STUDY PROTOCOL [Feasibility Trial- Stage 3] &

STATISTICAL ANALYSIS PLAN

Official title: Developing a self-persuasion intervention promoting adolescent HPV vaccination

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PROJECT SUMMARY

Principal Investigators: Jasmin A. Tiro and Austin Baldwin (SMU)

Study Title: Developing a self-persuasion intervention promoting adolescent HPV vaccination

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Purpose
This multi-stage study will develop and refine a parent-targeted intervention for HPV vaccination in 9-17 year old girls and boys attending safety-net primary care clinics. We will use a tablet-based application to address parental motivation and indecision by helping parents verbally articulate and/or choose their own pro-vaccine arguments. We will study a cohort of undecided parents (or guardians with medical decision-making ability) of unvaccinated adolescents seen through Parkland Hospital and Health System. We will develop and refine a self-persuasion intervention and test basic self-persuasion mechanisms. This study has 3 Aims:

Aim 1: Characterize the content and scope of: a) parents' self-generated HPV vaccine arguments and b) parent-provider HPV vaccine discussions.

Aim 2: Develop 4 self-persuasion intervention conditions (based on Aim 1 results) that vary by cognitive processing level (parents verbalize vs. listen to arguments) and choice of argument topics (parents choose vs. are assigned topics) and (b) identify which intervention condition is optimal through a controlled proof of concept study that quantitatively examines basic self-persuasion mechanisms (cognitive processing, choice) and qualitatively explores experiences with intervention tasks.

Aim 3: Examine feasibility of the optimal intervention (identified in Aim 2) with a pilot study in the safety-net clinics.

Background

Strains of human papillomavirus (HPV), a sexually transmitted infection, can cause several cancer types (cervical, oropharyngeal, anal, vaginal, penile) that pose a significant public health burden in the US.[1-4] In the pre-vaccination era, over 25,000 US adults were diagnosed annually with HPV-related cancers.[5] Cervical cancer, the most prevalent one, is a key marker of US health disparities[6,7] with higher incidence and mortality among underserved groups— the uninsured, poor, racial and ethnic minorities, and immigrants.[6,8-11]

The HPV vaccine is highly efficacious and universally recommended,[12-15] yet US rates are suboptimal, particularly among the types of patients seen in safety net healthcare systems.[16] Bivalent and quadrivalent HPV vaccines are efficacious in protecting against HPV-related cancers; the latter also against genital warts.[17-20] Clinical guidelines recommend 3 doses for females and males ages 11-12, and catch-up administration for non-vaccinated adolescents and young adults (females 13-26; males 13-21).[12-15] Cost effectiveness analyses assume 3-dose rates of 75%;[2-4] however, after 4 years of availability, rates remain well below that goal as the 3-dose rate among US females ages 13-17 in 2010 was 32%.[21] An Internet survey estimated male 1-dose rate in 2010 to be 2%.[22] Safety-nets (e.g., county-based systems, federally qualified health centers) are mandated to maintain an "open door" for underserved patients; thus, safety-nets are the ideal setting to promote HPV vaccination.[23]

One reason for suboptimal rates is that many parents (primary decision-makers for child immunization) remain ambivalent about the vaccine, thus delay making a decision.[24,25] Parents often remain undecided even with a provider recommendation.[25-28] Undecided parents are a heterogeneous group – some perceive low risk or poor vaccine efficacy, others are concerned about promoting sex, unknown side effects, or are simply not motivated.[24,29] Most interventions to date have focused on reminding parents about immunizations.[30-35] **Thus, novel basic and applied research about parental decision-making is needed to design novel HPV vaccine interventions addressing parental indecision.**[36]

Self-persuasion – the process of generating one's own arguments for changing behavior – is an effective approach to influence motivation and behavior. Based in theories of persuasion[37,38] and cognitive dissonance,[39,40] basic research has demonstrated that self-generated arguments are more effective than arguments from an external source.[38,40] Approaches eliciting self-persuasion have improved diverse behaviors including smoking cessation,[41-43] dietary behaviors,[44,45] and safer sex practices.[39] In our own work, self-written arguments had a medium-sized effect on behavioral intentions for regular exercise (d = .60);[41] others also found a medium effect for written and verbalized arguments on eating disorder behaviors (hazard ratio = 2.50).[45] Effects of self-persuasion have been shown to persist for 2-3 months[39,44] to 2-3 years.[43,45] Some argue that self-persuasion is the most effective way to change behavior because motivation for change comes from within the individual.[40] **Yet, evidence is unclear about the processes underlying self-persuasion that explain *why* it is effective.** This is particularly true among underserved populations seen in safety-net systems, given that self-persuasion studies to date have been conducted among diverse, but largely well-educated populations.[39,41,42,44,45]

Generating one's own arguments for changing behavior is characterized by two processes—choice and deep cognitive processing—that can address the basic science question of why self-persuasion is effective. First, people choose which arguments, among various alternatives, are most compelling to them. Consistent with Self-Determination Theory,[46] choice elicits motivation for behavior. Across different behaviors, people are more likely to change a behavior when it has been freely chosen.[47-50] Second, people cognitively process self-generated argument content deeply.[51] Consistent with theories of persuasion,[37,52] argument content is more likely to be convincing when processed deeply,[38,53] because it is more accessible in memory.[54,55] Therefore, we hypothesize that self-persuasion will motivate parents to opt for HPV vaccination *because* they (1) choose arguments that resonate with them, and/or (2) cognitively process the arguments deeply. Examining choice and deep cognitive processing as basic mechanisms of self-persuasion is a **novel** synthesis of two research literatures. We will use quantitative and qualitative methods to clarify each mechanism's effects, jointly addressing (a) an important basic science question and (b) how to construct an optimal self-persuasion intervention for underserved populations.

By leveraging people's own arguments for HPV vaccination, self-persuasion is also an efficient way to deliver personally relevant messages. Our basic research indicates that self-generated messages are similar to tailored messages,[41] for which experts collect data from each patient to generate customized feedback addressing their unique needs. Tailored messages are effective *because* they are perceived as more personally relevant.[56] However, because constructing tailored interventions is time- and cost-intensive,[57] directing parents to *generate their own* arguments for the vaccine may be a more efficient way to deliver personally relevant messages, especially given that factors influencing HPV vaccine decision making vary across different racial/ ethnic groups.[58] Although some studies applying self-persuasion have asked people to *write* their arguments for the target health behavior,[39,41,45,55] some have had people *verbalize* their arguments.[39,45] We propose that *verbalizing* will be an effective and feasible strategy for underserved populations attending safety-nets.[54]

In safety-net clinics, self-persuasion interventions may also be valuable in priming parents to engage in discussion with their child's provider about the vaccine. It is possible that a self-persuasion approach may actually prompt parents to generate concerns or arguments against the vaccine—a potential negative effect.[41] However, the process of identifying vaccine concerns may also help prepare parents to express and discuss their concerns with the provider.[36,59] By timing intervention delivery immediately prior to a clinic visit, we can increase the opportunity for parents to take advantage and respond to the provider's cue about the vaccine and for the provider to address concerns. This is valuable because providers are seen as credible sources of information about immunizations, particularly for underserved populations.[36]

This research will elucidate basic mechanisms of self-persuasion, identify the optimal method for eliciting self-persuasion in an underserved population, and provide key information about factors that contribute to HPV vaccine decision-making among parents. It will also generate evidence for intervention feasibility and acceptability that positions our interdisciplinary team to conduct a future efficacy intervention trial for underserved, undecided parents of adolescents at risk for HPV-related cancers.

Concise Summary of Project

This 3-stage trial will develop a parent-targeted intervention for HPV vaccination in 9-17 year old girls & boys attending Parkland clinics. Drs. Tiro, Baldwin, & Persaud will work with EMR programmers to identify parent-child dyads meeting eligibility criteria. We are requesting a HIPAA waiver of privacy authorization for research to verify the adolescent's vaccination status prior to contacting the parent, as well as examine visit history data to ascertain recruitment clinic/provider. Parents will be mailed an invitation letter, which will provide a toll-free telephone number to ask questions or notify staff of refusal. Parents who have not refused contact will be called by a bilingual research assistant (RA) who will explain the project and offer a verbal invitation to participate. If the parent is interested, the RA will verify eligibility and arrange an in-person meeting. RAs will verbally consent eligible parents who agree to participate and administer a baseline survey. We will obtain verbal informed consent from the parent and provider for all study procedures described below. For Stage 3 recruitment, RAs will meet parents at an upcoming clinic appointment to verify eligibility, instead of contacting over the phone.

Prior to Stage 1a recruitment, we will conduct a small group of cognitive testing interviews on the baseline and exit surveys. These cognitive interviews are necessary to ensure that the survey questions asked will be understood to mean the same in both English and Spanish, and that we are measuring the concepts expected for each item. We will conduct 16 interviews (8 English and 8 Spanish) using the same population of parents for Stages 1-3. The eligibility criteria will be the same as the other stages in the project. Just as in Stage 1a, the RA will obtain verbal consent and the interview will be recorded. Recruitment procedures will be the same for cognitive interviews as it is for Stage 1a, with the exception that we will also recruit participants from the Community Research Registry. Also, instead of conducting the baseline survey over the phone, the parent will meet an RA at UT Southwestern Medical Center, and the RA will read the survey aloud to the parent in person. After survey completion, the parent will participate in the cognitive interview to review the language of the survey and discuss their comprehension of the questions. The parent will received a $15 gift card for their time.

Stage 1. Aim 1a: We will recruit 42 parents of unvaccinated adolescents & 11 parents of adolescents who initiated the series. The RA will show the parent how to use a tablet-based application (a short video will provide HPV vaccine info suited for parents of adolescent females & males). The RA will use a series of questions to prompt parents to verbalize pro-vaccine arguments. Parents will then be asked to listen to, rate, and choose among *peer-generated* arguments. Finally, participants will be given the entire set of arguments. We will use probes to determine whether they can distinguish among and select their preferred arguments. Aim 1b: We will recruit 53 parents of unvaccinated adolescents with upcoming clinic appointments. We will audiorecord parent-provider discussions. Afterwards, parents will be asked about their prior experience with this provider and whether the HPV vaccine was discussed during the visit. The RA will administer a survey about provider recommendations, HPV vaccine benefits/barriers, & perceived involvement in medical care.

Stage 2. Aim 2: We will randomly assign 168 undecided parents to 1 of 4 intervention conditions. Parents will use a tablet-based application to either verbalize their own arguments based on topics they choose (deep processing/high choice), verbalize arguments based on topics assigned to them (deep processing/low choice), listen to arguments based on topics they choose (shallow processing/high choice), or listen to arguments based on topics assigned to them (shallow processing/low choice). We will assess parents' perspective on the tablet application, self-persuasion condition, and how their beliefs/experiences shape feelings about the HPV vaccine. Adolescents who accompany their parents to the appointment at their Parkland clinic will be offered the 1st HPV vaccine dose from a Parkland nurse immediately after the exit interview.

Stage 3. Aim 3: We will recruit from pediatric and youth & family clinics. Parents will be randomly assigned to either self-persuasion plus information (Aim 2 optimal intervention condition; n=48), or HPV information only (n=47). For the self-persuasion group, we will follow procedures in Stage 1. Parents in the info-only group will be given a tablet and instructed to listen to information about HPV infections and the benefits/risks of the HPV vaccine. We will audiorecord the parent-provider discussion. Immediately after the visit, participants will be asked questions about their experiences using the tablet and their communication with the provider.

We expect to review the medical records of 369 patients whose parents were enrolled in our study. Medical records will be reviewed after 12 months for HPV vaccine dates. We will also abstract info for 3 other vaccines

(TDAP, MCV4, & influenza) that are correlated with HPV vaccination.

Study Procedures

In a 3-stage strategy, using basic and applied social science methods, we will develop and refine a self-persuasion intervention and test basic self-persuasion mechanisms.

Usual care at the Parkland clinics includes the following:

a) Age-appropriate standing orders in the EMR to remind providers (physicians or nurses) to offer the HPV vaccine and document parental decisions during the clinic visit, and

In addition to their adolescents receiving usual care, all parents in this study will be:

a) Mailed an invitation letter describing the study;
b) Called to verbally describe study, invite to participate, and confirm willingness to come to an in-person meeting; and
c) Asked to complete a baseline survey during/after the recruitment call, except for Stage 3, when parents will not complete the baseline survey and will be approached in-person instead of by phone to obtain consent and verify eligibility

Parents enrolled in Aim1a will be asked to generate pro-vaccine arguments after using a tablet-based application that provides HPV vaccine information suited for parents of adolescent females & males.

Parents enrolled in Aim1b will be:

a) Administered a survey about provider recommendation, HPV vaccine benefits and barriers, & perceived involvement in medical care;
b) Audiorecorded having a discussion with their child's provider; and
c) Asked open-ended questions about their prior experience with this provider and whether the HPV vaccine was discussed during the visit.

Parents enrolled in Aim2 will be:

a) Asked to either: verbalize their own arguments based on topics they choose, verbalize arguments based on topics assigned to them, listen to arguments based on topics they choose, or listen to arguments based on topics assigned to the, and
b) Asked about their experiences using the tablet application, self-persuasion condition, and how their beliefs shape feelings about the HPV vaccine.

Adolescents who accompany the parent/guardian for the Aim 2 appointment at their Parkland clinic will be offered the 1st HPV vaccine dose by a Parkland nurse immediately following the exit interview.

Parents enrolled in Aim 3 will be:

a) Asked to use a tablet-based application that provides either self-persuasion intervention developed in Aim 2 or HPV Vaccine information only,
b) Audiorecorded having a discussion with their child's provider, and
c) Asked questions about their experiences using the tablet and their communication with the provider.

Patients will be identified through EMR review, by ICD-9 or procedure codes, through HIPAA-compliant methods, which will enable our team to invite patient parents with the permission of the Parkland Medical Director (Noel Santini, MD). Parents of patients will be mailed an invitation letter on Parkland letterhead and signed by Drs. Santini and Tiro requesting participation in a "study to improve patient satisfaction with healthcare and delivery of vaccines/shots." The letter will provide a telephone number parents can use to ask questions or notify staff of refusal. Letters will be sent in English or Spanish based on the family's preferred language listed in the EMR.

Following the mailing, parents of patients who have not refused contact will be called by a bilingual research assistant (RA). The RA will explain the project and screen parents for eligibility. The RA will screen parents by asking: 1) if their child has ever had the vaccine (yes/no), 2) whether they had ever heard of the vaccine (yes/no), and 3) what best describes their thoughts about it (never thought, undecided, do not want, or do want). Parents who are undecided or never thought about the vaccine will be invited. If the parent agrees, the RA will obtain

verbal consent, administer the baseline survey, and arrange to meet the parent at either UT Southwestern Medical Center (Aim 1a), a Parkland clinic at a chosen time (Aim 1a and Aim 2), or at a Parkland clinic prior to an upcoming appointment (Aims 1b and 3).. Up to 6 contact attempts (3 day, 3 night) will be made. Based on data from previous projects, we expect 6-8% will actively refuse, 13-15% will have a non-working number, and 20-22% will be unreachable. For Aim 3, parents will be sent a letter, and eligibility will be determined in-person before the child's upcoming medical appointment. Eligibility criteria for Aim 3 will be determined by asking the parent if their child has ever had the HPV vaccine (yes/no). If never had the vaccine, the parent will be invited in clinic that day and consent will be obtained.

During the study appointment, a bilingual RA will 1) obtain HIPAA authorization to review the adolescent patient's EMR, and 2) instruct the participant on how to use either the English or Spanish version of the tablet application. For Aims 1a and 2, the study appointment will last about 60 minutes and will be audio-recorded. For Aims 1b and 3, pre-clinic visit study activities will take 10-20 minutes; post-visit activities will take another 20-25 minutes. All study staff will be trained by Drs. Tiro and Baldwin. Parent participants will receive a $50 honorarium in the form of a gift card.
We will conduct study visits with a total of 369 parent participants. We expect very few parents will be fathers (<5%; n = 19) and have powered our analysis to only analyze data from mothers of adolescent patients (n = 350). For Aim 1, we will enroll 106 parents: 53 for formative research on self-generated arguments (Aim 1a), and 53 to characterize parent-provider discussions about the HPV vaccine (Aim 1b). For Aim 2, 168 parents will be enrolled for self-persuasion intervention conditions comparing levels of choice and cognitive processing. We will enroll 95 parents for Aim 3, recording provider/patient interaction and testing of tablet-based application. We expect to enroll 18 providers in order to audiorecord the parent-provider discussions for Aims 1b and 3.

Additional Procedures for Each Stage
Stage 1: To accomplish Aim 1a, we will recruit 42 parents of unvaccinated adolescents and 11 parents of adolescents who *have* started the series to gather the full range of arguments for HPV vaccination (n=53, stratified by sex). During a 1-hour study session, a bilingual RA will obtain informed consent and show the parent how to use a tablet-based application. A short video will provide HPV vaccine information suited for parents of adolescent females and males. Then the RA will use a series of questions to prompt parents to verbalize as many pro-vaccine arguments as they can. Afterward, the RA will use a cognitive interviewing-based guide to probe about the self-generated arguments. Parents will then be asked to listen to, rate, and choose among *peer-generated* arguments. The RA will ask questions to clarify whether peer-generated arguments are clear and understood. Finally, participants will be given the entire set of arguments. We will use probes to determine whether they can distinguish among and select their preferred arguments.

To accomplish Aim 1b, we will identify parents of unvaccinated adolescents with upcoming appointments at the 3 neighborhood and 3 school clinics that see the most adolescents. At least 5 parent-child dyads per provider will be recruited (n=53). We will only record discussions between parents and providers who are language concordant. Audiorecording equipment will be set up in the clinic room; research staff will not be present during discussions. After the participant meets with the provider and is discharged, the RA will conduct a 10-minute interview. Parents will be asked open-ended questions about their prior experience with this provider and whether the HPV vaccine was discussed during the visit. Then, we will administer a survey about provider recommendation, HPV vaccine benefits and barriers, and perceived involvement in medical care.

Stage 2: To accomplish Aim 2, we will randomly assign 168 undecided parents (of 84 girls & 84 boys) to 1 of 4 intervention conditions that differ by levels of cognitive processing and choice. In a 1-hour study session, parents will use a tablet-based application that directs them to either: verbalize their own arguments based on topics they choose (deep processing, high choice), verbalize arguments based on topics assigned to them (deep processing, low choice), listen to arguments based on topics they choose (shallow processing, high choice), or listen to arguments based on topics assigned to them (shallow processing, low choice). We will conduct exit interviews to assess parents' perspective on the tablet application, self-persuasion condition, and how their beliefs and experiences shape feelings about the HPV vaccine. Adolescents who accompany their parent to the study appointment at their Parkland clinic will have the opportunity to receive the 1st HPV vaccine dose from a Parkland nurse immediately after the exit interview. We will synthesize quantitative and qualitative data to select the optimal intervention condition for that will be used in Stage 3.

Stage 3: To accomplish Aim 3, we will recruit from pediatric neighborhood and school-based clinics, with a target of 15 parents per site (n=95). Parents will be randomly assigned to either: 1) self-persuasion plus information (optimal intervention condition from Aim 2; n=48), or 2) HPV information only (n=47). For the self-persuasion group, we will follow procedures in Stage 1. Parents in the information only group will be given a tablet and instructed to listen to information about HPV infections and the benefits and risks of the HPV vaccine. We will audiorecord the parent-provider discussion. Immediately after the visit, an RA will conduct an exit interview in which participants will be asked questions about their experiences using the tablet and their communication with the provider.

We expect to review the medical records of 369 adolescents whose parents were enrolled in our study. Medical records will be reviewed after 12 months for HPV vaccine dates. We will also abstract info for 3 other vaccines (TDAP, MCV4, & influenza) that are correlated with HPV vaccination.

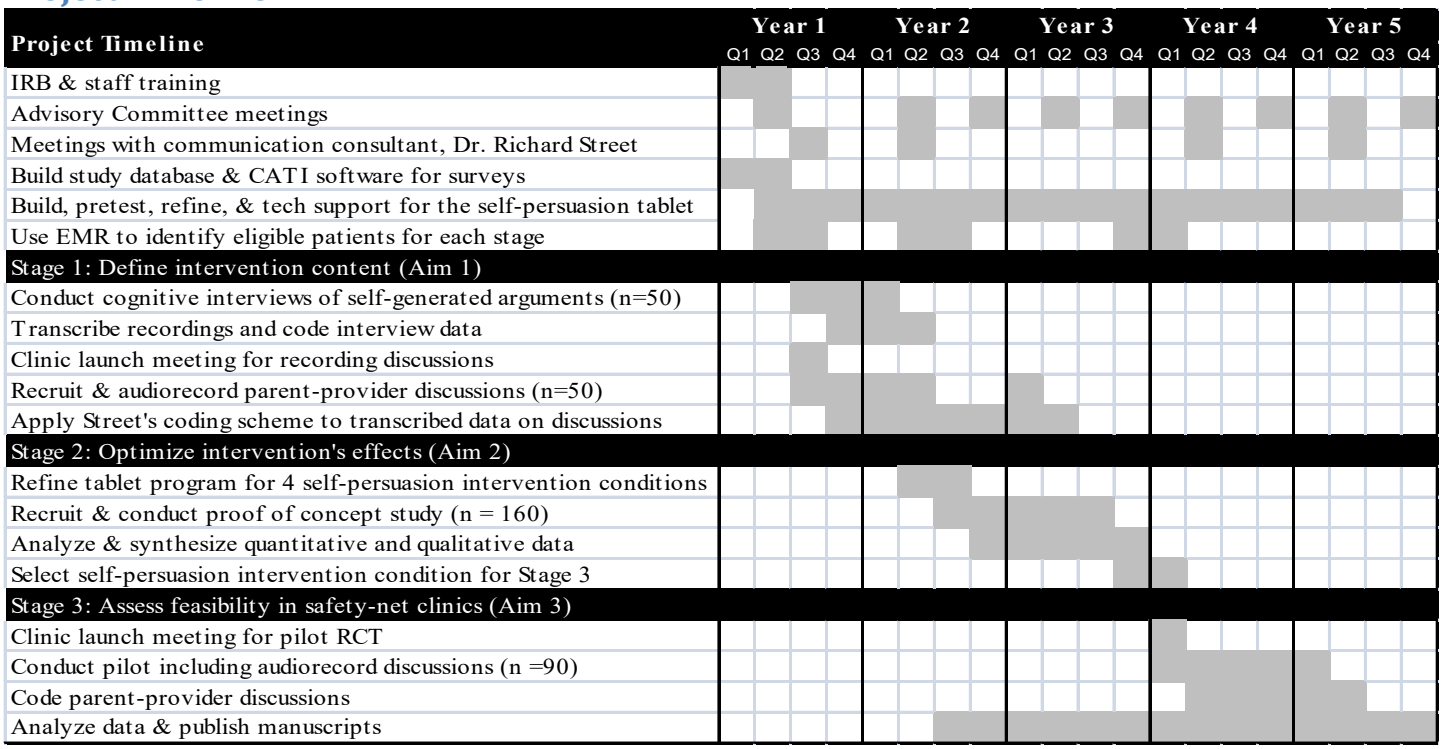
Measurement of Primary Outcomes:

Our primary quantitative outcomes will be change in parents' HPV vaccine intentions (Aim 2) and adolescent HPV vaccine uptake (Aims 1-3). Medical records will be reviewed after 12 months to ascertain HPV vaccine status. Medical records will also be reviewed for receipt of three other adolescent vaccines (TDAP, MCV4, and influenza) as well as number and location of primary care visits in the 2 years prior to study participation.

The baseline survey will be administered to all enrolled parents (n=369) after or at the end of the recruitment call by a trained research assistant (RA), except for Aim 3 participants. The self-persuasion interview data (Aims 1A & 2), exit interviews (Aims 1-3), and audiorecorded parent-provider discussions (Aims 1B & 3) will be collected in-person by a trained RA.

Change in parents' HPV vaccine intentions (Aim 2) will be collected through the iPad application.

Project Timeline



Data Management

Drs. Tiro and Baldwin will oversee the data collection process. A Microsoft SQL Server database stored on a secure UTSW server and accessed with a Microsoft Access Data Project user interface will house the data. Several procedures will be used to maintain data integrity and ensure that data shared between Parkland and UTSW are

secure. Dr. Tiro will conduct audits to assure appropriate safeguards of participant privacy are maintained. Study team personnel will send the MRNs of the most recent subjects randomized who were not eliminated at the clinic visit and were consented back to Parkland so these persons will continue to be included in the reports of study participants.

Drs. Tiro and Baldwin will work with the project manager to oversee the data collection process and training of project staff. Project staff will undergo extensive training, using protocols developed in our prior work. A two-day training session will include: (1) project rationale and overview; (2) detailed information on data collection procedures, (3) training and certification in protection of human subjects, confidentiality and HIPAA regulations, and (4) role playing for administering interviews or hands-on practice in retrieving records data, depending on job description. Telephone interviews will be digitally recorded for quality assurance; all recordings will be reviewed during the first two weeks and a random sample will be reviewed thereafter.
For a description of the statistical analyses, see Biostatics section.

Criteria for Inclusion of Subjects

The intervention target for this study are undecided parents of adolescent patients aged 9-17 who have not started the HPV vaccine series and are receiving primary care through Parkland's neighborhood- and school-based clinics. All research procedures will be conducted with the parents of adolescent patients. Adolescent patients themselves are only indirectly exposed to research procedures because we will access their EMR data for recruitment and to track subsequent vaccination, and by virtue of being the adolescent being present at a medical visit during which the parent-provider discussion may be recorded.

To ascertain eligibility, we will use the adolescent's Parkland electronic medical record (EMR) to determine age, HPV vaccine status, and clinic site. We are requesting a waiver of HIPAA authorization to review the EMR for recruitment purposes only. Parents/ guardians of eligible adolescent patients will be invited and verbal informed consent will be obtained during the recruitment telephone call (except in the case of Aim 3, which will be obtained in-person). Child assent for EMR review is not necessary with parent consent. Informed consent process and documentation will clearly explain to parents that their participation in the research protocol involves data abstraction from their child's EMR related to HPV vaccination. In Aims 1b and 3, parents are asked for informed consent to record parent-provider discussion within the medical visit, and will be informed that comments made by their child during this same interaction could be captured.

Parents enrolled in Aim 2 (proof-of-concept study examining the 4 self-persuasion intervention conditions) may opt for their adolescent child to receive the first dose of the HPV vaccine during the research study visit at the Parkland clinic where the appointment will occur; vaccine administration is not a required research procedure. Appointments will ocurr during clinic hours where vaccine administration from a Parkland nurse is available as a part of usual care. We include this option to facilitate delivery of care at the request of Parkland Health & Hospital System and for the following reasons. Receipt of the HPV vaccine series is concordant with clinical guidelines for this age group, all immunizations administered to children under age 18 requires parental consent, and HPV immunization is standard of care at Parkland (providers have standing orders to administer this vaccine).

Criteria for Exclusion of Subjects

Age was restricted to 9-17 based on clinical guidelines and eligibility for free vaccines through the VFC program (i.e., eliminating cost as a barrier), and parental consent being required for vaccines. We will exclude pregnant adolescents due to contraindication and parents who do not provide informed consent, lack telephone access, or have impaired hearing or speech (i.e., cannot complete study activities). Parents who participate in Stage 1 or 2 will be excluded from later stages.

For Aim 2 and Aim 3, we will select adolescents who have been seen or those with upcoming appointments at any of the Parkland neighborhood and school clinics. Table 3 summarizes the inclusion and exclusion criteria for the study.

Table 3. Inclusion and exclusion criteria and methods of ascertainment

Eligibility Criteria	Ascertainment Method
Inclusion	
Age 9-17 years	EMR audit
Visited clinic in past 18 months	" " (except CRR¥)
Have not started HPV vaccine series*	" "
Undecided about the vaccine	Phone call
Exclusion	
Pregnancy of the adolescent	EMR audit
Sibling already enrolled in project	EMR audit/phone call
No access to a telephone	" "
Does not give informed consent	Phone call/ clinic visit
Impaired hearing or speech of parent	" "
Participation in earlier stages	Study database

*In Aim 1a, we will recruit 11 parents of adolescents who have been immunized to capture the full range of pro-vaccine arguments.
¥ The participants taken from the Commnity Research Registry will not have the requirement of a clinic visit in the past 18 months.

Sources of Research Material

Quantitative data will be extracted from the Parkland electronic medical record (EMR) by programmers, provided to the Principal Investigators and cleaned, recoded, and analyzed by research staff to: 1) facilitate study recruitment and 2) to assess HPV vaccine status after exposure to the intervention (Aim 3). Additional quantitative data will be collected from parent participants' responses to baseline and exit surveys (Aims 1, 2, and 3).

Qualitative data will be drawn from audio-recordings of participants' self-generated arguments (Aim 1a), audio-recordings of parent/provider interactions (Aims 1b and 3), and responses to open-ended interview questions in the exit survey after exposure to one of the 4 intervention conditions comparing levels of choice and cognitive processing (Aim 2).

Recruitment Methods and Consenting Process

We are requesting a waiver of HIPAA Authorization to identify patients who are eligible to be approached with requests to participate in the study (Aims 1, 2, 3). Such a waiver is justified because: minimal risk is anticipated; the waiver will not adversely affect the rights and welfare of subjects; and this aspect of the project cannot be practically conducted without waiver.

We are also requesting a waiver of documentation of consent for study procedures involving clinicians. For parent surveys and interviews, verbal consent and verbal HIPAA authorization will be requested. Token gift cards will be provided to participants as an acknowledgment of their time and effort. All data will only be accessible to authorized study personnel.

Parents: Eligible participants will include parents of female and male Dallas county residents ages 9 to 17 years old who receive primary care at a Parkland neighborhood or school-based clinic. We will exclude patients who have already received at least one dose of the HPV vaccine. We will also exclude patients who have not been seen within the past 18 months. For the cognitive interview stage only, we will also recruit participants from the Community Research Registry using the same eligibility criteria above, with the exception of having to receive a primary care visit at a Parkland neighborhood or school-based clinic.

Patients will be identified through EMR review, by ICD-9 or procedure codes, through HIPAA-compliant methods, which will enable our team to invite patient parents with the permission of the Parkland Medical Director (Noel Santini, MD). Parents of patients will be mailed an invitation letter on Parkland letterhead and signed by Drs. Santini and Tiro requesting participation in a "study to improve patient satisfaction with healthcare and delivery of vaccines/shots." The letter will provide a telephone number parents can use to ask questions or notify staff of refusal. Letters will be sent in English or Spanish based on the family's preferred language listed in the EMR.

Following the mailing, parents of patients who have not refused contact will be called by a bilingual research assistant (RA). The RA will explain the project and screen parents for eligibility. The RA will screen parents by asking: 1) if their child has ever had the vaccine (yes/no), 2) whether they had ever heard of the vaccine (yes/no),

and 3) what best describes their thoughts about it (never thought, undecided, do not want, or do want). Parents who are undecided or never thought about the vaccine will be invited. If the parent agrees, the RA will obtain verbal consent, administer the baseline survey, and arrange to meet the parent at either Ut Southwestern Medical Center (Aim 1a), a Parkland clinic at a chosen time (Aim 1a and Aim 2), or a Parkland clinic prior to an upcoming appointment (Aims 1b and 3). Up to 6 contact attempts (3 day, 3 night) will be made. Based on data from previous projects, we expect 6-8% will actively refuse, 13-15% will have a non-working number, and 20-22% will be unreachable. For Aim 3, parents will be sent a letter, and eligibility will be determined in-person before the child's upcoming medical appointment. Eligibility criteria for Aim 3 will be determined by asking the parent if their child has ever had the HPV vaccine (yes/no). If never had the vaccine, the parent will be invited in-clinic that day and consent will be obtained.

During the study appointment, a bilingual RA will 1) obtain HIPAA authorization to review the adolescent patient's EMR, and 2) instruct the participant on how to use either the English or Spanish version of the tablet application. For Aims 1a and 2, the study appointment will last about 60 minutes and will be audio-recorded. For Aims 1b and 3, pre-clinic visit study activities will take 10-20 minutes; post-visit activities will take another 20-25 minutes. All study staff will be trained by Drs. Tiro and Baldwin. Parent participants will receive a $50 honorarium in the form of a gift card.

We will conduct study visits with a total of 369 parent participants. We expect very few parents will be fathers (<5%; n = 19) and have powered our analysis to only analyze data from mothers of adolescent patients (n = 350). For Aim 1, we will enroll 106 parents: 53 for formative research on self-generated arguments (Aim 1a), and 53 to characterize parent-provider discussions about the HPV vaccine (Aim 1b). For Aim 2, 168 parents will be enrolled for self-persuasion intervention conditions comparing levels of choice and cognitive processing. We will enroll 95 parents for Aim 3, recording provider/patient interaction and testing of tablet-based application. We expect to enroll 18 providers in order to audiorecord the parent-provider discussions for Aims 1b and 3.

Providers: Subject identification and recruitment is based on professional role and job responsibilities related to the HPV vaccination process. The study purpose and objectives will be explained during an introductory clinic site visit. Ample opportunity for clarification and opt-out will be provided. Oral consent will be requested in advance, with a written information sheet explaining the study purpose and aims, in order to minimize disruption of work. Parkland's Medical Director, Dr. Santini, will endorse and initiate all participant invitations. We estimate that up to 18 providers at the neighborhood and school clinics will choose to participate.

Any and all personal identifiers will be removed from transcripts of the appointment recording, in addition to usual data protection safeguards. Other members of the research team will only have access to de-identified materials. Audiorecordings and transcripts are exchanged through an encrypted, account-specific, password-controlled FTP site.

Potential Risks

Risks associated with the proposed study are minimal because discussing thoughts and feelings regarding the HPV vaccine generally promotes good health, not endangers it. The only identified risks are that patient confidentiality could be breached, leading to a third party gaining access to personal health information, or that participants might experience psychological stress if questions asked as part of the study make them uncomfortable. There may possibly be other side effects that are unknown at this time. If a patient reports any other side effects, they will be recorded as an adverse event and the IRB will be notified. Methods for protecting against these risks are described below. Patients who choose not to participate will continue to receive their usual care from their primary care provider.

Special Precautions

Each member of the project research team will be required to undergo extensive project training, in addition to standardized conduct of research and human subject protections certification required by UT Southwestern and Parkland Hospital. Project training sessions will include the following components that will be fully described in a training manual: 1) project rationale and overview; 2) detailed information about interviewing techniques and audio-recording protocols; and 3) the importance of collecting data free from bias. Research staff and the project manager will also be trained to document and report any deviations from the protocol, adverse events, or unusual

responses immediately to the PIs. The project manager and the Principal Investigators will monitor data collection procedures on a regular basis for quality assurance purposes. Evaluation checklists will be used to assess data quality and adherence to study protocols.

Once data collection begins, we will have weekly research team meetings that will include the investigators, project manager, and research assistants to discuss project implementation, address questions or concerns that might arise, and monitor recruitment and enrollment. Research assistants, the project manager and the PIs will record, review and discuss any unusual events, such as deviations from protocol or adverse events that have occurred since the last meeting. Decisions will be recorded in meeting minutes.

We do not anticipate any real harm to patients, but adverse events will be monitored. Potential adverse events for this project are all non-medical in nature. Should a parent participant become distressed during observation or interviews, the usual standard of care within the site practice will be employed. That is, the research assistant, who will be trained to detect psychological distress, will refer the participant to a designated clinic nurse, just as care takes place for any patient in the practice. Adverse event forms will be used to report all unanticipated events. The following information will be included in the report: date of event, attribution to intervention, and outcome of adverse events. Unanticipated adverse events will be reported within 7 days. Reports will be submitted via overnight courier or facsimile to the IRB, the Cancer Center's Protocol Review and Monitoring Committee, and the National Institutes of Health. A written follow-up will be submitted within 30 calendar days. All adverse events (serious or not, related or unrelated, anticipated or unanticipated) will be reported in the annual progress reports to the aforementioned groups.

Parallel procedures will be in place to monitor psychological distress or discomfort among providers. Parkland promotes an active quality improvement culture and we expect staff will engage this study in that light. In comparable studies, our investigators have found that providers generally responded well to these research procedures and have not had any adverse events.

Procedures to Maintain Confidentiality

As described above, the most important risks to participants are threats to privacy and confidentiality. Participants will be informed that all data are completely confidential, except in cases required by law to break confidentiality. All data will be identified by a unique study ID, rather than by any identifying information. The code that links participant ID to identifying information will be stored separately from other study data, and will be accessible only to trained research staff who are directly involved with running the project. Identifiers will be destroyed after 12 months. Paper copies of data (e.g., transcripts) will be stored in locked filing cabinets, while electronic data will be stored in secure password-protected computer files. Research participants will also be informed they can refuse any questions that they do not wish to answer, and they can withdraw from the study at any time. All research staff will be trained in the appropriate safeguarding of confidential data and in the protection of human subjects as required at each study site (e.g., human subject's protection, HIPAA regulations).

All reports and data transactions within and between Parkland and UTSW subsystems will run through controlled, secure transactions to ensure the preservation of database integrity and privacy. Once the data have been transferred to the network, they will be available for integration into other statistical and database applications (e.g., SAS or MS Access) designed to support this study. All study data will be backed up on a nightly, monthly, and biannual schedule. Nightly backups recycle every 30 days. Monthly and biannual backups will be kept on static media throughout the duration of the study and up to 5 years after. Restoration requests will be routed through the IR Call center. The process of restoring data from a backup will be conducted to preserve as many data as possible, while ensuring that database integrity has been preserved.

Server hardware will have built-in redundant systems. A systems administrator will monitor server hardware, operating system and database service performance. Workstations, laptops, and other devices will receive periodic maintenance to ensure high performance and secure operation. The primary database engine will be a SQL Server. Automated processes will be monitored daily. The system will be configured to notify systems administrators if an automated process fails to run successfully.

In the unlikely event of loss of patient confidentiality, we will have a procedure in place for responding in timely

and appropriate manner. The study participant who experiences loss of confidentiality will be informed by the study principal investigators (Jasmin Tiro, PhD or Austin Baldwin, PhD) in writing and by phone of the loss of confidentiality. Parkland clinical leadership, the IRB and NIH will be informed in the case of such an event.

Potential Benefits

Parents of patients: This study offers no direct benefit to research subjects identified through the EMR for participation in surveys/interviews. Some parents of patients may find indirect benefit from identifying their reasons in favor of the HPV vaccine and their concerns, which may enable them to have more productive discussions about the HPV vaccine with their child's provider.

Providers: This study offers no direct benefit to providers although some may find indirect benefit if participation enables subjects to understand and address issues with the delivery of the HPV vaccine and discussions with parents.

Our innovative mixed-methods approach will elucidate basic mechanisms of self-persuasion, identify the optimal method for eliciting self-persuasion in an underserved population, and provide key information about factors that contribute to HPV vaccine decision-making among parents. We expect that findings will help address needs of disadvantaged populations served by safety-net healthcare systems. It will also generate evidence for intervention feasibility and acceptability that positions our interdisciplinary team to conduct a future efficacy intervention trial for underserved, undecided parents of adolescents at risk for HPV-related cancers.

Biostatistics

Drs**.** Tiro and Baldwin will work with Drs. Hong Zhu and Simon Lee at UT Southwestern to run the quantitative and qualitative analysis for each specific aim. We will use SAS 9.3 (SAS Institute, Cary, NC) to conduct all of the statistical analyses described below.

Aim 1. Characterize the content and scope of: a) parents' self-generated HPV vaccine arguments and b) parent-provider HPV vaccine discussions.

Analysis Plan for Aim 1a: Drs. Baldwin, Tiro, and Lee will develop a scheme to code participants' self-generated arguments for topic (e.g., cancer prevention, HPV threat), length, number, and time to generate each; they will also create codes for argument clarity, comprehension, distinctions among arguments, and clarity of argument choices. Through an iterative process, investigators will use codes and participant ratings to examine (1) range of topics, (2) which argument topics are the strongest, (3) how many strong arguments parents are likely to generate, and (4) distribution of time spent verbalizing each argument. We will also examine the outcomes by adolescent sex to ensure we select arguments for Stage 2 that are relevant to boys and girls. Two RAs will apply the coding scheme; coding discrepancies will be resolved through consultation with Drs. Baldwin, Tiro, and Lee. Drs. Skinner and Wiebe will be consulted before proceeding to Stage 2.

In partnership with Dr. Noel Santini, a co-investigator on this project and in preparation for our large scale efficacy trial, we will to analyze a subset of our existing data for Stage 1a of our project. Using our existing data, we will analyze the patterns of HPV vaccine dosing and adherence for 9-17 year old patients and stratify by race/ethnicity and sex.

Analysis Plan for Aim 1b:

Coding and Analyses of Audiorecordings. We will modify Street's Active Patient Participation Coding scheme, a well-validated observational tool for behavior coding, to code audiorecordings of parent and provider participation in HPV vaccine discussions.[60-65] Dr. Street, a recognized health communication expert will consult with the team on categories relevant to parents' participation about immunizations. We will measure both parent and provider communication outcomes.

For parents, three types of *active* communication will be captured—1) asking questions, 2) assertive expressions (offering preferences, making a request), and 3) expressing concerns (worries, seeking reassurance). Active

"verbalizations" are those that influence discussion content and provider's beliefs and behaviors.[63,65] Drs. Tiro, Lee, and Street will train RAs how to assign verbal utterances according to the categories above.[60] Summary scores of the total number in each category per patient per interaction will be generated. Statements to both nurses and physicians will be counted, as nurses are often involved in vaccine discussions.[66] We will use the phrasing used by parents to inform the content of arguments in Stage 2. For example, parents may express important values (e.g., best interest of my child), concerns, or hesitations that can help us craft relevant, easy to understand arguments.

For providers, we will assess: 1) vaccine recommendations; 2) provision of information about immunizations and HPV vaccine (three types of utterances: description, benefits, and risks); 3) partnership building (open-ended questions encouraging patients to share opinions, feelings, ask questions, and participate in decision-making); and 4) supportive talk (verbal statements of reassurance, empathy, or sensitivity).[60]

Coders will co-code 5 recordings to establish rating agreement, and will code 3 more recordings semi-independently engaging in discussion to resolve differences. To evaluate inter-coder reliability, we will use Krippendorf's alpha, a measure of agreement that allows for the analysis of categorical and continuous variables in the presence of missing data.[67] To describe the communicative environment, we will compute means, standard deviations, and ranges of parent and provider communications. To explore the effect of provider discussions, we will compare parents' responses to baseline and exit survey items regarding vaccine benefits and barriers (decisional balance),[24] and post-visit perceived involvement in care.[68,69]

Qualitative Data Analysis. Interviews will be audiotaped and transcribed. Drs. Lee, Baldwin, and Tiro will perform in-depth analysis of all transcripts using NVivo 9.0 (QSR International). Data will be analyzed within and across transcripts. Through iterative coding and interpretation, the team will code actual utterances, expressions and concepts against participant characteristics to identify themes and relationships.[70] We will organize these codes into a codebook that relates data to behavioral theory.[71,72] Regular meetings will enable the team to test emergent themes and interpretation against the knowledge base of experts in pediatrics (e.g. Persaud, Kassa), self-persuasion (Baldwin), vaccination (Tiro), and intervention development (Skinner).

At the end of Stage 1, we will know: (1) the range of pro-vaccine arguments underserved parents generate, (2) which arguments are easiest to generate, most prevalent, and persuasive, and (3) range and degree to which parents participated in HPV vaccine discussions. We will also know which peer-generated arguments are rated as clear, comprehensible, and distinct from other arguments. With these data, we will select the most prevalent argument topics with easy-to-generate arguments for the self-persuasion intervention conditions in Aim 2. Baseline descriptive information about the communicative environment will be compared with parent-provider discussions after exposure to the optimal self-persuasion intervention in Aim 3.

Aim 2. Develop 4 self-persuasion intervention conditions (based on Aim 1 results) that vary by cognitive processing level (parents verbalize vs. listen to arguments) and choice of argument topics (parents choose vs. are assigned topics) and (b) identify which intervention condition is optimal through a controlled proof of concept study that quantitatively examines basic self-persuasion mechanisms (cognitive processing, choice) and qualitatively explores experiences with intervention tasks.

Analysis Plan for Aim 2:
Quantitative Analysis. Data will initially be examined using univariate statistics and graphical techniques. Continuous measures will be described using medians, means, and standard deviations; dichotomous variables will be summarized as proportions. Across self-persuasion conditions, demographic characteristics will be compared at baseline via two-way ANOVA or chi-square tests, as appropriate. If groups differ on any of these variables, further analyses will be conducted both with and without these variables as covariates to determine whether these demographic variables are of relevance to group differences.

We will compare the effects of choice and cognitive processing on vaccination intentions (primary outcome) using linear regression. Independent variables will be dummy-coded variables based on two main effects (choice: high = 0, low = 1; processing: deep = 0; shallow = 1), plus their interaction. If equivalence assumptions of initial scores and parallel regression slopes for the groups are met, baseline intentions will be included as a covariate to properly model change.[73] If not, repeated measures ANOVA will be used.[74] We anticipate changes in intentions will be

highest in the deep processing, high choice condition, indicating an additive effect. We will also explore the interaction of the two effects. We will use a similar analytic strategy to examine the effects of choice and processing on decisional balance (secondary outcome).

Vaccination rates. Using eligibility data, we will assess whether vaccination rates are similar across all clinic sites.

Qualitative Data Analysis. We will use the same analytic process described in Aim 1b.

Synthesis of Quantitative and Qualitative Analyses. To determine which self-persuasion condition (1, 2, or 3) is optimal for our safety-net population and will be tested in Stage 3, we will triangulate quantitative and qualitative findings by creating a summary profile for each condition. The optimal condition will be one that has a positive effect on intentions, but also minimizes participants' negative reactions to using the tablet application. A condition that does not affect intentions will not be considered optimal, regardless of its effect on other quantitative and qualitative outcomes. Likewise, a condition that affects intentions but for many participants raises new concerns, is rated as difficult to complete, or takes significant time to complete will not be considered optimal. Drs. Baldwin and Tiro will jointly make this decision in consultation with the team.

At the end of Stage 2, we will have quantitative and qualitative data that clarify whether it is best to ask parents to verbalize their own arguments, to choose argument topics they prefer, or both, and which self-persuasion condition is optimal in our underserved, safety-net population. Evidence clarifying which of the two specific mechanisms (deep processing, choice) has an effect, or whether they have an additive effect, will be critical to how we select the optimal self-persuasion condition to implement in Stage 3. For example, if there is an effect of processing but not choice, we would use Condition 2 that has parents verbalize arguments based on assigned topics that are most persuasive rather than allowing them to generate arguments based on chosen topics that may be less persuasive. If there is an effect of choice but not processing, we would use Condition 3 that has parents choose argument topics they want to hear rather than having them go through the more taxing process of generating their own. If both have an effect, Condition 1 will be selected for Stage 3.

Aim 3. Examine feasibility of the optimal intervention (identified in Aim 2) with a pilot study (n = 90) in the safety-net clinics.

Analysis Plan for Aim 3: We will obtain information on the following outcomes that will be important for developing a subsequent efficacy randomized controlled trial (RCT).

Enrollment rates. We will assess whether enrollment rates are similar across the clinic sites.

Sufficient time for intervention procedures. Because clinic sites may differ in their patient flow and visit wait times, we will track the number of participants who complete the tablet-based procedure within the time constraints allowed by the clinic and determine whether time allotted for completing the intervention is similar and sufficient across all sites. We expect an 85-90% completion rate to determine feasibility.

Potential for contamination. We will determine the appropriate level of randomization (patient, provider, or clinic) and the degree to which contamination occurs at each level. We will use visit history data in the EMR to examine the percentage of patients who visit more than one clinic and see more than one provider. For example, if there is significant crossover of patients to different providers at the same clinic, then we will randomize at the clinic-level in the subsequent efficacy trial.

Intermediate outcome – active parent participation. We hypothesize that exposure to the self-persuasion intervention will positively influence active parent participation in discussions with providers. We will apply Street's scheme to code the 3 types of active communication (Aim 1b).[60] To estimate effect sizes for the subsequent efficacy RCT, we will compute means, standard deviations, and ranges of parent and provider communications and compare them to data collected in Aim 1b. We will use multivariable mixed linear regression modeling to explore factors associated with parent degree of participation (e.g., English vs. Spanish language).[63] This method models the provider as a random effect to adjust for potential clustering of patients by provider; parent/patient characteristics of interest will be modeled as fixed effects.

Primary, quantitative outcomes – HPV vaccine uptake: We hypothesize that exposure to the self-persuasion intervention will increase 1-dose and 3-dose HPV vaccine coverage rates. We will use the EMR to measure vaccine uptake. These data will help estimate effect sizes of the self-persuasion intervention, compared to the information-only group, guiding the design and sample size for the subsequent efficacy RCT. We will also measure HPV vaccine-specific measures of intentions, benefits, and barriers .

After completing Stage 3, we will have quantitative and qualitative data to determine whether our self-persuasion intervention is feasible and acceptable across clinics – data that will guide us in refining intervention and measurement procedures. Thus, at the end of this stage, we will have a well-characterized and feasible intervention promoting HPV vaccination ready to be tested in future efficacy trial.

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