccination intention from before to after viewing the iPad materials (tailored and untailored arms only), time between study enrollment and HPV vaccine doses received (all arms), and patterns of utilization of the tailored and untailored websites.

**Results:** Significant Latino community input through a series of 6 focus group and quarterly meetings with a community advisory board in phase I was used to create CHICOs. Phase II enrolled 1294 parents and young adults. In the ITT analyses, nearly all vaccination outcomes assessed in 2-way comparisons demonstrated no statistically significant differences between groups. The 1 exception was completion of the series among adolescents who entered the study with at least 1 dose. In this analysis, the tailored group performed significantly better than the untailored group (odds ratio [OR] 2.0; 95% confidence interval [CI], 1.1-3.8) but there were no statistically significant differences in completing the 3-dose series among this subgroup when the tailored intervention was compared against usual care (OR 1.6; 95% CI, 0.8-3.2). Few young adults received HPV doses. Individuals in the untailored arm took a statistically nonsignificant longer time to receive vaccine doses than those in the untailored or usual care arms. The untailored and tailored interventions significantly improved vaccination intention from baseline to postintervention; the amount of change was the same in the 2 groups.

**Conclusions:** Neither the tailored intervention nor the untailored intervention improved HPV vaccination outcomes in adolescents and young adults. In young adults, the rate of HPV vaccination was uniformly low across the 3 study arms, resulting in high rates of missing data.
**Definitions:**

**Decision quality related to HPV vaccination** – How comfortable participants feel with their decision to get or not get the vaccine, assessed with a variety of validated measures

**Entering the study unvaccinated** – Enrolling the study without any prior HPV vaccine doses

**Vaccine acceptance** – Generally agreeing with receiving the vaccine, but not necessarily stating it

**Vaccine initiation** – Receiving the first of the needed 3 doses in the HPV vaccine series

**Vaccination intention** – Specifically stating that one plans to get (or have one’s adolescent get) vaccinated

**Vaccine series completion** – Receiving all 3 doses in the HPV vaccine series

**Vaccine uptake** – Receiving a vaccine dose

**Abbreviations**

**CAB** – community advisory board

**CDC** – Centers for Disease Control and Prevention

**CHICOS** – Combatting HPV Infection and Cancers, an individually tailored, web-based educational intervention

**CIIS** – Colorado Immunization Information System, a statewide vaccine registry

**EMR** – Electronic Medical Record

**HPV** – human papillomavirus

**PCORI** – Patient-Centered Outcomes Research Institute

**PP** – per protocol

**RA** – research assistant
I. Background

This application discusses the development and assessment of an educational website called CHICOS (Combatting HPV Infection and Cancers), which the investigators created with an overall goal to inform parents of Latino adolescents and young adult Latinos about human papillomavirus (HPV) infection and vaccination in a culturally relevant and sensitive way.1 The overarching goal of the project was to understand whether this web-based intervention designed to address the unique attitudinal, infrastructural, and insurance/cost barriers faced by individual Latino parents and young adults in making decisions about the HPV vaccine could increase HPV vaccine utilization.

HPV is a family of viruses transmitted mainly through intimate sexual contact. Consistent with the US population overall, Latinos have a high prevalence of HPV infection, estimated to affect more than 80% of sexually active adults during their lifetime.2 Most infections (~75%) occur during adolescence and young adulthood.3,4 Diseases caused by HPV include cervical, oropharyngeal, anal, vaginal, penile, and vulvar cancers, and noncancerous conditions such as cervical precancers (i.e., abnormal Pap smears) and genital warts. HPV affects large numbers of both women and men.3-5

More than 14 million people are newly infected with HPV in the United States each year, with 79 million (~12 million Latinos) infected at any given time, exacting a significant emotional, financial, and medical toll.2,5-7 Though HPV infection is similarly prevalent in nearly all race and ethnicity groups, significant disparities in HPV-associated cancers exist for Latinos. For example, Latinas have the highest risk of contracting cervical cancer compared with all other population groups in the US, and Latinos have the highest risk of developing penile cancer.5 Other HPV-related illnesses like genital warts, abnormal Pap smears, anal cancer, and oropharyngeal cancer are also highly prevalent in this population.5

HPV vaccines that protect against the most clinically prevalent types of HPV have been available since 2006 for females and 2009 for males.8 These vaccines are highly effective and, based per-
protocol analyses from randomized controlled trials of the vaccine’s ability to prevent HPV infection, genital warts, and cervical precancers, their potential to protect against infection with the HPV types responsible for 90% of genital warts cases and 50% of abnormal Pap smears. At the time we implemented the study, 3 doses of vaccine were required for full protection against HPV infection, and were preferentially recommended for adolescents so as to provide the vaccine prior to exposure to the virus, which typically occurs shortly after the onset of becoming sexually active. In 2015, after the study was complete, the recommendation changed to 2 doses of vaccine if the series was initiated before age 15, and 3 doses of vaccine if the series was initiated at age 15 or older. Although the vaccine has been recommended by the Centers for Disease Control and Prevention (CDC) for the past several years for routine use among all adolescents aged 11 years and older, vaccination rates have been, and continue to remain, low in the United States. As of 2015, it was estimated that only 41.9% of girls and 28.1% of boys aged 13-17 nationally had received the full 3-dose vaccine series. Vaccination rates are slightly higher among Latinos (46.2% for girls, 35.0% for boys), but still far below that of other adolescent vaccines, and significantly below the national vaccination target level of 80% coverage. Without significant increases in HPV vaccination, especially among high-risk populations like Latinos, disparities in HPV-related cancers are likely to continue.

Numerous barriers to HPV vaccination have been described in the literature, including barriers specific to the Latino population. These include issues related to parents’ concerns about the safety and necessity of HPV vaccines, that children will misconstrue their parents’ consent to vaccination as permission to engage in sexual behavior at a young age, and about the vaccine’s cost. While understanding the various barriers to HPV vaccination is useful, numerous medical organizations have recently put forth a “call to action” for research on effective interventions to improve HPV vaccine utilization. However, despite significant effort in this area, few interventions have been shown to have demonstrated effectiveness in improving vaccination rates, especially interventions targeting parents. This is a critical gap in knowledge because adolescents are the preferred target population for vaccination, and parents are the “gatekeepers” for adolescent vaccines—parental consent is required for any
vaccine to be administered to adolescents younger than age 18. Thus, while the reasons individuals in general, and the Latino population specifically, do not get the HPV vaccine have been well described in the literature, there is a paucity of information on effective interventions to mitigate these issues.

We sought to address this knowledge gap by developing a web-based intervention for Latinos about HPV vaccination. This intervention was driven by community input regarding what information this population wanted and needed when considering the HPV vaccination decision. The resultant CHICOs intervention was novel in that it used individual-level responses to a baseline questionnaire to create personalized educational web pages on HPV infection and vaccination that were responsive to each user’s unique informational needs. We then conducted a randomized controlled trial to evaluate the relative efficacy of CHICOs versus an untailored intervention versus usual care in improving HPV vaccination rates among Latino adolescents and young adults. The notion behind this research was that if an intervention could be identified that effectively improved HPV vaccination rates among Latinos, and was widely disseminated, this could lead to eventual decreases in disparities in HPV-related cancers experienced by this population.

In the following Methods and Results sections, information is divided into separate sections to delineate activities involved in phase I (intervention development) and phase II (intervention assessment). A discussion at the end synthesizes results from both phases and contextualizes them within the published literature.

II. Engagement

While the original idea for the project arose from the research team, stakeholders were involved throughout the project. At the time of the project’s conception, the idea for the study (that is, creating an individualized, web-based educational tool about HPV vaccination for Latinos) was vetted among 3 potential end-users of the intervention (2 parents of adolescents and 1 young adult) at the clinical sites (primary care clinics) where the study was proposed to take place. We provided quotes from these participants as well as letters of support with the
original grant proposal to the Patient-Centered Outcomes Research Institute (PCORI), which funded this work. Decisions about stakeholder involvement were made prior to the project starting and are described in more detail in the Methods section below.

After the study began, patient engagement continued throughout the project in the form of an ongoing community advisory board (CAB; described in detail below) throughout the 3-year duration of the project. The CAB, which met quarterly, provided significant input into the intervention design, helped with participant recruitment, facilitated study implementation at the clinics, assisted in data interpretation, helped present results at a national conference, and collaborated on developing a dissemination plan. We continue to be in touch with members of the CAB as we discuss additional plans for the intervention in the future.

III. Methods

Rationale for the Intervention
The main intervention developed and tested in this study was an educational website, called CHICOS, that provided individually customized information about HPV infection and vaccination to parents and young adults. CHICOS was developed in close collaboration with the CAB, and further informed by focus groups. The scientific premise of the intervention is rooted in the concept of message tailoring. Message tailoring refers to customization of information to each individual and has been shown in a number of web- and paper-based interventions to improve compliance with recommended health procedures across diverse settings, clinical issues, and populations.\textsuperscript{35,36} It is believed to work by making the information provided more personally relevant, and therefore more engaging and likely to be acted on. Prior studies have demonstrated that there is a wide array of attitudinal barriers to HPV vaccination, that barriers differ depending on whether a patient is considering initiating the series or completing it, that some barriers are culturally specific, and that providers often lack enough time during clinical visits to discuss the HPV vaccine in depth with patients. Thus, our hypothesis was that a
message tailoring intervention for HPV vaccination, delivered immediately prior to the clinical visit, could provide parents and young adults with the right kind of personally tailored information that would answer questions or alleviate concerns they may have had about the vaccine. In turn, this would result in increases in HPV vaccine utilization compared with an untailored or usual care intervention.

**III.A Phase I: Intervention Development Using Community Feedback**

**Overview**

The first phase of the study used an iterative, community-oriented modification approach to adapt for the Latino population a previous version of a web-based educational vaccine intervention that provided individually tailored messages about HPV and 3 other adolescent vaccines. Described below are the CAB meetings and community focus groups that informed the modifications to this intervention. All study activities were approved by the Institutional Review Board of the University of Colorado Denver. A detailed description of the focus group study, providing more details on the study procedures and results, has been published.¹

**Study Design and Setting**

To develop CHICOS, we modified Teen VaxScene, a website that was developed primarily for a Caucasian population in the Midwest (https://www.teen-vaxscene-info.org/sign-up/). Our modification approach incorporated feedback from a CAB that represented our target population (parents of Latino adolescents and young adult Latinos), and data from a series of community focus groups with members of the target population. CAB meetings were held in a community center meeting room at a location central to the participants (i.e., library, rec center). Focus group meetings were held in a community meeting building in Aurora, Colorado.

**Participants—CAB Population**

Our CAB was derived using a purposeful snowball recruitment strategy and comprised 5 Latino parents of adolescents and 4 young adult Latinas. Though attempted, we were unsuccessful in recruiting male participants for the CAB. We recruited participants from community
organizations that serve Latino families, staff from the clinics where the planned randomized trial was to take place, and the general community. Three additional members on the CAB represented community and academic stakeholder agencies serving Latinos.

Participants—Focus Group Population
We recruited 20 Latina young adults and 27 Latino parents of adolescents for focus groups from 5 primary care clinics in Colorado that serve low-income, primarily Latino, medically underserved and migrant farmworker populations as the priority clientele, and from the Denver metro area Latino community. These 5 sites were also the clinics where the randomized controlled trial was to take place. Recruitment occurred via advertisements posted in the 5 clinics and community venues. Eligible parents self-identified as being Hispanic or Latino, were ≥ 18 years old, were able to converse in English or Spanish, and reported having an adolescent between the ages of 11 and 17 years old who had not been fully vaccinated. Eligible young adults self-identified as being Hispanic or Latino, were between 18 and 26 years old, were able to converse in English or Spanish, and had not received all 3 doses of the HPV vaccine (ie, 0, 1, or 2 doses). We considered young adult and parent participants ineligible if they could not converse in English or Spanish, or if they/their adolescent had already completed the 3-dose HPV vaccine series. In the end, 20 Latina young adults and 27 Latino parents of adolescents participated in the focus groups.

Outcomes
Outcomes consisted of qualitative feedback from focus groups and the CAB on ways to modify the Teen VaxScene intervention

Setting
CAB meetings and focus groups took place in community settings (ie, library, community center) near the participants’ homes.

Time Frame
All focus group and CAB meetings related to intervention development occurred over a 12-month period from June 2012 to May 2013.

**Research Process, Data Collection, and Data Sources**

Our initial CAB meetings focused on ways to potentially modify Teen VaxScene for the Latino population. We solicited feedback regarding the design, navigation, and content of the website. The research team collated these suggestions and used them to develop a focus group guide and related materials for subsequent focus group sessions with English- and Spanish-speaking young adults and parents of adolescents. The focus group guide (English version) is provided in the Appendix.

We then held focus group meetings to solicit broader input about modifying Teen VaxScene content and design for the Latino population, and to further understand the perspectives of this population about factors that impact decisions around initiating and completing the recommended HPV vaccine series. Trained members of the research team conducted 6 focus group meetings, each of which lasted approximately 90 minutes. Three meetings were conducted in English, and native Spanish speakers conducted 3 meetings in Spanish. Facilitators followed a written interview guide that included a discussion about attitudinal, infrastructural, and cultural factors that impact decisions about HPV vaccination. Following this, the groups provided structured feedback on the HPV component of Teen VaxScene, specifically its overall appeal, design, layout, functionality, and content. Groups were also asked to suggest additional information and features to include in the future iteration of the intervention. All focus groups were audio-recorded and transcribed verbatim. Spanish transcripts were translated into English by a native Spanish speaker, and then validated by a second native Spanish speaker for accuracy and clarity.

After the focus groups were complete, the CAB held 3 subsequent meetings to make iterative revisions to the intervention logo, color scheme, and content that incorporated their evolving opinions about the intervention. In these meetings, the CAB also assisted the research team in

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interpreting results from the focus groups and operationalizing these results into intervention modifications. Two members of the study team collected CAB feedback through detailed written meeting notes and best practices documents, and then combined feedback to complete a final summary. The study team subsequently shared notes with CAB members to ensure all relevant information was adequately captured and modified as needed. The CAB also participated heavily in phase II of the project, detailed below.

**Analytical Approach**

CAB members reviewed all meeting notes to ensure clarity and completeness. We conducted focus group data analysis using established qualitative content analysis methods. Two members of the study team reviewed transcripts and CAB meeting notes to categorize responses into themes pertaining to factors impacting decision making regarding HPV vaccination, and suggestions for modifying the intervention. The 2 study team members developed initial code categories independently and then compared and discussed them with a third member of the study team until they achieved code agreement. Analysts then applied the resulting codes to the transcripts, and subsequently met routinely to check new findings, discuss emergent new codes and themes, and assess the preliminary results of the analysis process. Discrepancies in coding were resolved by mutual agreement between the reviewers. Throughout the analytic process, we used the qualitative data software program ATLAS.ti ([computer program]. Version 7.0. Berlin, Germany: Scientific Software Development GmbH) for data organization and management. Comments from the CAB and focus groups were synthesized and summarized into a list of edits for the intervention development team and subsequently incorporated into the final version of the intervention. Ultimately, the CAB renamed the intervention, which was now HPV-specific, to CHICOs (Combatting HPV Infections and Cancers).

**III.B Phase II: Intervention Implementation**

*Study Design Overview*
Phase II of the study was a 3-armed randomized controlled trial comparing different strategies for informing decisions about HPV vaccines: (1) the culturally and individually tailored educational website intervention, CHICOS, as described above; (2) an untailored, web-based intervention modeled on the CDC’s Vaccine Information Sheet for HPV (these sheets are required to be given to patients in paper format prior to HPV vaccine administration and therefore represented an electronic version of usual care); and (3) “usual care” (described in detail below). We enrolled 2 groups of participants—Latino young adults aged 18-26 years who were making the vaccination decision for themselves, and Latino parents of adolescents aged 9-17 years old who were making vaccination decisions for the adolescent child. The main outcomes assessed were measures of HPV vaccination uptake (assessed for young adults and adolescents separately), and self-reported decision quality related to HPV vaccine decision making and utilization (assessed for young adults and parents of the adolescents). The main intervention took place in the clinics’ waiting rooms during a single clinic visit. The intervention lasted 16 months. Vaccination assessments occurred after 5 additional months of data collection on vaccination outcomes. We provided to participants an optional follow-up survey 3 months after study enrollment to assess their views on the interventions provided and how these may have impacted their vaccination decision making. The study was registered on ClinicalTrials.gov (NCT02145156). All study activities were approved by the Institutional Review Board of the University of Colorado Denver.

**Study Design**

The study was an individual-level, 3-armed randomized trial.

**Participants**

**Enrollment Procedures**

Enrollment for the study was facilitated by 2 methods: (1) self-referral to an informational table/desk set up by research assistants (RAs) in clinic waiting rooms (passive recruitment); and (2) RAs approaching specific individuals sitting in the waiting room to assess interest (active recruitment). For the active recruitment, each morning the RAs reviewed the clinic’s
appointment schedule to determine if any patients scheduled for that day might be eligible for participation based on age. The RAs approached these patients (or their parents) directly at the time of check-in for their clinic visit to assess their interest and eligibility. Several CAB members were employees at the clinics where participants were enrolled and assisted the research assistants in identifying participants and facilitating recruitment (i.e., finding a quiet space to discuss the study with the participant).

Eligibility

The RAs assessed eligibility using a predetermined set of questions programmed onto an iPad. RAs read the questions aloud, in either English or Spanish (depending on participant preference), and directly entered responses into the iPad.

We considered parents of adolescents eligible to participate in the study if they met all of the following criteria:

1) Reported they were the parent or primary guardian of an adolescent between the ages of 9 and 17
2) Reported that the adolescent had not yet received all 3 doses of the HPV vaccine at the time of study enrollment
3) Were able to read and converse in either English or Spanish
4) Reported that the adolescent was a patient at a participating clinic

We considered young adults eligible to participate in the study if they met the following criteria:

1) Were between the ages of 18 and 26
2) Reported that they had not yet received all 3 doses of the HPV vaccine at the time of study enrollment
3) Were able to read and converse in either English or Spanish
4) Reported they were a patient at a participating clinic
We excluded potential participants if their/their adolescent’s reported age range fell outside that acceptable for HPV vaccination, they were not able to read in English or Spanish, they reported they/their adolescent had already completed the 3-dose HPV vaccine series, or they were not/their adolescent was not a patient at the clinic. So as to gather preliminary data on how the intervention may perform in other groups, Latino ethnicity was not an eligibility requirement, but ethnicity data were collected for participants enrolled in the study.

**Consent**

The iPad was programmed to recognize eligible participants based on their responses to the eligibility questions. Those who were deemed not eligible were thanked for their interest and told they could not participate. RAs asked those who were eligible about their willingness to participate in the study. If they were willing to participate, the RA obtained written informed consent at that time. Participants were provided with a copy of the consent form that described the study purpose, population, risks and benefits, and voluntary nature of the study, and provided contact information for further questions. Receipt of consent was then input into the iPad to continue the study for that participant.

**Enrollment**

More than 4600 participants were approached for participation in the randomized controlled trial. Of these, 1585 were not screened for eligibility due to their already participating in the study or lack of interest in the study. Of the 3100 participants screened for eligibility, 1780 were found to be ineligible based on the iPad assessment of answers to eligibility questions, 3 did not consent, and 13 left before being randomized. This left a sample of 1294 participants to be randomized (Figure 1). This cohort comprised the intent-to-treat population for the analysis.

**Per-protocol (PP) Population**

Shortly after the intervention began, we discovered that we had not instituted a process for collecting adolescents’ names from parent participants—a data element needed for matching them to vaccination records. This information was collected for the tailored and untailored
groups as part of the baseline survey, but a similar process was not initially in place for the usual care arm as this survey was delivered on paper. This resulted in more than 150 parents in the usual care arm completing the postintervention survey for which we did not have the name of their adolescent and thus could not link to their vaccination records. When we discovered this, the research team reached out by phone and mail to gather this information. These efforts were only partially successful. In the end, we did not know the names of 72 adolescents of parents in the usual care arm. These participants with missing data were eliminated from the PP analysis, which is presented in the Appendix to this report.

Figure 1. CHICOS Consort Diagram for Vaccination Outcomes

- **Enrollment**
  - Assessed for eligibility (n = 4680)
  - Excluded (n = 3386)
    - Did not consent (n = 8)
    - Did not meet inclusion criteria (n = 1780)
    - Declined to participate (n = 777)
    - Already participated (n = 808)
    - Never randomized (n = 13)
  - Enrolled, consented, and randomized (n = 1294)

- **Allocation**
  - Tailored intervention (n = 430)
  - Untailored intervention (n = 425)
  - Usual care (n = 439)

- **ITT Analysis**
  - Analyzed (n = 430)
    - Young adult, n = 143
    - Adolescent, n = 287
  - Analyzed (n = 425)
    - Young adult, n = 151
    - Adolescent, n = 274
  - Analyzed (n = 439)
    - Young adult, n = 152
    - Adolescent, n = 287

- **Follow-up**
  - Completed in office study (n = 408)
  - Completed in office study (n = 404)
  - Completed in office study (n = 438)

- **PP Analysis**
  - Completed in office study (n = 404)
  - Completed in office study (n = 438)
As described above, 1294 participants were randomized. Of these, we could not match 281 to any vaccination or EMR records at the end of the study period and thus also excluded them from both the intention-to-treat and per-protocol vaccination analysis (tailored n = 84, untailored n = 79, usual care n = 118). The main reasons for not being able to match records were variations in the names provided by the parent or participant and the EMR/ Colorado Immunization Information System (CIIS), records which precluded us from being able to definitively conclude there was a match. In addition, some patients indicated they were a patient in the clinic (a requirement for study participation) when in fact they were not—these patients did not have EMR records, and if they had also not been vaccinated, would not have any CIIS records. Of the participants enrolled in the study, 85% had EMR data available, 76% had CIIS data available (not mutually exclusive categories), and 22% participants had no data available in either CIIS or EMR records.

In the per-protocol sample we further eliminated 44 participants who did not complete all elements of the main study and were considered lost to follow-up, 153 participants who were found/whose adolescent was found at the time of vaccination assessment to have already completed the 3-dose HPV vaccination series at the time of study enrollment, and 11 additional participants who were found at the time of vaccination assessment to have been outside the age range for HPV vaccination at the time of study enrollment. With these exclusions, we assessed 805 individuals (tailored n = 280, untailored n = 259, usual care n = 266) in the per-protocol analysis for vaccination status.

**Description of Study Interventions and Comparators**

**Tailored Intervention (CHICOS):** Those in the tailored intervention received an iPad with the CHICOS intervention programmed onto it. This intervention was developed by an academic health communication group that specializes in designing tailored messaging interventions (chcr.umich.edu) and was written at a sixth-grade reading level. The intervention was developed collaboratively with the CAB, which provided feedback on the intervention. The
research team conveyed the iterative feedback provided by the CAB to the academic health communication group, which then implemented the changes for further CAB review. Three cycles of review of the intervention were completed in this way to result in the final intervention. A description of this process has been published. The intervention commenced with a short baseline survey that collected information about the participants'/participants’ adolescent’s name and birthday (to link to vaccination records), attitudes and beliefs about HPV infection and vaccination, patient demographics, and vaccination status. This baseline survey was used to individually customize the tailored information in CHICOS that was provided directly on the iPad immediately following completion of the survey. For example, the information was tailored to provide pictures that reflected each participant’s self-reported race and gender. Participants entered their/their adolescent’s name, which was incorporated throughout. Finally, the content changed depending on the participants’ stated concerns. For example, if a participant was most concerned about vaccine safety, information on this topic was provided first on the web page, whereas if a participant was most concerned about efficacy, information on this topic was provided first. Participants viewed the CHICOS information at their own pace for as long as they wished. Following this, they completed a postintervention survey directly on the iPad. The Appendix provides screen shots of the baseline and postintervention surveys and the entire CHICOS intervention.

Untailored Intervention: Those randomized to the untailored intervention also initiated the study with the same iPad-based baseline survey as in the tailored intervention. However, information from the survey was not used to customize the information provided by the intervention. Instead, upon completion of the baseline survey the participant was provided with information from the CDC’s HPV Vaccine Information Sheet, which had been transcribed verbatim to be shown over a series of 7 web pages. Again, participants could view the information at their own pace for as long as they wished. Following this, they completed a postintervention survey directly on the iPad. The Appendix provides screen shots of the untailored intervention.
Usual Care: Those in the usual care arm received whatever care the provider gave during the clinical visit. This varied by provider but based on our prestudy informational interviews with the practices involved in the study typically consisted of bringing up the need for the HPV vaccine during routine physicals (ie, not illness visits) and providing a written version of the Vaccine Information Sheet for HPV at the time the vaccine was administered. However, these activities were completely at provider discretion. Past studies have shown a high degree of variability among providers regarding with which patients HPV vaccines are discussed, under what circumstances, and whether and how the Vaccine Information Sheets are used during visits.39 None of the providers in the usual care arm had access to web-based patient information for HPV. Information on specific HPV-related activities that occurred during the visit was not collected. The patients in the usual care arm did not interact with the iPad directly. They did, however, receive a paper version of the postintervention survey that included the same questions as the iPad-based version of the survey given to those in the tailored and untailored study arms.

Primary Outcome Measures
The primary outcome of interest was HPV vaccine utilization among young adults and adolescent children of the parent participants in the study. We assessed this outcome 5 months after the 16-month study was completed, which meant that individuals had between 5 and 21 months of follow-up time in which to get vaccinated following study enrollment. Vaccination data for adolescents and young adults were planned a priori to be assessed separately. We assessed 6 measures of vaccine uptake in each group:

1) Receipt of any needed dose of HPV vaccine during the study period
2) Initiation of the series among those who entered the study with 0 doses
3) Initiation, but not completion, of the series during the study period among those who entered the study with 0 doses
4) Completion of the vaccine series among anyone in the study
5) Completion of the series specifically among those entering the study with 1 or 2 doses
6) Completion of the series specifically among those entering the study with 0 doses
We included appropriate minimal time intervals between vaccination doses when counting valid doses (ie, doses were not counted as valid if they were erroneously administered too soon after the preceding dose; this occurred in < 2% of doses provided). Denominators for the 6 vaccination outcome measures varied based on receipt of prior valid doses and remaining time left in the study period. That is, we eliminated participants from analyses if they did not have enough time left in the vaccination data assessment period to receive the next dose in the series (e.g., did not have the minimal 4-month window left in the study period to receive the third dose after a second dose had been administered).

**Secondary Outcomes**

We assessed 3 secondary outcomes.

**Quality of HPV Vaccine Decision Making:** We assessed this outcome for all 3 study arms using questions modified from a validated decision-making scale measure\(^4^0\) that was provided after the visit/intervention in the postintervention survey, and also in the follow-up survey provided by email or postal mail 1 to 2 months after study enrollment. This measure included 4 yes/no questions that we assessed individually.

**Patterns of Website Utilization:** We assessed this outcome specifically for the untailored and tailored participants. We used data automatically collected on the iPad server (called paradata) that provide information on the user’s navigation through the educational pages.

**Timing of Vaccine Doses:** We assessed this outcome in all 3 arms by calculating the time between study enrollment and receipt of any subsequent HPV vaccination doses.

**Study Setting**

The study took place in the waiting rooms of the 5 primary care clinics enrolled in the trial, which were all part of a single health system. These included 5 family health care clinics in suburban and rural Colorado that serve low-income, primarily Latino, medically underserved clientele.
Time Frame
We recruited parent and young adult participants between June 2014 and September 2015 (with a vaccination follow-up period extending to February 2016).

Data Collection and Sources
Randomization
After the RA registered on the iPad that participant consent had been obtained, the iPad used an internal randomization program to assign participants to 1 of the 3 study arms in a 1:1:1 ratio (Figure 1). Because of the possibility of clustering of patient responses to the intervention by their preferred language (Spanish or English), clinic (5 possible sites), type of participant (parent or young adult), and prior HPV doses (none or some), we used these variables as stratification variables in the randomization process to ensure even distribution across study arms. RAs were aware of which study arm participants were assigned to, but the participants and the providers at the clinic were blinded to group allocation.

In-clinic Participant Flow—Tailored and Untailored Arms
After the eligibility assessment, consent, and randomization, participants in the tailored and untailored arms were given the iPad by the RA and asked to start the intervention. As described above, for the tailored and untailored arms the intervention began with the baseline survey. Although the participants were encouraged to navigate through the baseline survey on their own, RAs were available to assist participants with questions.

Following completion of the baseline survey, the iPad automatically brought participants to either the tailored or untailored website. For both the tailored and untailored arms, when finished viewing the information, participants were prompted by the iPad (and also the RA) to complete a postintervention survey on the iPad directly.

In-clinic Participant Flow—Usual Care Arm
Those in the usual care arm did not complete a baseline survey or interact with the iPad. Instead, after consent, they continued to their scheduled appointment and received whatever HPV-related information the clinician provided. Data on what occurred during the visit were not collected. After completing their clinic visit, participants returned to the waiting room, where they completed a paper version of the postintervention survey.

**Participant Incentives**

Each eligible participant who consented to the study and completed the baseline (tailored and untailored arms only) and postintervention surveys (all arms) received a $10 incentive, as they were considered to have “completed” the study.

**After-clinic Follow-up Survey**

We assessed parents’ and young adult patients’ satisfaction with the HPV vaccine decision-making process in an optional follow-up survey. After completion of the in-clinic study procedures, RAs asked participants if they would be willing to fill out a mailed survey 1 to 2 months after their visit. Willing participants provided contact information to the RA at that time. One to 2 months after the enrollment visit, those who chose to participate in this follow-up survey were sent it via postal mail or email. We attempted up to 3 mailings/emailings to solicit a response. Upon completion of the survey, participants were provided an additional $10 incentive. The follow-up survey questions are detailed in the Appendix.

**Data Sources**

Eligibility data were collected directly into files on the iPad. For the untailored and tailored arms, baseline and postintervention survey data were also recorded on the iPad directly by the participant. All iPad-based information was stored on the website’s remote secure server. Data from the postintervention survey for participants in the usual care arm were collected on paper forms and later entered into a RedCap database. We used a similar approach for paper responses to the mailed follow-up survey. Web-based versions of the follow-up survey were collected when users clicked on a live link in an email invitation to the survey that took them to
a RedCap site that collected their survey responses directly online into a RedCap database. Data on participants’ use of the tailored or untailored websites were tracked automatically through the paradata function embedded in the website and also stored on the remote server. Vaccination data were derived from the clinic’s electronic medical records and the statewide immunization registry, Colorado Immunization Information System. We used these 2 data sources for vaccination assessments, as we have found in past studies that this combined approach gives the most comprehensive and valid data. We linked vaccination data between the 2 sources using patient name, birth date, ethnicity, and address when possible. A vaccination event was counted if it was documented in either source.

**CIIS**

CIIS is a voluntary immunization registry covering the state of Colorado that includes data from most (75%) private pediatric and family medicine offices in the state, as well as data from all vaccines provided at public health clinics. Internal CIIS audits indicate that more than 85% of Colorado children have > 2 immunizations recorded, but utilization of CIIS for tracking adult vaccination is estimated to be much lower (< 40%). Offices that use CIIS are required to have < 5% error rate in the registry.

**Analytical Approach**

**Sample Size**

We based the prestudy sample size on an a priori decision to analyze vaccination data for young adults and adolescents separately. We based this decision on the large body of research demonstrating that the barriers faced by these 2 populations regarding vaccination attitudes, access, and insurance coverage are significantly different. Based on previsit vaccination data from the clinic, sample size calculations suggested that we would need at least 573 parents and 426 young adults to be able to detect a 15% difference in vaccination levels between any 2 study arms.

**Imputation of Missing Data**
Of the 1294 participants, about 22% were missing outcome data, and about 11.5% were missing gender, age, and/or race/ethnicity. Together with these variables, we used site of recruitment, induction date, and arm assignment to develop multiple imputation models,\textsuperscript{41} separately for young adults and adolescents. We imputed nominal variables with binary or multinomial logistic regression, and quantitative variables using predictive mean matching. We carried out the imputation with the SAS\textsuperscript{®} (\textit{SAS/STAT\textsuperscript{®} 14.1 User’s Guide} [computer program]. Cary, NC: SAS Institute Inc; 2015) MI procedure using the Fully Conditional Specification method.\textsuperscript{42} For the adolescent data the number of imputations was set at 30 using the percentage missing as a guide.\textsuperscript{43} For young adults the percentage-missing method yielded only 12 imputations, so the number was reset to the default of 25. We analyzed the resulting data sets individually with logistic regression and performed a combined analysis with the SAS MIANALYZE procedure. Many of the outcomes were very rare in the young adult group, so we used a Firth’s penalized maximum likelihood estimation to guard against potential bias.

**Primary Outcomes:** For assessment of HPV vaccination, we stratified all analyses by patient age (young adult versus adolescent). The main analyses were separate 2-way analyses comparing usual care with either the tailored or untailored interventions, and the tailored compared with untailored intervention. We also performed 3-way analyses in which all groups were simultaneously considered. In keeping with methodology standards, intention-to-treat analyses are presented in the main report. PP results are available for the vaccination outcomes in the Appendix.

**Secondary Outcomes:** To evaluate the impact of the different study arms on vaccination timing, we used Cox proportional hazards models examining the number of days between study enrollment and first HPV vaccine dose during the study. We also assessed the number of days between study enrollment and first HPV vaccine dose (i.e., series initiation) among the subgroup of participants entering the study unvaccinated. Analyses accounted for clustering at the clinical site.
The primary analysis of the decision quality outcome used chi-square tests to assess variation in this outcome by study arm. To assess vaccination intention over time, Bhapkar’s tests of marginal homogeneity and repeated measures binomial regression were the tests of choice as these measures occurred twice per individual (in the postintervention and follow-up surveys). To assess patterns of website utilization, we used t tests to determine differences in time spent by study arm.

Post Hoc Analyses
We performed assessments of baseline survey data as post hoc analyses. We assessed baseline survey data for tailored and untailored arms only, as the usual care group did not receive the baseline survey. The main outcome assessed from the survey was vaccination intention before versus after viewing the educational materials. Assessment occurred in the baseline and postintervention surveys and used a single item that read, “Now that you have read a bit about HPV infection and vaccination, how likely would you be to get a dose of the HPV vaccine today if the doctor recommended it?” We used a 4-point Likert scale (Very Unlikely, Unlikely, Likely, Very Likely) to measure this outcome. We compared analyses between arms and by age (young adult versus parent of an adolescent). Since this was a post hoc assessment, we did not impute missing data.

Role of the CAB
We presented all results to the CAB members over a series of meetings. We asked the CAB to help the study team interpret the data findings and to provide hypotheses to explain the lack of recruitment of males to the young adult portion of the study and poor vaccination uptake among young adults overall. Following this, the CAB helped the study team identify ways to disseminate the findings and the intervention itself to other members of the Latino population.

Modifications to Original Clinical Trials Record
There were modifications to the ClinicalTrials.gov record due to an error in the initial submission and lack of familiarity with how results would ultimately need to be reported to the registry. Initially when the trial was registered, in May 2014, the primary and secondary
outcomes’ labels were switched, and the trial period was planned for 18 months. Ultimately the trial lasted only 16 months due to a significant delay in the contracting process with PCORI.
When it came time to enter results at ClinicalTrials.gov, the study team became aware that the primary and secondary outcome labels needed to be switched, and also that the format of the vaccination outcomes was not entered at trial registration in a way that would allow the study team to report on all 6 vaccination outcomes. We rectified this in the June 2016 modification to the protocol. It is important to note that no changes occurred to the actual conduct of the trial from that originally planned except for the slight decrease from 18 to 16 months in the study’s duration.

IV. Results

IV.A. Phase I: Intervention Development

Participant Characteristics

Table 1 shows the characteristics of the focus group participants. As depicted, both Spanish and English speakers were well represented, and most parent participants were mothers. Only females attended the young adult focus groups. The CAB consisted of 12 members, including the principal investigator for the project, 2 research team members, 5 parents of Latino adolescents, and 4 young adult Latinas. The CAB also included 2 representatives of community organizations that served Latinos, 1 of whom was also the mother of an adolescent.

Table 1. Demographic Characteristics of Focus Group Participants

<table>
<thead>
<tr>
<th>Focus Groups</th>
<th>English (n)</th>
<th>Spanish (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>By Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>23</td>
</tr>
<tr>
<td><strong>By Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents (with daughters 11-17 years old)</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Young adults (18-26 years old)</td>
<td>14</td>
<td>6</td>
</tr>
</tbody>
</table>
**CAB Feedback**

CAB members provided discussion-based feedback about the content, look, and feel of the Teen VaxScene website, and about potential ways to modify Teen VaxScene. Based on this feedback, we made modifications prior to the start of the intervention to include basic information about HPV for both genders. Members also helped select the color scheme, design the logo, and review and make iterative changes so the intervention design would appear less clinical, use a more approachable font, incorporate more vibrant colors, and use a more eye-catching logo. Members also suggested that participants could choose the content and photos they wanted to view in more detail as opposed to being presented with all information at once. Finally, members helped devise the name—CHICOS (Combatting HPV Infection and Cancers)—for the revised intervention, which was specifically chosen to reflect the Latino community and also to be inclusive of both males and females (as opposed to CHICAS, which would be reflective of females only).

**Focus Group Feedback**

Three main themes emerged from the focus groups: barriers to vaccination, the need for additional information about HPV, and intervention modifications. These are described in detail below. Table 2 depicts quotes representative of these themes.

Based on focus group feedback, we identified several barriers to vaccination that should be incorporated into the modified intervention. Participants generally had low levels of awareness about the vaccine and the need for 3 doses. They also perceived that they lacked enough general information about both HPV infection and the HPV vaccine to make an informed decision about whether to get vaccinated and suggested incorporating this information very early into the interventional website. In addition, there was a lack of awareness that HPV could impact males, and that males could get vaccinated. Participants believed the cost of the vaccine to be prohibitive, suggesting that information to address the cost of the vaccine was critical to include in the new intervention. Most parent participants suggested that talking about the vaccine with their adolescent children would be a good conversation-starter about safe sexual
practices, but they believed that many parents would likely fear that teens would see the vaccine as a clearance for sexual promiscuity. Particular to participants in the Spanish-speaking focus groups were concerns of future reproductive consequences associated with the HPV vaccine. Spanish speakers also asserted that preventive medicine (such as vaccinations) was not a strong cultural norm and that their families tended to prefer home remedies. In addition, they indicated that many within their community hold strong religious values related to sexual activity and abstinence and would be especially reluctant to get the HPV vaccine, particularly for their adolescent children.

Table 2. Supportive Quotes for the Barriers to Vaccination and Basic Information Themes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Supporting Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers to Vaccination</strong></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>“And some people are like, OK, where can I go? Or how much is it going to cost me? And do I have to pay? Can I get it free? So those were the main things that I know actually affect the difference [of whether people will get the vaccine].”</td>
</tr>
<tr>
<td>Sexual promiscuity</td>
<td>“I think people are afraid; what I’ve heard from other friends who have daughters, is they are afraid it is a ‘free for all.’ Because their daughter has [the vaccine], they think they are free and clear and they are going to be protected and they are just having sex.”</td>
</tr>
</tbody>
</table>
| Lack of preventive care       | “If you do not have a history in your family [of] these problems . . . you say, ‘No, not me. It won’t happen to me. My family never had [HPV], and there is no chance of me getting [it]. You see these diseases [as being] far from you.”

“As Hispanics we think that we won’t get the diseases. [You say,] ‘No . . . I’m healthy, and I feel fine, my kids feel fine, and this and that,’ and so we refuse to go to the doctor, because we want to do everything at home, with home remedies only.”

| Religious values              | “I think all the women in my family are very supportive of [the HPV vaccine]. But the males in my family, who have daughters, they are really kind of wary about it and in denial. ‘She doesn’t need it,’ and that kind of thing. Going back to [that] they don’t want to encourage their teenager to have sex.” |
| **Additional Basic Information** |                                                                                                                                                  |
| Introductory information      | “The symptoms . . . for example, if I get the [HPV] virus, I won’t have the symptoms tomorrow, or the day after tomorrow. . . . So, then you say, OK, you have contracted this virus, but . . . what are the symptoms to notice—temperature, fatigue, or what are they?”

“Why isn’t there a study that says that it’s proven that [the HPV vaccine] protects? I mean, I haven’t heard so much of them saying, ‘Yes, look, it works,’ how it works, or that there are testimonies that say it worked. Better yet, I think that those of us who are not sure if it is unsafe [are not sure] because of this lack of information.”
Statistical information

“It is important to know where and who this type of thing affects, and if it affects everybody all over the country. So, to have statistics to weigh against your [own] statistics . . . would be a good idea.”

“I like the nationwide statistics. It is interesting to see the HPV and STD rates across America. Just to see how different areas are . . . affected by it compared to us.”

The theme of desiring additional basic information about HPV was pervasive among all of the focus group discussions. Participants requested that we include more introductory information about HPV on the intervention website, along with additional logistical information about the HPV vaccine. Specifically, both parents and young adults indicated that they were interested in learning about how HPV is transmitted, risk of contracting HPV, other health or disease risks related to contracting HPV, what symptoms HPV produces, possibilities for treatment of HPV, and the extent to which males are at risk for HPV. Participants also agreed that they wanted to learn more about research efforts and results pertaining to the HPV vaccine, the optimal age range for getting the vaccine, when to initiate the vaccine series, and when to pursue subsequent doses. Parents in particular expressed the desire to review evidence about whether the vaccine is effective, the vaccine’s side effects, and how the vaccine works with the immune system. Parent participants in groups conducted in Spanish requested more information about HPV detection and prevention, as well as resources related to attenuating the cost of the HPV vaccine. For many of these information needs, participants requested access to statistical information (i.e., cancer prevalence) that was specific to the Latino population. Table 2 shows supporting quotes for these themes.

Participants’ evaluation of Teen VaxScene resulted in 3 subcategories of intervention modifications that would make an HPV-specific educational intervention more useful for Latinos. The first related to streamlining content. Both parents and young adults suggested that the amount of text should be minimized, and that more photos of HPV-related cancers and other diseases should be included. Spanish-speaking parents reiterated the suggestion of our CAB that the photos be optional for viewing and that they contain a warning statement about the photos’ graphic nature. The second subcategory pertained to the intervention’s look and
feel. Most participants described the existing theme as too clinical and suggested that the design incorporate brighter colors and a more appealing, family-oriented logo. In line with minimizing the amount of text to read, both parents and young adults requested that more of the content be presented as graphic representations. The third subcategory incorporated suggestions about technical aspects of the intervention. Specifically, both parents and young adults thought users should be able to choose which disease-related photos they wanted to view and be more easily able to choose the variety of content in order to select that which they wanted to read about in more detail. Finally, participants suggested increased utility for users by including additional navigational features throughout the intervention, such as arrows and pop-up menus describing how to navigate through the site.

**IV.B. Phase II: Intervention Implementation**

*Primary Outcomes—Vaccination Results*

*Study Sample and Demographic Characteristics of Participants With Vaccination Data Assessed*

Table 3 depicts the demographic characteristics of participants analyzed for vaccination data. Notably, no male young adults enrolled in the study. Most participants in the study were Hispanic. However, most participants selected “other” race. Anecdotal information from the RAs indicated that many participants identified “Hispanic” as their race, but because this choice was not available on the race question, they chose “other” instead.

*Impact of the Intervention on HPV Vaccination Levels*

Table 4 depicts the 3-way comparisons of HPV vaccination levels by study arm among adolescents and young adults. Overall, few young adults in any study arm received HPV vaccine doses, with only 2% to 6% of those eligible receiving a dose over the 16-month study period. There were no statistically significant differences by study arm in any of the vaccination uptake measures in 3-way comparisons. The 2-way comparisons for both young adults and adolescents showed the same result (Table 5). The one exception was adolescents who entered the study with at least 1 dose. For these adolescents, the tailored group performed significantly better
than the untailored group (odds ratio [OR] 2.0; 95% confidence interval [CI], 1.1-3.8), but there were no statistically significant differences in series completion when the tailored intervention was compared with usual care (OR 1.6; 95% CI, 0.8-3.2).

Secondary Outcomes—Vaccination Timing, Decision Quality, and Website Utilization

Impact of the Intervention on Vaccination Timing

Table 6 depicts analysis of the timing of HPV vaccine doses by study arm. There was a general pattern of vaccine doses being administered sooner after enrollment in the tailored arm than in either the usual care or untailored arms. However, none of these differences in vaccination timing were statistically significant.

Table 3. Demographic Characteristics of Participants With Vaccination Data Assessed

<table>
<thead>
<tr>
<th>Participant Characteristics</th>
<th>Arm Assignment</th>
<th>All % (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual Care % (n)</td>
<td>Untailored % (n)</td>
</tr>
<tr>
<td>Young adults</td>
<td>34.6% (152)</td>
<td>35.5% (151)</td>
</tr>
<tr>
<td>Parents</td>
<td>65.4% (287)</td>
<td>64.55 (274)</td>
</tr>
<tr>
<td>TOTAL (100% column)</td>
<td>100% (439)</td>
<td>100% (425)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young adults</td>
<td>Male</td>
<td>0% (0)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>100% (152)</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents (adolescent gender)</td>
<td>Male</td>
<td>51.6% (148)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>48.4% (139)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100% (287)</td>
<td>100% (274)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young adults</td>
<td>Hispanic</td>
<td>85.5% (130)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>White, non-Hispanic</td>
<td>Other, non-Hispanic</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>12.5% (19)</td>
<td>13.2% (20)</td>
</tr>
<tr>
<td></td>
<td>2.0% (3)</td>
<td>2.6% (4)</td>
</tr>
<tr>
<td></td>
<td>100% (152)</td>
<td>100% (151)</td>
</tr>
<tr>
<td>Parents (adolescent race/ethnicity)</td>
<td>Hispanic</td>
<td>93.7% (269)</td>
</tr>
<tr>
<td></td>
<td>White, non-Hispanic</td>
<td>5.9% (17)</td>
</tr>
<tr>
<td></td>
<td>Other, non-Hispanic</td>
<td>0.3% (1)</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>100% (287)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age at Baseline</th>
<th>Median Age (MED)</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young adults</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>Parents (adolescent age)</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Participant Population</td>
<td>Arm Assignment</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Usual Care</td>
<td>Untailored</td>
</tr>
<tr>
<td></td>
<td># Eligible for Outcome Assessed</td>
<td>% of Eligible Vaccinated (n)</td>
</tr>
<tr>
<td><strong>Young Adults</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Got any dose of HPV during study</td>
<td>152</td>
<td>2%</td>
</tr>
<tr>
<td>Initiated the vaccine series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>106</td>
<td>3%</td>
</tr>
<tr>
<td>Initiated the vaccine, series not completed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>11</td>
<td>55%</td>
</tr>
<tr>
<td>Completed the vaccine series, among all eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>117</td>
<td>2%</td>
</tr>
<tr>
<td>Completed the vaccine series, among those initiated at study start&lt;sup&gt;e&lt;/sup&gt;</td>
<td>42</td>
<td>1%</td>
</tr>
<tr>
<td>Completed the vaccine series, among those who initiated during the study&lt;sup&gt;f&lt;/sup&gt;</td>
<td>11</td>
<td>45%</td>
</tr>
<tr>
<td><strong>Adolescents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Got any dose of HPV during study</td>
<td>287</td>
<td>42%</td>
</tr>
<tr>
<td>Initiated the vaccine series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>197</td>
<td>38%</td>
</tr>
<tr>
<td>Initiated the vaccine, series not completed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>124</td>
<td>71%</td>
</tr>
<tr>
<td>Completed the vaccine series, among all eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>241</td>
<td>20%</td>
</tr>
<tr>
<td>Completed the vaccine series, among those</td>
<td>165</td>
<td>33%</td>
</tr>
<tr>
<td>Outcome</td>
<td>Comparison Arms</td>
<td>Odds Ratio, 95% CI</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td><strong>Young Adults</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Got any dose of HPV during study</td>
<td>Tailored versus usual care</td>
<td>2.3 (0.6, 8.3)</td>
</tr>
<tr>
<td></td>
<td>Untailed versus usual care</td>
<td>2.4 (0.7, 8.9)</td>
</tr>
<tr>
<td></td>
<td>Tailored versus untailored</td>
<td>0.9 (0.3, 2.6)</td>
</tr>
<tr>
<td>Initiated the vaccine series(^{b})</td>
<td>Tailored versus usual care</td>
<td>2.3 (0.6, 8.8)</td>
</tr>
<tr>
<td></td>
<td>Untailed versus usual care</td>
<td>1.00 (0.2, 4.6)</td>
</tr>
<tr>
<td></td>
<td>Tailored versus untailored</td>
<td>2.3 (0.6, 8.6)</td>
</tr>
<tr>
<td>Initiated the vaccine, series not completed(^{c})</td>
<td>Tailored versus usual care</td>
<td>5.8 (0.3, 112.8)</td>
</tr>
<tr>
<td></td>
<td>Untailed versus usual care</td>
<td>12.4 (0.2, 722.4)</td>
</tr>
<tr>
<td></td>
<td>Tailored versus untailored</td>
<td>0.5 (0.0, 22.4)</td>
</tr>
<tr>
<td>Completed the vaccine series, among all eligible(^{d})</td>
<td>Tailored versus usual care</td>
<td>0.7 (0.1, 5.3)</td>
</tr>
<tr>
<td></td>
<td>Untailed versus usual care</td>
<td>1.7 (0.3, 8.3)</td>
</tr>
<tr>
<td></td>
<td>Tailored versus untailored</td>
<td>0.4 (0.1, 2.6)</td>
</tr>
</tbody>
</table>

\(^{a}\)P value for 3-arm comparison of percentage vaccinated.

\(^{b}\)Describes those who had 0 doses at study enrollment and received at least 1 dose during the study period.

\(^{c}\)Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, but did not complete the series during the study period.

\(^{d}\)Describes those who enrolled in the study with 0, 1, or 2 doses; had enough time in the study period after the most recent dose to complete the series; and completed the series during the study period.

\(^{e}\)Describes those who enrolled in the study with 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

\(^{f}\)Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Note: Bolded \(P\) values highlight significant or near significant results.
<table>
<thead>
<tr>
<th>Completed the vaccine series, among those already initiated at study start&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Untailed versus usual care</th>
<th>9.3 (0.5, 193.9)</th>
<th>0.15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tailored versus untailed</td>
<td>0.1 (0.0, 2.4)</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Completed the vaccine series, among those who initiated during the study&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>0.2 (0.0, 3.4)</td>
<td>0.25</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>0.1 (0.0, 4.7)</td>
<td>0.23</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>2.2 (0.0, 103.5)</td>
<td>0.70</td>
<td></td>
</tr>
</tbody>
</table>

### Adolescents

<table>
<thead>
<tr>
<th>Got any dose of HPV during study</th>
<th>Tailored versus usual care</th>
<th>1.05 (0.7, 1.5)</th>
<th>0.81</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untailed versus usual care</td>
<td>1.1 (0.7, 1.7)</td>
<td>0.62</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>0.9 (0.7, 1.3)</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Initiated the vaccine series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>1.2 (0.7, 2.0)</td>
<td>0.59</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>1.3 (0.7, 2.2)</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>0.9 (0.5, 1.5)</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>Initiated the vaccine, series not completed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>1.3 (0.4, 4.1)</td>
<td>0.60</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>2.3 (0.7, 7.3)</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>0.6 (0.2, 1.8)</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>Completed the vaccine series, among all eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>1.2 (0.7, 2.1)</td>
<td>0.49</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>0.8 (0.5, 1.5)</td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>1.5 (0.9, 2.5)</td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>Completed the vaccine series, among those already initiated at study start&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>1.6 (0.8, 3.2)</td>
<td>0.15</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>0.8 (0.4, 1.6)</td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>2.0 (1.1, 3.8)</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Completed the vaccine series, among those who initiated during the study&lt;sup&gt;f&lt;/sup&gt;</td>
<td>Tailored versus usual care</td>
<td>0.7 (0.2, 2.2)</td>
<td>0.60</td>
</tr>
<tr>
<td>Untailed versus usual care</td>
<td>0.4 (0.1, 1.4)</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>Tailored versus untailed</td>
<td>1.7 (0.6, 5.0)</td>
<td>0.35</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> P value for the percentage vaccinated among the 2 arms denoted.

<sup>b</sup> Describes those who had 0 doses at study enrollment and received at least 1 dose during the study period.

<sup>c</sup> Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, but did not complete the series during the study period.

<sup>d</sup> Describes those who enrolled in the study with 0, 1, or 2 doses; had enough time in the study period after the most recent dose to complete the series; and completed the series during the study period.

<sup>e</sup> Describes those who enrolled in the study with 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series; and completed the series during the study period.

<sup>f</sup> Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Note: Bolded P values highlight significant or near significant results.
Table 6. Time to Vaccination, by Study Arm

<table>
<thead>
<tr>
<th>Vaccine Dose</th>
<th>Usual Care</th>
<th>Untailored</th>
<th>Tailored</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Young Adults</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days from study enrollment to next dose of HPV vaccine, median (range)</td>
<td>0 (0-110)</td>
<td>58 (0-131)</td>
<td>48 (0-361)</td>
</tr>
<tr>
<td>Days from study enrollment to HPV series initiation, among those previously unvaccinated, median (range)</td>
<td>0 (0-110)</td>
<td>58 (0-131)</td>
<td>64 (48-308)</td>
</tr>
<tr>
<td><strong>Adolescents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days from study enrollment to next dose of HPV vaccine, median (range)</td>
<td>62 (0-356)</td>
<td>73 (0-468)</td>
<td>126 (0-506)</td>
</tr>
<tr>
<td>Days from study enrollment to HPV series initiation, among those previously unvaccinated, median (range)</td>
<td>92 (0-356)</td>
<td>85 (0-407)</td>
<td>141 (0-506)</td>
</tr>
</tbody>
</table>

**Impact on HPV Decision Quality**

We used 4 items to measure vaccination decision quality after participants had viewed the intervention materials or, in the case of the usual care group, completed their normal provider visit without interacting with the iPad. In the postintervention survey (Table 7), only the item asking “Are you clear about which benefits and risks matter most to you?” demonstrated significant differences between study arms. The usual care group had a lower rate (71%) of “Yes” responses than either the untailored (87%) or tailored (85%) groups ($p = .001$).

In the follow-up survey (Table 8), the item “Are you clear about which benefits and risks matter most to you?” again demonstrated significant differences between study arms, where the tailored and untailored invention groups had significantly higher rates of “Yes” responses (78%) compared with the usual care group (65%; $p = .006$). Additionally, we also observed differences by arm for the item “Do you feel like you know enough about the benefits and risks of getting the vaccine versus not getting the vaccine?” In this instance, participants who viewed the tailored intervention had a larger percentage of “Yes” responses (76%) than the untailored (73%) and the usual care arms (60%; $p = .0015$).
**Website Utilization Patterns**

We assessed total amount of time spent on the intervention web pages (Table 9). Participants who viewed the tailored intervention materials spent significantly longer (2.64 minutes) compared with those who viewed the untailored materials (0.76 minutes; \( p < 0.001 \)). Those who chose Spanish as their preferred language for the intervention spent close to the same amount of time (1.78 minutes) as those who chose English as their preferred language (1.55 minutes; \( p = 0.11 \)). Young adults and parents spent the same amount of time viewing intervention pages.

**Table 7. HPV Vaccination Decision Quality; Postintervention Survey**

<table>
<thead>
<tr>
<th>Item</th>
<th>Response</th>
<th>Trial Arm**</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Usual Care</td>
<td>Untailed</td>
</tr>
<tr>
<td>Do you feel you can make the best choice regarding the vaccine?</td>
<td>% yes</td>
<td>89%</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>% no</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>87</td>
<td>372</td>
</tr>
<tr>
<td>Do you feel like you know enough about the benefits and risks of</td>
<td>% yes</td>
<td>69%</td>
<td>77%</td>
</tr>
<tr>
<td>getting versus not getting the vaccine?</td>
<td>% no</td>
<td>31%</td>
<td>23%</td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>87</td>
<td>372</td>
</tr>
<tr>
<td>Are you clear about which benefits and risks matter most to you?</td>
<td>% yes</td>
<td>71%</td>
<td>87%</td>
</tr>
<tr>
<td></td>
<td>% no</td>
<td>29%</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>87</td>
<td>372</td>
</tr>
<tr>
<td>Do you feel like you have enough support to make a decision about</td>
<td>% yes</td>
<td>86%</td>
<td>87%</td>
</tr>
<tr>
<td>whether to get the vaccine?</td>
<td>% no</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>87</td>
<td>372</td>
</tr>
</tbody>
</table>

* Difference significant at \( p < 0.05 \).
** Parents and young adults combined.
### Table 8. HPV Vaccination Decision Quality: Follow-up Survey

<table>
<thead>
<tr>
<th>Item</th>
<th>Response</th>
<th>Trial Arm**</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you feel you can make the best choice regarding the vaccine?</td>
<td>% yes</td>
<td>94% 95% 96%</td>
<td>0.58</td>
</tr>
<tr>
<td></td>
<td>% no</td>
<td>6% 5% 4%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>176 155 149</td>
<td></td>
</tr>
<tr>
<td>Do you feel like you know enough about the benefits and risks of</td>
<td>% yes</td>
<td>60% 73% 76%</td>
<td>0.0015</td>
</tr>
<tr>
<td>getting versus not getting the vaccine?</td>
<td>% no</td>
<td>40% 27% 24%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>177 153 149</td>
<td></td>
</tr>
<tr>
<td>Are you clear about which benefits and risks matter most to you?</td>
<td>% yes</td>
<td>65% 78% 78%</td>
<td>0.0056</td>
</tr>
<tr>
<td></td>
<td>% no</td>
<td>35% 22% 22%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>178 154 148</td>
<td></td>
</tr>
<tr>
<td>Do you feel like you have enough support to make a decision about</td>
<td>% yes</td>
<td>77% 84% 85%</td>
<td>0.21</td>
</tr>
<tr>
<td>whether to get the vaccine?</td>
<td>% no</td>
<td>23% 16% 15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total n</td>
<td>176 155 150</td>
<td></td>
</tr>
<tr>
<td><strong>Parents and young adults combined.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 9. Website Utilization Pattern Based on Condition

<table>
<thead>
<tr>
<th>Variable</th>
<th>Condition</th>
<th>Avg. Time (Min)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention arm</td>
<td>Tailored</td>
<td>2.64</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td></td>
<td>Untailored</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Young adult</td>
<td>1.77</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>Parent</td>
<td>1.64</td>
<td></td>
</tr>
<tr>
<td>Preferred language</td>
<td>English</td>
<td>1.55</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>Spanish</td>
<td>1.78</td>
<td></td>
</tr>
</tbody>
</table>

**Post Hoc Analyses of Baseline Survey Data**
Table 10 depicts the demographic characteristics of participants in the untailored and tailored arms who completed the baseline survey (the survey was not provided to the usual care group). There were no substantial differences ($p = 0.91$) between the tailored and untailed arms in the proportion of participants who self-reported acceptance of the HPV vaccine—i.e., indicated they were “very likely” to get the vaccine after viewing the content (Table 11). With both study arms combined (Table 12), the proportion of participants who responded they would be “very likely” to get the HPV vaccine increased between the baseline and postintervention surveys for both parents (72% to 77%) and young adults (49% to 60%; $p < 0.0001$; Figure 2). As shown in Table 12, parents of adolescents were generally more accepting of the vaccine than young adults were. However, comparing baseline to postintervention surveys, young adults had a greater absolute percentage point increase in their vaccine acceptance rates than parents (young adults, 11% increase from 49% to 60%; parents, 5% increase from 72% to 77%; $p = 0.12$).

Table 10. Demographic Characteristics of Participants in the Tailored or Untailored Study Arms Who Completed the Baseline and Postintervention Surveys

<table>
<thead>
<tr>
<th>Participant Characteristics</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>752</td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>485</td>
<td>64%</td>
</tr>
<tr>
<td>Young adults</td>
<td>267</td>
<td>36%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Female</td>
<td>750</td>
<td>99%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>178</td>
<td>24%</td>
</tr>
<tr>
<td>African American</td>
<td>5</td>
<td>1%</td>
</tr>
<tr>
<td>Asian</td>
<td>3</td>
<td>0.4%</td>
</tr>
<tr>
<td>American Indian</td>
<td>12</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>552</td>
<td>73%</td>
</tr>
<tr>
<td>Missing/unknown</td>
<td>2</td>
<td>0.3%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>678</td>
<td>90%</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>72</td>
<td>10%</td>
</tr>
<tr>
<td>Missing/unknown</td>
<td>2</td>
<td>0.3%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>M = 36.7 SD = 6.45</td>
<td></td>
</tr>
<tr>
<td>Young adults</td>
<td>M = 22.3 SD = 2.56</td>
<td></td>
</tr>
</tbody>
</table>
Table 11. HPV Vaccination Intentions Before and After Viewing Educational Materials, Tailored Versus Untailored Arms**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Baseline Response</th>
<th>Measure</th>
<th>Postintervention Response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Very Likely</td>
<td>Other</td>
</tr>
<tr>
<td>Tailored</td>
<td>Very likely</td>
<td>Frequency (n)</td>
<td>221</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent (%)</td>
<td>59%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>(n)</td>
<td>46</td>
<td>88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>12%</td>
<td>24%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>(n)</td>
<td>267</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>72%</td>
<td>28%</td>
</tr>
<tr>
<td>Untailored</td>
<td>Very likely</td>
<td>Frequency (n)</td>
<td>226</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent (%)</td>
<td>59%</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>(n)</td>
<td>43</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>11%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>(n)</td>
<td>269</td>
<td>111</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>71%</td>
<td>29%</td>
</tr>
</tbody>
</table>

* Missing data for n = 18.
** p = 0.91; denotes the difference between tailored and untailored study arms in the change from baseline to postintervention (i.e., difference in difference).

Table 12. HPV Vaccination Intentions Before and After Viewing Educational Materials, Young Adults Versus Parents**

<table>
<thead>
<tr>
<th>Participant</th>
<th>Baseline Response</th>
<th>Measure % (n)</th>
<th>Postintervention Response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young Adults</td>
<td>Very likely</td>
<td>Frequency (n)</td>
<td>116</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent (%)</td>
<td>43%</td>
<td>6%</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>(n)</td>
<td>45</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>17%</td>
<td>34%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>(n)</td>
<td>161</td>
<td>106</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Parents</td>
<td>Very likely</td>
<td>Frequency (n)</td>
<td>331</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent (%)</td>
<td>68%</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>(n)</td>
<td>44</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(%)</td>
<td>9%</td>
<td>19%</td>
</tr>
<tr>
<td>Total</td>
<td>(n)</td>
<td>375</td>
<td>110</td>
<td>485*</td>
</tr>
<tr>
<td>--------</td>
<td>-----</td>
<td>-----</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
<td>77%</td>
<td>23%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Missing data for n = 18.
** $p = 0.12$; denotes the difference between young adults and parents in the change from baseline to postintervention (i.e., difference in difference).

Figure 2. Overall Likelihood to Receive the HPV Vaccine Before Versus After Viewing Web-based Material ($p < 0.0001$, Tailored and Untailored Arms Combined)

V. Discussion

**Decisional Context of the Study Results**

In this 2-phase project we modified an existing immunization-related, web-based, tailored educational intervention to focus on improving HPV vaccination among the Latino population in the Denver metro area. We then tested the relative efficacy of this intervention, called CHICOs, versus an untailored intervention or usual care for improving HPV vaccination among Latino adolescents and young adults. For the first phase of the study, we successfully engaged a community advisory board consisting of end-users of our product and other community stakeholders focused on the Latino population to create an intervention that incorporated their feedback and that from a series of community focus groups. In the second phase, we found that use of CHICOs resulted in no differences compared with the untailored intervention and usual care in nearly all vaccination outcomes assessed. This was true for both adolescents and young...
adults, though conclusions about the impact of CHICOS on young adults is somewhat limited by the low vaccine utilization across all arms in this population. Moreover, while vaccination intention improved after reading the educational material in both the tailored and untailored groups, the improvement was the same in the 2 study arms. From this we conclude the CHICOS was not an effective way to improve HPV vaccination among the Latino population targeted for the study.

The Study Results in Context of Prior Research

Increasing HPV vaccination, particularly among adolescents, for whom the vaccine is preferentially recommended, is a national health priority. Many groups have recently sought to develop and test interventions to improve this outcome, and several effective interventions targeted at the provider or clinic level have been identified. For example, in a 2010 study, Fiks et al. revealed that electronic medical record prompts plus parent reminders increased HPV vaccine initiation among females (males were not included in the study) by 9% compared with the control (from 16% to 25%; \( p < 0.001 \)). Another study by Perkins et al. of a provider-focused intervention that provided a combination of education, feedback on vaccination rates, and quality improvement incentives found a 10% to 20% increase (depending on month of analysis) in adolescent HPV vaccine initiation compared with controls. Interventions targeted to parents have been less successful as the vast majority of these studies use parental intention for adolescent vaccination as the outcome of interest rather than actual adolescent HPV vaccine receipt. While several studies have demonstrated improvements in parental vaccination intention with a variety of interventions, the degree to which these improvements translate into actual increases in vaccination remains unclear. This was borne out again in our study—among young adults in the study, vaccination intentions increased significantly over baseline in both the tailored and untailored arms. Despite this, only 2% to 6% of the overall young adult population received any dose of the vaccine during the study period. It is clear from this study that vaccination intention did not translate well into vaccination behaviors, which suggests that researchers should use caution when interpreting results of
intervention studies that use vaccination intention as a proxy measure for efficacy regarding vaccine uptake.

Implementation of Study Results

Our study was essentially a negative trial, with no significant differences in vaccine uptake between the study arms. Thus, we do not believe that it is likely that our intervention will be implemented widely in the future, at least in its current state. Should future studies find different results in other populations, for example non-Latinos, then our intervention could be scaled for relatively low cost given that it is web based. However, a major barrier to doing so would be finding ways to prompt participants to engage in the intervention independently. In our study, a research assistant was present throughout the participants’ engagement with the intervention and could answer any questions that arose during this interaction (anecdotally, this occurred frequently). To make the intervention sustainable and feasible to implement in a clinic setting more broadly, it would be essential to make sure that participants are capable and willing to engage with the intervention independently.

The low vaccination rate in the young adult population, despite high vaccination intentions, suggests significant and systematic barriers that could not be overcome by the information the interventions provided. The most likely cause of this relates to insurance coverage. Adolescents without health insurance are able to get vaccinated free of charge under the Vaccines For Children program from the US government. This program provides free vaccines to all children of certain ethnicities (e.g., American Indians) and/or to those who are underinsured or uninsured for vaccines.47 A similar program does not exist for adults. This means that individuals older than the age of 18 who want the HPV vaccine must pay for it out of pocket. The cost, which averages about $500 for the full 3-dose vaccination series, is prohibitive for many people. This was an issue for the young adult Latino population seen in these clinics, specifically because many of them are undocumented and therefore have no insurance coverage, likely contributing to the low levels of HPV vaccination among young adults across all the study arms. Although our study did not collect insurance information, we believe lack of
insurance was a significant driver of the low levels of HPV vaccination seen among young adults. Prior to the study we had confirmed that the clinics had in place a vaccine assistance program run by 1 of the HPV vaccine manufacturers that enables low-income individuals to receive a free vaccine after filling out an online form, regardless of insurance status. This program was available at each of the 5 primary care clinics in the trial, and information on the program was also included in the tailored intervention for young adults. However, feedback from the office staff indicated that the process for enrolling patients in this program was extremely cumbersome, and thus access to the vaccine was a significant barrier for most uninsured patients. Moreover, our CAB suggested that registering for the program may be construed as risky by Latino individuals living in Colorado illegally, which also may have contributed. The extent to which the CHICOS intervention impacts the Latino young adult population, particularly those with health insurance, therefore remains unknown.

**Generalizability**

Men were not well represented in our study. The entire CAB was composed of females, most of the focus group participants were women, and the young adult population enrolled in our clinical trial was exclusively women, even though gender was not one of the eligibility criteria for enrollment. In contrast, there was nearly equal representation of male and female adolescents among parents enrolling in the study. This low level of adult male participation may reflect young adults’ misperceptions that HPV is a “woman’s problem” and thus not very relevant to males. Consistent with this misperception are our focus group data, which show a general lack of knowledge about the risk of HPV infection and cancer among males and knowledge that males can get the vaccine, and the finding from our trial that, among adolescents, vaccination was more likely to occur among girls than boys across all study arms. Lack of male participation in the trial was somewhat disappointing, as we made a concerted effort to highlight in CHICOS the risk of HPV infection and the need for HPV vaccination among people of both genders, as was advised by our CAB. Without this perspective, one cannot make conclusions about the efficacy of our intervention for young adult males. Lack of male participation in young adult focus groups and in the CAB could mean we failed to include
important messages in our intervention that would motivate young men to get vaccinated. However, given the lack of impact from CHICOs in vaccination outcomes in other populations represented in the study, we suspect that CHICOs would similarly lack impact for males.

Subpopulation Considerations
The study was underpowered for comparing vaccination rates in subgroups (e.g., adolescents versus young adults).

Study Limitations
It is necessary to view this project’s results in light of several important limitations. Regarding phase I of the project, the CAB and focus group results were based on people who volunteered to be involved in these discussions. These participants may therefore be more involved in community issues, have higher health literacy, or have stronger opinions about the HPV vaccine than average end-users for the intervention. Second, it is possible that the social desirability bias caused focus group participants to provide more desirable feedback about the website when facing the research team. Mitigating this somewhat is the consistency of our focus group data with that of others regarding barriers to HPV vaccination,48-57 and the fact that we have had an additional 2 years of ongoing feedback from the CAB after these data were collected and integrated into the website without substantial changes in their opinions about the current CHICOS intervention.

Regarding phase II of the project, a significant limitation to the study was that there was a high proportion of missing data, which required imputation. The result of this process was very high uncertainty in the point estimates from the analysis (some 95% CI extended above an OR of 700). In the PP analysis, which was based on the significantly lower number of participants who had full data available, our study ended up being significantly underpowered to detect the differences between arms we had anticipated (15%). The decreased sample size was due primarily to the fact that a substantial proportion of the individuals whose vaccination status we tried to assess could not be matched to any vaccination record in CIIS or any of the clinic’s
electronic medical records. This primarily impacted adolescents and was usually because the name the parent wrote down as his or her adolescent’s name at the time of study enrollment could not be definitively matched to a record, even when birth date was added as a parameter. For an additional 72 parents in the usual care arm, we had a problem with our initial study processes in which we failed to record the adolescent’s name, also preventing us from being able to link these parents’ responses to adolescent vaccination outcome. Moreover, we eliminated a number of additional participants from the per-protocol analysis because they erroneously reported that they/their adolescent had not completed the 3-dose series at the time of study enrollment when in fact they had completed the series (as judged by their vaccination records, which were reviewed at the end of the study period), and/or that they were in the eligible age range when they were not. It is possible that some participants purposefully misrepresented their/the adolescent’s age or vaccination status in order to participate in the study. However, prior research demonstrates that parents (and to some extent young adults) are often unaware of how many doses of the HPV vaccine they have received previously, which could have also played a role. In either case, the removal of so many participants from the PP analysis due to lack of eligibility or inability to match to clinical records was not expected and hindered our statistical power to detect differences between study arms. In developing our study, we had hypothesized that the untailored intervention would be better than usual care, but inferior to the tailored intervention CHICOs. Our study was powered to identify a 15% difference between study groups, which was not achieved for any of our outcomes.

Another limitation from phase II of the study is that participants were interested in participating when approached by RAs. Participants may have thus already had fairly positive attitudes toward HPV vaccination, which could account in part for the high baseline levels of HPV vaccination intention reported in both the tailored and untailored arms. Also, many participants requested RA assistance in using the intervention. Because of this, social desirability may have influenced our results, particularly related to vaccination intention, as study subjects might not have felt comfortable expressing hesitancies about the HPV vaccine or ambiguous intentions.
about getting vaccinated directly to the RA. The need for RA assistance to use the iPads also raises questions about how easy or difficult it would be for participants to use the intervention on their own, an important issue to consider when determining the feasibility of disseminating iPad based widely. Mitigating this concern somewhat are national data showing that Latinos are more likely than any other race or ethnicity group to look for health information on the web, particularly using smart phone technology. Finally, our CHICOs intervention was clinic based and therefore captured patients with ready access to care (and thus the vaccine). It is not known how effective our intervention would be in high-risk populations that do not routinely access primary care.

Future Research
Though our intervention was not effective at improving vaccination rates among Latino adolescents and young adults, it is possible that the intervention could be effective in other populations. Thus, future research should continue to examine the overall efficacy of tailored messaging for improving HPV vaccination, as HPV vaccination rates are below national goals in essentially all subpopulations.

VI. Conclusion
The CHICOs intervention, which we developed in close collaboration with the Denver metro area Latino community, did not appear to be any more effective than an untailored web-based intervention or usual care for improving HPV vaccination rates among Latino adolescents or young women. While both the tailored and untailed interventions significantly improved parents’ and young adults’ HPV vaccination intentions, this did not appear to translate into improvements in actual HPV vaccine uptake. This was particularly notable in the young adult population, which had very low levels of HPV vaccine utilization across all 3 study arms, likely reflecting substantial systematic barriers to vaccination that could not be overcome by the information provided. Ongoing research is needed to identify effective mechanisms to improve HPV vaccination among Latinos, a high-risk group for HPV-related cancers and other diseases.
VII. References


31. Vanderpool RC, Crosby RA, Stradtman LR. Protecting a new generation against HPV: are we willing to be bold? *Hum Vaccin Immunother*. 2014;10(9):2559-2561.


APPENDICES

Revised Peer Review Report on:
A Randomized, Controlled Trial of a Web-based Educational Intervention for Latino Young Adults and Parents of Adolescents to Minimize Disparities in HPV Vaccination
A. Parent Focus Group Guide
B. Young Adult Focus Group Guide
C. CHICOS Randomized Controlled Trial Eligibility Survey
D. CHICOS Randomized Controlled Trial Baseline Survey for Tailored and Untailored Arms
E. CHICOS Randomized Controlled Trial Post-Intervention Survey for Tailored and Untailored Arms
F. CHICOS Randomized Controlled Trial Post-Intervention Survey Usual Care Arm
G. CHICOS Randomized Controlled Trial Follow Up Survey for Parents
H. CHICOS Randomized Controlled Trial Follow Up Survey for Young Adults
I. Screenshots of CHICOS Tailored Website
J. Screenshots of Untailored Website Depicting Text from the HPV Vaccine Information Statement from the CDC
K. Tables 3-5 from the Peer Review Report Reflecting Per-Protocol Analyses Of Vaccination Outcomes
L. Exploratory Analysis of Other Factors Potentially Impacting Vaccination
APPENDIX A: PARENT FOCUS GROUP GUIDE

CHICOS
Parent Focus Group Guide

Welcome
Hello everyone! Welcome, and thank you for agreeing to be part of our focus group tonight.

Introductions
Let me introduce our team: I’m (name of facilitator) and I will be facilitating the discussion and this is (name of co-facilitator) and she will be taking notes this evening. We are working with the University of Colorado and the Patient-Centered Outcomes Research Institute on a research project about adolescents and vaccines. Some parents aren’t able to get their adolescents to see a doctor or other health care provider very often. And, when they do, they may not get information about adolescent vaccines, or think about which vaccines their adolescent may need.

Tonight we want to get your ideas and opinions about some questions we have about adolescent health care, vaccinations for adolescents in general, and about a particular vaccine called the HPV vaccine. We will be using the terms “vaccination” and “immunization” interchangeably tonight. And when we say the word “adolescent” we mean an adolescent between 11 and 17 years of age. So, we are asking about your thoughts and experiences with your daughter(s) between 11 and 17 years.

We really appreciate your time today. The way we look at it, YOU are the experts- you are all parents or guardians of adolescents. We value your opinions and want you to know that what you tell us during these discussions may help girls get recommended preventive health care.

Ground Rules
Before we begin, let me mention a few things about how we usually conduct these groups:

1) I will be the facilitator for the group. My role is to ask the questions we have for the group, and to encourage everyone to participate. I won’t be doing much talking, but may ask you to explain more or to give an example. Also, it’s my job to see that everyone has a chance to voice their opinions, as well as to keep us moving along so that we have time to discuss all of the questions. So, at times, it might seem as though I am cutting you off, and this is not meant to be rude, but rather to make sure that we have time to have a complete discussion of each question.

2) It’s really important that everyone hear this: THERE ARE NO RIGHT OR WRONG ANSWERS!!! Each person’s experiences and opinions are valid, and we want to hear a wide range of opinions on the questions we’ll be asking. So, please speak up, whether you agree or disagree with what’s being said, and let us know what you think.

3) Sometimes participants bring up sensitive issues during these discussions, and we want to be sure that everyone agrees that anything of a personal nature that is mentioned in this room will NOT be repeated to others outside of this discussion group. Can I see a nod from everyone showing me that you agree with this confidentiality ground rule? (If anyone is not willing to give their consent to confidentiality, they may be excused from the group.)
4) Let me tell you about our recording process. As you can see, we are using two recorders to record our discussion. We usually record these focus groups because we want to capture everything that all of you say, and we simply can’t write fast enough to get it all down. We use first names only in the transcript, and when we put together the results from all the groups, we don’t include any names. All recordings and records will be kept in a locked file cabinet or on a password protected computer that only members of the research team have access to.

It is VERY IMPORTANT that we speak ONE AT A TIME, so that the recorder picks up everything that is said. So, now that you know what our process is, is everyone OK with being recorded? *(Wait for affirmative responses from everyone.)*

5) We plan to be finished with our discussion by (time). You do not have to be part of this discussion group if you don’t want to. If you do choose to be in the group, a $30 gift card will be provided to you as compensation. The very last thing we need to ask of you is your signature to show that you received your gift card at the end of the discussion. Are there questions about any of this? You can see that we’ve posted our contact information at the front of the room, and you can call us to ask questions at any time after the group ends.

6) Lastly, everyone, please be sure to shut off any phones/pagers you have with you tonight. If you strongly prefer not to turn off your phone, then please put it on vibrate.

*Focus Groups Questions (Turn on recorders now.)*

Let’s start by going around the room and introducing ourselves. Please tell the group:

- a. Your first name?
- b. How many daughters you have, and their ages?

Okay, great. Welcome, everyone. The first thing we are going to do tonight is discuss some of your thoughts about and preferences for getting your daughter vaccinated against HPV. HPV stands for human papillomavirus. HPV is sexually transmitted, and it can cause cervical cancer in women and genital warts in both men and women. There is a new vaccine against HPV that can prevent most genital warts and most cases of cervical cancer.

1. When I say “HPV vaccine,” what kind of thoughts come to mind? *(Probe: why?)*
   - a. What do you know, or what have you heard, about how the HPV vaccine works?
   - b. Do you think the HPV vaccine is safe? *(Probe: why or why not? Under what circumstances?)*

2. Do you believe that the HPV vaccine is effective at preventing genital warts and cervical cancer?
   - a. Why or why not?
   - b. Do you think your daughter needs all 3 doses of the vaccine in order to prevent these diseases?
   - c. Can you tell me more about that?

3. We understand that you may need more information about the vaccine. But based on what I’ve told you so far, or what you already know, how do you feel about your daughter getting HPV vaccine?
   - a. Why do you feel that way?
     - i. Do you think getting the vaccine for your daughter is important for her health?
     - ii. Why or why not?
Okay, now I want to give you a little bit more information. The HPV vaccine is recommended for all girls at age 11 to 12 years, with “catch-up” vaccination for 13- to 26-year-olds. The vaccine is given as 3 doses over a 6-month period. The vaccine costs approximately $120 per dose, and is covered by many private and public health insurance programs.

4. Now with that additional information in mind, do you feel any differently about your daughter getting HPV vaccine?
   a. Why do you feel that way? (Probe for details if feelings have changed.)
   b. Do you still think that getting/not getting the vaccine for your daughter is important for her health? (Why/why not?)

5. What are your thoughts about the fact that the HPV vaccine is a new vaccine? (Probe: why?)

6. How does your family feel about the HPV vaccine? (Probes: why? Do their opinions influence your opinions about it? In what way(s)?)

7. As I mentioned a few minutes ago, HPV is transmitted through intimate contact. How does that affect your feelings about getting/not getting your daughter vaccinated? (Probe: why?)

8. How do you feel about the fact that you need 3 doses of the vaccine to be vaccinated? (Probes: Does it make you more or less likely to get your daughter vaccinated? Why or why not?)

9. How does the cost of the vaccine affect your feelings about vaccination? (Probes: does it make you more or less likely to get your daughter vaccinated? Why or why not?)

10. Does your daughter’s age affect your feelings about getting her vaccinated for HPV? (Probes: Why or why not? At what age would you feel most comfortable having her vaccinated? At what age do you feel it would be most appropriate?)

11. Would having more information about HPV or the HPV vaccine make you feel more comfortable with the idea of getting your daughter vaccinated? (Probe: why or why not?)
   a. IF YES: What kinds of information would be helpful? (Probes: Why? Who would you prefer that this information come from?)

12. Who is the person that would make the decision about having your daughter get the HPV vaccination: You? Your daughter? Or you both together?

Thanks for that information! It is very helpful and interesting. Now we are going to walk you through a website designed to help people understand more about the HPV vaccine. At each page I’ll ask for feedback about what you like and don’t like about the information.

13. Questions/probes for each intervention/website page:
   a. What on this page speaks to you or is the most interesting? (Probe: why?)
   b. What don’t you like? (Probes: Why? What would you like better?)
   c. What is confusing? (Probes: Why? How could we make it less confusing?)
   d. What do you think of the pictures? (Probes: Which ones? Why? How could we improve this?)
14. What do you think about the website overall?
   a. What would make it more useful? (Probe: why?)
   b. What would make it more interesting? (Probe: why?)
   c. Is more/less text needed? (Probe: Where? Why?)
   d. Are more/less pictures needed? (Probe: Where? why?)
   e. Is anything missing from the website? (Probe: what? Why is that important?)

15. Okay, great. We’re almost done now. Before we end, though, I want to make sure that there isn’t anything we have missed. Is there anything else that we haven’t talked about that you think would be helpful for us to know about your feelings about HPV, HPV vaccinations, or this website?

Thank you so much for being here tonight and for sharing your ideas with us!

Do you have any more questions for us? As I mentioned earlier, we will be transcribing tonight’s session but no names or proper nouns will be included. Also, if any of you are interested in the results of our work, we would be happy to notify you about the results of this and similar focus groups carried out by our research team.

Thank you again!

[Pass out incentives and ask for participant signatures]
Welcome
Hello everyone! Welcome, and thank you for agreeing to be part of our focus group tonight.

Introductions
Let me introduce our team: I’m (name of facilitator) and I will be facilitating the discussion and this is (name of co-facilitator) and she will be taking notes this evening. We are working with the University of Colorado and the Patient-Centered Outcomes Research Institute on a research project about adolescents and vaccines. Some people don’t go to see a doctor or other health care provider very often. And, when they do, they may not get information about vaccines, or think about which vaccines they may need.

Tonight we want to get your ideas and opinions about some questions we have about your health care, vaccinations in general, and about a particular vaccine called the HPV vaccine. We will be using the terms “vaccination” and “immunization” interchangeably tonight.

We really appreciate your time today. The way we look at it, YOU are the experts. We value your opinions and want you to know that what you tell us during these discussions may help women get recommended preventive health care.

Ground Rules
Before we begin, let me mention a few things about how we usually conduct these groups:

7) I will be the facilitator for the group. My role is to ask the questions we have for the group, and to encourage everyone to participate. I won’t be doing much talking, but may ask you to explain more or to give an example. Also, it’s my job to see that everyone has a chance to voice their opinions, as well as to keep us moving along so that we have time to discuss all of the questions. So, at times, it might seem as though I am cutting you off, and this is not meant to be rude, but rather to make sure that we have time to have a complete discussion of each question.

8) It’s really important that everyone hear this: THERE ARE NO RIGHT OR WRONG ANSWERS!!! Each person’s experiences and opinions are valid, and we want to hear a wide range of opinions on the questions we’ll be asking. So, please speak up, whether you agree or disagree with what’s being said, and let us know what you think.

9) Sometimes participants bring up sensitive issues during these discussions, and we want to be sure that everyone agrees that anything of a personal nature that is mentioned in this room will NOT be repeated to others outside of this discussion group. Can I see a nod from everyone showing me that you agree with this confidentiality ground rule? (If anyone is not willing to give their consent to confidentiality, they may be excused from the group.)

10) Let me tell you about our recording process. As you can see, we are using two recorders to record our discussion. We usually record these focus groups because we want to capture everything that
all of you say, and we simply can’t write fast enough to get it all down. We use first names only in the transcript, and when we put together the results from all the groups, we don’t include any names. All recordings and records will be kept in a locked file cabinet or on a password protected computer that only members of the research team have access to.

It is VERY IMPORTANT that we speak ONE AT A TIME, so that the recorder picks up everything that is said. So, now that you know what our process is, is everyone OK with being recorded? *(Wait for affirmative responses from everyone.)*

11) We plan to be finished with our discussion by (time). You do not have to be part of this discussion group if you don’t want to. If you do choose to be in the group, a $30 gift card will be provided to you as compensation. The very last thing we need to ask of you is your signature to show that you received your gift card at the end of the discussion. Are there questions about any of this? You can see that we’ve posted our contact information at the front of the room, and you can call us to ask questions at any time after the group ends.

12) Lastly, everyone, please be sure to shut off any phones/pagers you have with you tonight. If you strongly prefer not to turn off your phone, then please put it on vibrate.

**Focus Groups Questions (Turn on recorders now.)**

Let’s start by going around the room and introducing ourselves. Please tell the group:

- **c. Your first name?**

Okay, great. Welcome, everyone. The first thing we are going to do tonight is discuss some of your thoughts about and preferences for getting vaccinated against HPV. HPV stands for human papillomavirus. HPV is sexually transmitted, and it can cause cervical cancer in women and genital warts in both men and women. There is a new vaccine against HPV that can prevent most genital warts and most cases of cervical cancer.

16. When I say “HPV vaccine,” what kind of thoughts come to mind? (Probe: why?)
   - a. What do you know, or what have you heard, about how the HPV vaccine works?
   - b. Do you think the HPV vaccine is safe? (Probe: why or why not? Under what circumstances?)

17. Do you believe that the HPV vaccine is effective at preventing genital warts and cervical cancer?
   - a. Why or why not?
   - b. Do you think you need all 3 doses of the vaccine in order to prevent these diseases?
   - c. Can you tell me more about that?

18. We understand that you may need more information about the vaccine. But based on what I’ve told you so far, or what you already know, how do you feel about getting the HPV vaccine?
   - a. Why do you feel that way?
   - i. Do you think getting the vaccine is important for your health?
   - ii. Why or why not?
Okay, now I want to give you a little bit more information. The HPV vaccine is recommended for all girls at age 11 to 12 years, with “catch-up” vaccination for 13- to 26-year-olds. The vaccine is given as 3 doses over a 6-month period. The vaccine costs approximately $120 per dose, and is covered by many private and public health insurance programs.

19. Now with that additional information in mind, do you feel any differently about getting the HPV vaccine?
   a. Why do you feel that way? (Probe for details if feelings have changed.)
   b. Do you still think that getting/not getting the vaccine is important for your health? (Why/why not?)

20. What are your thoughts about the fact that the HPV vaccine is a new vaccine? (Probe: why?)

21. How does your family feel about the HPV vaccine? (Probes: why? Do their opinions influence your opinions about it? In what way(s)?)

22. How do you feel about the fact that you need 3 doses of the vaccine to be vaccinated? (Probes: Does it make you more or less likely to get vaccinated? Why or why not?)

23. How does the cost of the vaccine affect your feelings about vaccination? (Probes: does it make you more or less likely to get vaccinated? Why or why not?)

24. Would having more information about HPV or the HPV vaccine make you feel more comfortable with the idea of getting vaccinated? (Probe: why or why not?)
   a. IF YES: What kinds of information would be helpful? (Probes: Why? Who would you prefer that this information come from?)

Thanks for that information! It is very helpful and interesting. Now we are going to walk you through a website designed to help people understand more about the HPV vaccine. At each page I’ll ask for feedback about what you like and don’t like about the information.

25. Questions/probes for each intervention/website page:
   e. What on this page speaks to you or is the most interesting? (Probe: why?)
   f. What don’t you like? (Probes: Why? What would you like better?)
   g. What is confusing? (Probes: Why? How could we make it less confusing?)
   h. What do you think of the pictures? (Probes: Which ones? Why? How could we improve this?)

26. What do you think about the website overall?
   f. What would make it more useful? (Probe: why?)
   g. What would make it more interesting? (Probe: why?)
   h. Is more/less text needed? (Probe: Where? Why? )
   i. Are more/less pictures needed? (Probe: Where? why?)
   j. Is anything missing from the website? (Probe: what? Why is that important?)

27. Okay, great. We’re almost done now. Before we end, though, I want to make sure that there isn’t anything we have missed. Is there anything else that we haven’t talked about that you think would be helpful for us to know about your feelings about HPV, HPV vaccinations, or this website?
Thank you so much for being here tonight and for sharing your ideas with us!

Do you have any more questions for us? As I mentioned earlier, we will be transcribing tonight’s session but no names or proper nouns will be included. Also, if any of you are interested in the results of our work, we would be happy to notify you about the results of this and similar focus groups carried out by our research team.

Thank you again!

[Pass out incentives and ask for participant signatures]
APPENDIX C: PARTICIPANT ELIGIBILITY SURVEY

CHICOS
Eligibility Survey

1) Are you interested in this program for a child of yours?
   a. Yes
   b. No

2) Are you interested in this program for yourself?
   a. Yes
   b. No

3) What is your preferred language?
   a. Spanish
   b. English
   c. Other, please describe:

4) Are you the parent of an adolescent ages 9-17?
   a. Yes
   b. No

5) Are you between the ages of 18-26?
   a. Yes
   b. No

6) This study is about the HPV vaccine. This vaccine protects against human papillomavirus, a virus that can cause cervical cancer, genital warts, and other genital cancers.

   The vaccine is given to both males and females. It is a series of 3 shots, usually given sometime between the ages of 9 and 26 years. You may have heard of this vaccine by its other name, Gardasil, or as the “vaccine against cervical cancer.”

   Have you/Has your adolescents received all 3 doses of the HPV vaccine?
   a. Yes
   b. No
   c. Don’t know

Thank You!

Note to RA: Obtain paper consent for those who are eligible to participate.
APPENDIX D: PARTICIPANT BASELINE SURVEY

CHICOS
Baseline Survey

PROCESS FROM INTAKE LETTER TO BASELINE:

• Study Intake completed by RA entering information on iPad.
• RA complete Eligibility survey for/with participant on iPad.
• Determine whether participant is interested and eligible (as parent or young adult).
• If participant is eligible, obtain paper consent.
• iPad randomized to study Arm, based on: primary language, clinical site and parent vs. adult candidate.
• If in un/tailored arm/s: participant gets iPad for pre- and post-intervention surveys before the visit begins. Must complete both the pre- and post-intervention survey to get $.
• If in usual care arm: participant gets paper form; post visit survey and $ after the visit is complete.
• ALL questions for Intake, Eligibility & Baseline are required.

Green is characteristic name.
Green is for the values for each characteristic.
Red is survey commands, or instructions.

SURVEY: (Red T = tailoring variable)

First some questions about you and your family.

AdultAge (T)
How old are you?
(drop down 1-100)

Validation (Loose): if Age<18
Note to RA: (if parent enters less than 18 not eligible) – If young adult participant, must be between ages of 18-26, otherwise not eligible)

ParentMarital
Are you...
  o Single [Single]
  o Married [Married]
  o Divorced [Divorced]
  o Widowed [Widowed]
  o In a committed relationship but not married [Partnered]

HighestGrade
What is the highest grade or level of school you have completed?
  o Less than 12th grade [LessThanTwelve]
  o 12th grade or GED [HiSchOrGED]
Some college [SomeCollege]
College graduate [CollegeGrad]

Ethnicity="Yes"
Heritage
What is your heritage or cultural background?
- Mexican [Mexican]
- Other [Other]

PrevExpAnyone (T)
As far as you know, have you or anyone close to you ever had any of the following diseases? Please choose all that apply.
- Positive HPV test [ExpWHPV]
- Genital warts [ExpWGenWts]
- Abnormal Pap smear [ExpWAbPap]
- Cervical cancer [ExpWCervCanc]
- None of the above [ExpWNone]

AdultCandidate="Yes"
Intercourse
Have you ever had vaginal sexual intercourse?
- Yes [Yes]
- No [No]
- Prefer not to answer [NotAnswer]

AdultCandidate="Yes"
AdultName (T)
What name do you prefer to be called? ___________

ParentCandidate="Yes"
For the following, please answer questions about your adolescent child. In this study, a child is considered an adolescent if they are between 9 and 17 years old.

If you have more than one adolescent, pick one to do the survey about. If you have both sons and daughters that are adolescents, answer the questions about your daughter.

ChildGender
What is the gender of the child you have picked to answer questions about?
- Male [Male]
- Female [Female]

AgeChild
What is their age?
(drop down menu ranging 9-18 years)

ParentCandidate="Yes"
ChildName
What name does your
ChildGender=="Male"
son
ChildGender=="Female"
daughter

prefer to be called? __________ (T)

The next set of questions asks about your views on vaccines to prevent human papillomavirus infection.

Human papillomavirus (HPV) is a very common virus that is spread through intimate contact (this includes intimate touching with hands or mouth and also sexual intercourse). In most cases HPV infection does not cause any symptoms. However, in some people HPV infection can lead to genital warts, abnormal Pap smear tests, and/or cancers of the cervix, vagina, penis, anus, tonsils, and throat.

HPV vaccines are recommended for all females ages 9-26 years and all males ages 9-21 years. You need three doses (shots) of the vaccine to be protected from HPV infection.

DocRecHPV
Now that you have read a bit about HPV infection and vaccination, how likely would you be to

ParentCandidate=="Yes"
allow $ChildName to get
AdultCandidate=="Yes"
get

a dose of the HPV vaccine today if the doctor recommended it?
  o Very likely [VeryLikely]
  o Somewhat likely [SomewhatLikely]
  o Somewhat unlikely [SomewhatUnlikely]
  o Very unlikely [VeryUnlikely]

BELIEFS AND CONCERNS
There are many reasons why

ParentCandidate=="Yes"
parents may or may not want their
ChildGender=="Male"
sons
ChildGender=="Female"
daughters

AdultCandidate=="Yes"
people may or may not want
to get the HPV vaccine.

For each statement, please indicate how much you agree or disagree.
HPVRisk
ParentCandidate==“Yes”
I’m worried that $ChildName might get infected with HPV someday. (T)
AdultCandidate==“Yes”
I am worried I might get infected with HPV someday. (T)

HPVGenitalWarts
ParentCandidate==“Yes”
I’m worried that $ChildName might get genital warts someday. (T)
AdultCandidate==“Yes”
I am worried I might get genital warts someday. (T)

HPVCervical
ParentCandidate==“Yes” and ChildGender==“Female”
I’m worried that $ChildName might get cervical cancer someday (T)
AdultCandidate==“Yes” and AdultGender==“Female”
I am worried I might get cervical cancer someday (T)

HPVCancer
ParentCandidate==“Yes” and ChildGender==“Male”
I’m worried $ChildName might get cancer from HPV someday (T)
AdultCandidate==“Yes” and AdultGender==“Male”
I am worried I might get cancer from HPV someday (T)

HPVGetVirus
ParentCandidate==“Yes”
I am worried that $ChildName might get the HPV virus from the vaccine. (T)
AdultCandidate==“Yes”
I am worried that I might get the HPV virus from the vaccine. (T)

HPVReprodProb
ParentCandidate==“Yes”
I am worried that if I get $ChildName vaccinated against HPV, it might make it difficult for him/her to have children in the future (T)
AdultCandidate==“Yes”
I am worried that if I get vaccinated against HPV it might make it difficult for me to have children in the future. (T)

HPVImmuneProb
ParentCandidate==“Yes”
I am worried that $ChildName might have other health problems from the HPV vaccine. (T)
AdultCandidate==“Yes”
I am worried that I might have other health problems from the HPV vaccine. (T)

HPVCost
I am concerned that the HPV vaccine costs more than I can pay. (T)

HPVEffect
I think the HPV vaccine is effective. (T)

**HPVNotSafe**
I think the HPV vaccine is safe. (T)

**HPVSideEffects**
I am worried about side effects from the HPV vaccine. (T)

**HPVTooNew**
ParentCandidate="Yes"
The HPV vaccine is too new. I want to wait a while before deciding if \$ChildName should get it. (T)

AdultCandidate="Yes"
The HPV vaccine is too new. I want to wait a while before deciding if I should get it. (T)

**HPVTalkFam**
ParentCandidate="Yes"
I would want to talk to other family members or friends before deciding if \$ChildName should get the HPV vaccine. (T)

AdultCandidate="Yes"
I would want to talk to other family members or friends before deciding if I should get the HPV vaccine. (T)

**HPV3DosesImp**
It is important to get three doses of the HPV vaccine. (T)

**HPVSexOK**
ParentCandidate="Yes" and ChildGender="Male"
I worry that if I let \$ChildCame get the HPV vaccine, he might think it is OK to have sex. (T)

ParentCandidate="Yes" and ChildGender="Male"
I worry that if I let \$ChildCame get the HPV vaccine, she might think it is OK to have sex. (T)

**HPVTooYoung**
ParentCandidate="Yes"
I think \$ChildCame is too young to worry about sexually transmitted infections like HPV. (T)

Below is a list of things people may consider when making decisions about the HPV vaccine. (T)

Please indicate on the scale, from 1 meaning Not Important At All to 5 meaning Very Important, how important each of these issues are for you.

<table>
<thead>
<tr>
<th>Not Important At All</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

**VAPreventCancers**
Preventing HPV cancers (cancer of the cervix, penis, anus, vagina, throat)

**VAPreventGWarts**
Preventing genital warts (warts on
Not Important          Very   
At All                  Important
1                         3
2                         4
3                         5

the genitals that are not cancer)

**VASpreadHPV**  
Spreading HPV infection to others

**VANoPain**  
Not having to experience pain

**VADocRec**  
Doing what the doctor recommends

**VAAvoidEffects**  
Avoiding side effects from vaccines

**Thank You!**

That's it! You've reached the end of the questionnaire. Thank you for your time and input.

Please click NEXT to continue.
APPENDIX E: PARTICIPANT POST INTERVENTION SURVEY

CHICOS
Post Intervention Survey

Based on the information you just viewed, please answer the following questions. When you are done, hand the tablet back to the research assistant and she will process your payment for participating in this study.

DocRecHPV
Now that you have viewed the information about HPV infection and vaccination, how likely would you be to
ParentCandidate=="Yes"
allow $ChildName to get
AdultCandidate=="Yes"
get a dose of the HPV vaccine today if the doctor recommended it?
  o Very likely [VeryLikely]
  o Somewhat likely [SomewhatLikely]
  o Somewhat unlikely [SomewhatUnlikely]
  o Very unlikely [VeryUnlikely]

Thinking about this decision, please answer the following questions.

FeelBestChoice Yes No
Do you feel sure about what is the best choice regarding the vaccine for
AdultCandidate=="Yes"
you?
ParentCandidate=="Yes" and ChildGender=="Male"
your son?
ParentCandidate=="Yes" and ChildGender=="Female"
your daughter?

FeelKnowEnough Yes No
Do you feel like you know enough about what are the benefits and risks of getting the vaccine versus not getting the vaccine?

ClearBenefitsRisks Yes No
Are you clear about which benefits and risks matter most to you?

FeelHaveSupport Yes No
Do you feel like you have enough support and advice to make a decision about whether or not to
AdultCandidate=="Yes"
get the vaccine?
ParentCandidate="Yes" have $ChildName get the vaccine?

Now, think about using the **iPad program**. Please answer the following questions on a scale from 1 to 5, with 1 meaning strongly disagree and 5 meaning strongly agree.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EaseOfUse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I thought the program was easy to use</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td><strong>LearnUseEasily</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would imagine most people would learn how to use this program easily</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td><strong>WouldUseInternet</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think that people would use this program frequently if it were available on the internet</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td><strong>EasyToUnderstand</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Everything in the program was easy to understand</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td><strong>AmountInformation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The amount of information was:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Too much [TooMuch]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Too little [TooLittle]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Just right [JustRight]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

That’s it! Thank you.
APPENDIX F: PARTICIPANT POST INTERVENTION SURVEY – USUAL CARE ARM

CHICOS
Post Intervention Survey – Usual Care Arm

1) During the clinical visit, did you discuss the HPV vaccine with the medical provider?
    __Yes → complete the rest of the survey
    ---No → Hand the survey back to the research assistant.

2) Which best describes the discussion about the HPV vaccine
    ___We talked about the vaccine, but the vaccine wasn’t offered to be given today
        → Hand the survey back to the research assistant if you selected this choice
    ___The provider offered the vaccine, but I decided not to get it → continue survey
    ___The provider offered the vaccine, and I received a dose today → continue survey

3) Thinking about this decision, please answer the following questions.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you feel sure about what is the best choice regarding the vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you know enough about what are the benefits and risks of getting the vaccine versus not getting the vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you clear about which benefits and risks matter most to you?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you have enough support and advice to make a decision about whether or not to get the vaccine?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

That’s it! Thank you. Please hand the survey back to the Research Assistant. She will process your payment.
Several weeks ago you agreed to participate in a research study being conducted at the SALUD clinics related to HPV Vaccination. Please take a few moments to answer the following questions that are part of this study.

Make sure to fill out your contact information at the end of the survey so that we can send you your $10 gift card as a thank you for your participation.

1) When you enrolled in this study, you said that your adolescent (ages 9-17 years) son or daughter had not received all three doses of the HPV vaccine. Thinking back to that specific visit, did your adolescent receive an HPV vaccine dose on that day?
   a. Yes
   b. No
   c. I don’t remember

→ If you answered YES, go to question 2

→ If you answered No, or I don’t remember:

Did your adolescent get any HPV vaccine doses after that visit?
   a. Yes
   b. No
   c. I don’t remember

2) Please indicate how many HPV vaccine doses your adolescent has received so far. If you are not sure, make your best guess.
   a. None
   b. 1
   c. 2
   d. 3 or more
3) Please indicate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know how to go about getting my adolescent the HPV vaccine.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have time to take my adolescent to get the vaccine.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>I can afford the HPV vaccine.</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

4) Please answer the following questions related to your opinions about the HPV vaccine for your adolescent:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you feel like you can make the best choice regarding the vaccine for your adolescent?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you know enough about the benefits and risks of getting the vaccine versus not getting the vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you clear about which benefits and risks matter most to you?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you have enough support and advice to make a decision about whether to have your adolescent get the vaccine?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5) Since the time of the visit when you enrolled in this study, has a health care provider offered your adolescent the HPV vaccine?

   a. Yes
   b. No
   c. I don’t remember

   ➔ If you answered **YES**, go to question 6.

   ➔ If you answered **No**, or **I don’t remember**, skip to question 8.

6) When the health care provider offered your adolescent the HPV vaccine, did you agree to let your adolescent get it?

   a. Yes
   b. No
   c. I don’t remember
7) Please answer how much you agree or disagree with the following statements about your decision on the HPV vaccine that you marked in Question 6:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
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</thead>
<tbody>
<tr>
<td>I am satisfied that I was given enough information about the issues important to my decision.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The decision I made was the best one for me personally.</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>I am satisfied that my decision matched my personal values.</td>
<td></td>
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<tr>
<td>I am satisfied that this was my decision to make.</td>
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<tr>
<td>I am satisfied with my decision.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8) How likely is your adolescent to get a dose of HPV vaccine in the next 12 months?
   a. Doesn’t apply – My adolescent has already received all 3 doses of the vaccine
   b. Very likely
   c. Somewhat likely
   d. Somewhat unlikely
   e. Very unlikely

9) Please tell us briefly why you answered question 8 this way:

   □ This doesn’t apply to me – my child already got all 3 doses, OR describe your reason below:

   ____________________________________________________________________________________
   ____________________________________________________________________________________
   ____________________________________________________________________________________
   ____________________________

10) Please provide your name and mailing address so that we can send you your $XX gift card.

THANK YOU for your participation in this important study!
Several weeks ago you agreed to participate in a research study being conducted at the SALUD clinics related to HPV Vaccination. Please take a few moments to answer the following questions that are part of this study.

Make sure to fill out your contact information at the end of the survey so that we can send you your $10 gift card as a thank you for your participation.

1) When you enrolled in this study, you said that you had not received all three doses of the HPV vaccine. Thinking back to that specific visit, did you receive an HPV vaccine dose on that day?
   a. Yes
   b. No
   c. I don’t remember

→ If you answered YES, go to question 2

→ If you answered No, or I don’t remember:

Did you get any HPV vaccine doses after that visit?
   a. Yes
   b. No
   c. I don’t remember

2) Please indicate how many HPV vaccine doses you have received so far. If you are not sure, make your best guess.
   a. None
   b. 1
   c. 2
   d. 3 or more
3) Please indicate your level of agreement with the following statements:

<table>
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<tbody>
<tr>
<td>I know how to go about getting the HPV vaccine.</td>
<td></td>
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4) Please answer the following questions related to your opinions about the HPV vaccine:

<table>
<thead>
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<th>No</th>
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</thead>
<tbody>
<tr>
<td>Do you feel like you can make the best choice regarding the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vaccine for yourself?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you know enough about the benefits and risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of getting the vaccine versus not getting the vaccine?</td>
<td></td>
<td></td>
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<tr>
<td>Are you clear about which benefits and risks matter most to you</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel like you have enough support and advice to make a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>decision about whether to get the vaccine?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5) **Since the time of the visit when you enrolled in this study**, have a health care provider offered you the HPV vaccine?

- a. Yes
- b. No
- c. I don’t remember

➔ If you answered **YES**, go to question 6.

➔ If you answered **No**, or **I don’t remember**, skip to question 8.

6) When the health care provider offered you the HPV vaccine, did you agree to get it?

- a. Yes
- b. No
- c. I don’t remember
7) Please answer how much you agree or disagree with the following statements about your decision on the HPV vaccine that you marked in Question 6:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
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<td></td>
</tr>
<tr>
<td>I am satisfied that this was my decision to make.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am satisfied with my decision.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8) How likely are you to get a dose of HPV vaccine in the next 12 months?

   a. Doesn’t apply – I have already received all 3 doses of the vaccine
   b. Very likely
   c. Somewhat likely
   d. Somewhat unlikely
   e. Very unlikely

9) Please tell us briefly why you answered question 8 this way:

   □ This doesn’t apply to me – I already got all 3 doses, OR describe your reason below:

   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________

10) Please provide your name and mailing address so that we can send you your $XX gift card.

THANK YOU for your participation in this important study!
APPENDIX I: CHICOS INTERVENTION/WEBSITE SCREENSHOTS
Welcome to CHICOS!
This program is designed to help parents like you learn about the HPV (Human Papillomavirus) vaccine.

Based on your survey answers, it looks like Kadence may not be up to date on her HPV vaccine. You can check with her doctor if you are unsure.

Tap to read more

Did you know?
What’s holding you back?

We can help answer your questions and put your fears to rest. Tap on the Introduction button to get started. We’re glad you’re here!

©2014 The Regents of the University of Michigan
Welcome to CHICOS!
This program is designed to help parents like you learn about the HPV (Human Papillomavirus) vaccine.

Based on your survey answers, it looks like Kadence may not be up to date on her HPV vaccine. You can check with her doctor if you are unsure.

Did you know?

What's holding you back?

It sounds like there might be something holding you back from getting Kadence vaccinated. Do you have unanswered questions or concerns? That's where we come in. Are any of these on your mind?

- Could Kadence get infected with HPV?
- Are there side effects with the HPV vaccine?
- Should I wait since the HPV vaccine is so new?
- Is the vaccine safe?

We can help answer your questions and put your fears to rest. Tap on the Introduction button to get started. We're glad you're here!
HPV and the HPV Vaccine
You clearly take Kadence's health seriously. The HPV vaccine will help protect her against:

- HPV
- Genital warts
- Abnormal pap tests
- Cervical cancer
- Other kinds of cancer, like cancer of the anus, vagina, vulva (area around the vagina) and possibly cancers of the throat

Info on HPV

- What is HPV?
- How do people get HPV?
- Do a lot of people get HPV?
- Does HPV have symptoms?
- Is there a cure for HPV?

Info on HPV Vaccine

- What does the vaccine do?
- Does the vaccine work?
HPV and the HPV Vaccine
You clearly take Kadence’s health seriously. The HPV vaccine will help protect her against:
- HPV
- Genital warts
- Abnormal pap tests
- Cervical cancer
- Other kinds of cancer, like cancer of the anus, vagina, vulva (area around the vagina) and possibly cancers of the throat

Info on HPV

What is HPV?

How do people get HPV?

Do a lot of people get HPV?

Does HPV have symptoms?

HPV infection does not always have symptoms.
- In women, infection is usually found through a Pap smear.
- Most men will never know they had an HPV infection since there is no routine test for HPV in men.

In some people, HPV can cause genital warts, and cancer of the penis, cervix, vagina, or anus.

Is there a cure for HPV?
Specific Concerns – Tailored Intervention

Your Questions About the HPV Vaccine
In your survey, you had some general questions about the HPV vaccine. We’ve listed each of those questions below. Tap a concern to read more.

- What are the side effects of the vaccine?
  Since 2006, more than 76 million doses of the vaccine have been given to girls and boys around the world.
  It’s safety has been studied very closely in the US and many other countries. HPV vaccines have a safety record that is equal to or better than the other vaccines given to children and adolescents.
  - Known side effects of HPV vaccines
  - Side effects that are NOT related to the vaccine

- How safe are HPV vaccines?
- Is it worth waiting to see if the vaccine is ok?
- Will the vaccine cause reproductive problems?
- Will HPV cause problems with the immune system?
Germs like the HPV virus are covered with proteins called antigens. Your body recognizes antigens, and uses something called antibodies to attack them to protect you from getting sick.

The HPV vaccine contains lab-created antigens that act just like the ones from a real human papillomavirus, except that they are not the virus, so cannot cause infection. Even though the antigens in the vaccine aren't real, your antibodies think they are from a real virus.

Your antibodies attack the man-made antigen in the vaccine, and then “remember” how to fight them off... ...if the real virus enters your body later.
Questions about the HPV Vaccine
It's not uncommon to have questions about the HPV vaccine. We've listed some common questions below. Tap a concern to read more.

✨ Is my child too young for the vaccine?

✨ How effective is the vaccine?

❗ Will the vaccine make my child think it is ok to have sex?

Are you concerned that getting Kadence vaccinated might make her think it's ok to have sex?

By the time they are teens, most children know how their parents feel about pre-marital sex. Some parents are able to talk openly about their views on this issue. But, even if you haven't talked about it with your child directly, she probably knows your views from hearing you talk about it with others.

It's unlikely that the HPV vaccine will change a child’s behavior. Parents teach their children values over many years. Getting the HPV vaccine is extremely unlikely to undo this.

Research has shown that a parent’s influence matters more than almost anything else. Parents like you have said that talking openly with their kids is the best way to influence behavior, and some say they even use the vaccine as a starting point for a conversation with their children about sex.

✨ Should I talk to other people before making my decision?

✨ How important is getting all three doses of the HPV vaccine?
Additional Information – Tailored Intervention

More on HPV

- How many people have gotten the HPV vaccine?
- How does the HPV vaccine work?
- How long does the vaccine last?
- Do women still need Pap smears after getting the vaccine?

Yes! The vaccine does not protect against every type of HPV. Also, someone who got the vaccine after becoming sexually active may have already been exposed to HPV before getting the vaccine.

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Graphic Photos – Tailored Intervention
Graphic Photos – Tailored Intervention
Graphic Photos – Tailored Intervention
Personalized Vignette – Tailored Intervention

A Parent’s Story

Like every parent, I worry about making the right choices for my daughter, Jenny. It feels like every day, there’s a new issue to tackle or choice to make. It was like that five years ago when Jenny’s doctor recommended she get the HPV vaccine. I wasn’t really sure what to do. It didn’t seem like Jenny really needed the vaccine – she was only 13. I thought it might make her more likely to have sex and I was scared that the vaccine was so new, maybe it wasn’t as safe as people said – so Jenny didn’t get it.

I have never regretted a decision more.

When she turned 18, Jenny said she was ready for her first Pap test. I remember that she was nervous and I just kept telling her that everything would be fine. It wasn’t. The test showed “abnormal cells” on Jenny’s cervix. They ran the test again, with an HPV screen this time, and the results were the same. Jenny had HPV. Even worse, it was one of the kinds that can cause cancer. The doctor said often the body may fight the virus on its own, so Jenny needed Pap tests every six months to keep an eye on things.

My world turned upside down. I couldn’t even process the HPV part. I was mostly shocked that Jenny was sexually active. I always thought she would wait until she got married. But, I shouldn’t have been surprised – she and her boyfriend had been together for several years and were really serious about each other. I knew I had to get over my disappointment quickly – Jenny needed me. She was so afraid that she had cancer. She kept asking me ‘Mom, what if I have cancer?’ I told her that I loved her and we would face whatever happened together.

I took her back for a check up six months later. The doctor told us that Jenny’s test was still abnormal. I could hardly breathe. The news got worse – Jenny would need a minor surgery, called a LEEP procedure, to cut out the cells. On top of that, she would need Pap tests every three months to make sure the cells didn’t come back.

The day of the surgery, Jenny’s eyes were wide with tears shining just in the corners. She held my hand, just like when she was little, as we walked into the clinic. During the procedure, the doctor numbed her cervix and used a tool to scrape away the cells. After it was over, I could see that Jenny was in pain, but trying to be strong.

Jenny recovered over the next few days – she was uncomfortable and scared. A few days after the surgery, the doctor said it looked like they got all the abnormal cells. But, Jenny will need yearly Pap tests for the rest of her life – to make sure the abnormal cells haven’t come back. Every year, Jenny will have to go to that appointment, afraid that this time she’ll have cancer.

Every day I wish that I had gotten Jenny vaccinated. Even if Jenny had waited to have sex until she got married, she could have gotten HPV from her husband. I can’t believe I left her unprotected against this virus.
Making Decisions About HPV Vaccines

This worksheet is being provided by your doctor's office for young adults (up to age 26) or parents of adolescents (9-18) who have not yet gotten vaccinated against human papillomavirus (also known as HPV).

HPV occurs in 80% of adults, but generally causes no health problems. However, in some people HPV causes cancers of the cervix, vagina, penis, and anus and also causes genital warts (a non-cancerous condition). In fact, the only way you can get cervical cancer and genital warts is from an HPV infection.

Getting vaccinated against HPV can decrease the chance of getting these diseases. The HPV vaccine is given as a series of 3 shots, ideally over a 6-12 month period. Many people have questions about the HPV vaccine even after talking to their doctor. Follow the three areas in this worksheet to weigh up the pros and cons of HPV vaccination for you or your family.

References: Gardasil product insert (Birmingham, MD: Glaxo, 2006); CDC (2013) Immunization Schedules, immunizations.gov/ (http://www.cdc.gov/hpv/vaccination/schedules.html) (Accessed May 2014). Funding Source: This tool was developed with support from the Patient Centered Outcomes Research Institute: Making decisions about HPV vaccine; pay for them in development.
Decision Aid – Tailored Intervention

Out of 100 People...

80 will have pain at the injection site
33 will get a headache
2 will get a fever over 100°

Out of 10,000 People...

250 people will get Genital Warts
1 person will get Genital Warts
99 people will have Abnormal Pap smear
1 person will have Abnormal Pap smear
67 people will get HPV-Related Cancer
20 people will get HPV-Related Cancer

Pros & Cons

Compare the pros and cons of getting vaccinated or not getting vaccinated. The graphs below show the chances of various events occurring over a person's lifetime.

Next Steps

Look back over what you saw were your health values, and the pros and cons of vaccinating versus not vaccinating. Weigh all the information together and decide on what is best for you or your family. Circle the choice below that is most in line with your decision. Then look at the action below your choice to see some next steps to take.

- I have decided I want the vaccine and I'm ready to take action.
  - Call your doctor's office to make an appointment to get the vaccine.

- I have decided I will get the vaccine, just not right now.
  - Pick a date on your calendar when you will go through things again and decide if it is time to get the vaccine.

- I want to talk to others first before making a decision.
  - Make an appointment with your provider to talk about the vaccine. If you want to talk to your family about this, put this conversation on your "to do" list.

- I want to get more information first before making a decision.
  - See the websites on this page for reliable Information about the vaccine, or make an appointment to talk about the vaccine with your medical provider.

- I have decided I don't want the vaccine.
  - Think about reconsidering your decision in a year or two. The vaccine can be given up to age 26.

For more information about HPV Infection and HPV vaccines please visit the following websites:

- Centers for Disease Control and Prevention: http://www.cdc.gov/hpv/vaccine.html
- American Cancer Society: http://www.cancer.org (search for HPV)
APPENDIX J: Basic/VIS Format – Untailed Intervention

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW

What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don’t cause any symptoms, and go away on their own. But HPV can cause cervical cancer in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 12,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women, and anal and oropharyngeal (back of the throat, including base of tongue and tonsils) cancers in both men and women. HPV can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW

HPV vaccine - Why get vaccinated?

There are two vaccines that can be given to prevent HPV. One vaccine (Gardasil®) may be given to both males and females.

This vaccine can prevent most cases of cervical cancer in females, if it is given before exposure to the virus. In addition, it can prevent vaginal and vulvar cancer in females, and genital warts and anal cancer in both males and females.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.
Basic/VIS Format – Untailored Intervention

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW
Who should get this HPV vaccine and when?

HPV vaccine is given as a 3-dose series

- 1st Dose: Now
- 2nd Dose: 1 to 2 months after Dose 1
- 3rd Dose: 6 months after Dose 1

Additional (booster) doses are not recommended.

Routine Vaccination

- This HPV vaccine is recommended for girls and boys 11 or 12 years of age. It may be given starting at age 9.
- Why is HPV vaccine recommended at 11 or 12 years of age?
  HPV infection is easily acquired, even with only one sex partner. That is why it is important to get HPV vaccine before any sexual contact takes place. Also, response to the vaccine is better at this age than at older ages.

Catch-Up Vaccination
This vaccine is recommended for the following people who have not completed the 3-dose series:

- Females 13 through 26 years of age.
- Males 13 through 21 years of age.

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW
Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.
- HPV vaccine is not recommended for pregnant women. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.
- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a moderate or severe illness should wait until they are better.
HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW
What are the risks from this vaccine?
This HPV vaccine has been used in the U.S. and around the world for about six years and has been very safe.
However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.
Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.
Several **mild** to **moderate** problems are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
  - Pain (about 8 people in 10)
  - Redness or swelling (about 1 person in 4)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)
  - Fainting. Brief fainting spells and related symptoms (such as jerking movements) can happen
Basic/VIS Format – Untailored Intervention

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW

What if there is a severe reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.
- Signs of a serious allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions, They do not give medical advice.

HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®

WHAT YOU NEED TO KNOW

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.
HPV (HUMAN PAPILLOMAVIRUS) VACCINE - Gardasil®
WHAT YOU NEED TO KNOW
How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/vaccines
### Table 3. Demographic Characteristics of Participants with Vaccination Data Assessed

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<tr>
<th>Participant Characteristics</th>
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#### Gender

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<tr>
<td>TOTAL</td>
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#### Race

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<td>Untailored % (n)</td>
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<td>TOTAL</td>
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#### Ethnicity

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<td>Untailored % (n)</td>
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<td>84</td>
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#### Age at Baseline

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<th>Participant Characteristics</th>
<th>Median Age (MED)</th>
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<td>Parents (Adolescent Age)</td>
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Table 4. HPV Vaccine Uptake in Young Adults and Adolescents Across the 3 Study Arms

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<tr>
<th>Participant Population</th>
<th>Arm Assignment</th>
<th>Usual Care</th>
<th>Tailored</th>
<th>Untailored</th>
<th>P-value&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td></td>
<td># eligible for outcome assessed</td>
<td>% of eligible vaccinated (n)</td>
<td># eligible for outcome assessed</td>
<td>% of eligible vaccinated (n)</td>
<td># eligible for outcome assessed</td>
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<tr>
<td><strong>Young Adults</strong></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Got Any Dose of HPV During Study</td>
<td>108</td>
<td>3% (3)</td>
<td>84</td>
<td>6% (5)</td>
<td>115</td>
</tr>
<tr>
<td>Initiated the Vaccine Series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>85</td>
<td>4% (3)</td>
<td>66</td>
<td>8% (5)</td>
<td>93</td>
</tr>
<tr>
<td>Initiated the Vaccine, Series not Completed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>3</td>
<td>33% (1)</td>
<td>5</td>
<td>80% (4)</td>
<td>3</td>
</tr>
<tr>
<td>Completed the Vaccine Series, Among All Eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>99</td>
<td>2% (2)</td>
<td>79</td>
<td>1% (1)</td>
<td>102</td>
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<tr>
<td>Completed the Vaccine Series, Among Those Initiated at Study Start&lt;sup&gt;e&lt;/sup&gt;</td>
<td>23</td>
<td>0% (0)</td>
<td>18</td>
<td>0% (0)</td>
<td>22</td>
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<tr>
<td>Completed the Vaccine Series, Among Those Who Initiated During the Study&lt;sup&gt;f&lt;/sup&gt;</td>
<td>3</td>
<td>67% (2)</td>
<td>5</td>
<td>20% (1)</td>
<td>3</td>
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<tr>
<td><strong>Adolescents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Got Any Dose of HPV During Study</td>
<td>158</td>
<td>47% (74)</td>
<td>175</td>
<td>49% (81)</td>
<td>165</td>
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<tr>
<td>Initiated the Vaccine Series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>93</td>
<td>34% (32)</td>
<td>115</td>
<td>42% (48)</td>
<td>95</td>
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<tr>
<td>Initiated the Vaccine, Series not Completed&lt;sup&gt;c&lt;/sup&gt;</td>
<td>30</td>
<td>77% (22)</td>
<td>42</td>
<td>79% (33)</td>
<td>41</td>
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<tr>
<td>Completed the Vaccine Series, Among All Eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>140</td>
<td>21% (29)</td>
<td>158</td>
<td>23% (37)</td>
<td>151</td>
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<tr>
<td>Completed the Vaccine Series, Among Those Initiated at Study Start&lt;sup&gt;e&lt;/sup&gt;</td>
<td>65</td>
<td>42% (27)</td>
<td>60</td>
<td>53% (32)</td>
<td>70</td>
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<tr>
<td>Completed the Vaccine Series, Among Those Who Initiated During the Study&lt;sup&gt;f&lt;/sup&gt;</td>
<td>30</td>
<td>23% (7)</td>
<td>42</td>
<td>21% (9)</td>
<td>41</td>
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</table>

<sup>a</sup>P-value for three arm comparison of % vaccinated

<sup>b</sup>Describes those who had 0 doses at study enrollment and received at least one dose during the study period.

<sup>c</sup>Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, but did not complete the series during the study period.
Describes those who enrolled in the study with 0, 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Describes those who enrolled in the study with 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Bolded p-values highlight significant or near significant results.
### Table 5. Two Way Comparisons of Adolescent Vaccination Between Study Arms

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Comparison Arms</th>
<th>Difference, 95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Got Any Dose of HPV During Study</td>
<td>Tailored vs. Usual Care</td>
<td>2.3 (-8.4, 13.0)</td>
<td>0.674</td>
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<tr>
<td></td>
<td>Untailed vs. Usual Care</td>
<td>6.5 (-4.4, 17.4)</td>
<td>0.242</td>
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<tr>
<td></td>
<td>Untailed vs. Tailored</td>
<td>4.2 (-6.4, 14.8)</td>
<td>0.439</td>
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<tr>
<td>Initiated the Vaccine Series&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Tailored vs. Usual Care</td>
<td>7.3 (-5.9, 20.5)</td>
<td>0.277</td>
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<td>Untailed vs. Usual Care</td>
<td>11.9 (-2.0, 25.8)</td>
<td>0.094</td>
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<td>Untailed vs. Tailored</td>
<td>4.6 (-8.9, 18.1)</td>
<td>0.506</td>
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<tr>
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<td>Tailored vs. Usual Care</td>
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<td>0.849</td>
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<tr>
<td></td>
<td>Untailed vs. Usual Care</td>
<td>11.1 (-7.0, 29.3)</td>
<td>0.229</td>
</tr>
<tr>
<td></td>
<td>Untailed vs. Tailored</td>
<td>9.2 (-6.7, 25.2)</td>
<td>0.256</td>
</tr>
<tr>
<td>Completed the Vaccine Series, Among All Eligible&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Tailored vs. Usual Care</td>
<td>2.7 (-6.7, 12.1)</td>
<td>0.574</td>
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<tr>
<td></td>
<td>Untailed vs. Usual Care</td>
<td>-2.8 (-11.9, 6.2)</td>
<td>0.541</td>
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<tr>
<td></td>
<td>Untailed vs. Tailored</td>
<td>-5.5 (-14.5, 3.5)</td>
<td>0.228</td>
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<tr>
<td>Completed the Vaccine Series Among Those Already Initiated at Study Start&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Tailored vs. Usual Care</td>
<td>11.8 (-5.6, 29.2)</td>
<td>0.184</td>
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<td>Untailed vs. Usual Care</td>
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<td>0.296</td>
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<td>Untailed vs. Tailored</td>
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<td>0.229</td>
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<tr>
<td></td>
<td>Untailed vs. Tailored</td>
<td>-9.2 (-25.2, 6.7)</td>
<td>0.256</td>
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</tbody>
</table>

<sup>a</sup> P-value for the % vaccinated among the two arms denoted

<sup>b</sup> Describes those who had 0 doses at study enrollment and received at least one dose during the study period.

<sup>c</sup> Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, but did not complete the series during the study period.

<sup>d</sup> Describes those who enrolled in the study with 0, 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

<sup>e</sup> Describes those who enrolled in the study with 1 or 2 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

<sup>f</sup> Describes those who enrolled in the study with 0 doses, had enough time in the study period after the most recent dose to complete the series, and completed the series during the study period.

Bolded p-values highlight significant or near significant results.
Exploratory Analysis of Other Factors Impacting Vaccination

A series of exploratory models examined among the PP population the association between clinical site, age, gender, and study arm among the adolescent population. Young adult models were not created given the low level of vaccination in this population. Among adolescents, in univariate models of individuals from all arms combined, there were significant increases in receiving an HPV dose during the study period among those who started the study with 1-2 doses compared to those starting with 0 doses (64% vs. 41%, p<0.001), females compared to males (58% vs. 42%, p<0.001), and differences by age (70% for 11-12 year olds vs. 44% for 9-10 year olds, 42% for 13-15 year olds, and 43% for 16-17 year olds, p<0.001). After adjusting for arm, study site, whether any doses of HPV had been received prior to the study enrollment, adolescent gender, and adolescent age category, having prior HPV vaccine doses was found to be associated with receipt of any vaccine dose during the study period (OR 2.75, 95% CI 1.78-4.25), as was female gender (OR 1.88, 95% CI 1.28-2.79), age 11-12 (OR 2.22, 95% CI 1.32-3.78, referent to 9-10; 13-15 OR 0.65, 95% CI 0.38-1.09, 16-17 OR 0.77, 95% CI 0.39-1.51) and clinic location (OR ranged 1.63-2.68 depending on site). Interaction terms between study arm and age, study arm and gender, and study arm and prior doses were not significant and therefore did not remain in the final model. Taken together, these results suggest that there was no differential impact of the study interventions by age or gender of the adolescent in the PP population.
Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

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