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Human Papillomavirus Vaccination Status And Endorsement Among Undergraduate Nursing Students: A Secondary Data Analysis

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HPV VACCINATION STATUS AND ENDORSEMENT AMONG UNDERGRADUATE NURSING STUDENTS: A SECONDARY DATA ANALYSIS

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

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CIZIK SCHOOL OF NURSING

BY

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Approval Form D-3

UTHealth

Houston, Texas

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Date

To the Dean for the School of Nursing:

I am submitting a dissertation written by Ashley Hollins and entitled "HPV Vaccination and Endorsement among Undergraduate Nursing Students." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Committee Chair

We have read this dissertation
and recommend its acceptance:

Diane Wardell

Maria B. Fernandez

Accepted

Dean for the School of Nursing

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Abstract

Human Papillomavirus Vaccination Status and Endorsement among Undergraduate Nursing Students: A Secondary Data Analysis

By Ashley Hollins, MSN-ED., RN, FNP-BC

May, 2019

Human papillomavirus (HPV) vaccination has immense potential to prevent HPV-related infections but vaccination rates remain suboptimal. Nurses could potentially increase vaccination rates by providing recommendations and addressing vaccine concerns. As student nurses' transition into practice, it is important to identify factors that could influence their attitudes and uptake of the HPV vaccine; however, these factors remain unknown.

Purpose: We proposed to: (1) identify factors associated with HPV vaccination status and (2) to identify student nurses' perception of parental vaccine hesitancy, preferred counseling strategies, and factors associated with their intention to counsel parents on HPV.

Methods: The current study was a secondary analysis of a randomized controlled trial (NCT02600884, PI: Santa Maria). UTHealth student nurses (n=153) provided data through a 172-item baseline Student Nurse Survey. Descriptive statistics, chi-square tests, and independent *t*-tests ($p < .05$) were utilized to characterize the sample and to compare responses between non-initiators, initiators, and completer groups. A logistic regression model was developed to identify factors associated with vaccination status.

Results: Only slightly more than half of student nurses (58%) had received at least one dose of the HPV vaccine. Those who were older and married or living with a partner were less likely to complete the HPV vaccine series. The most common reasons for receiving the vaccine were: doctor's recommendation, confidence in the HPV vaccine, and mother's recommendation. **Conclusion:** Interventions to increase vaccination rates among student nurses should address HPV risk misperceptions among young adults and healthcare providers to promote HPV vaccination.

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Summary of Study

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States, with potentially serious health consequences, including anogenital and oropharyngeal cancer (Markowitz et al., 2014). Student nurses of traditional college age have greater risk of infection, but many remain unvaccinated (Markowitz et al., 2014). As student nurses' transition into practice they could potentially increase vaccination rates by discouraging myths and providing strong vaccine endorsements (Warner et al., 2017).

The proposal entitled, "HPV Vaccination Status and Endorsement among Undergraduate Nursing Students" was a secondary data analysis of data from a randomized controlled trial conducted by Dr. Diane Santa Maria, of The University of Texas Health Science Center at Houston Cizik School of Nursing (UTHealth) (NCT02600884). The goals of this dissertation project were to 1) to identify factors associated with HPV vaccination status among student nurses and 2) to identify students' perception of factors associated with parental vaccine hesitancy, intent to counsel parents on the HPV vaccination, and preferences for counseling vaccine-hesitant parents.

The study proposal, which follows the summary, outlines the specific aims, significance of the problem, proposed methods, and statistical analyses. The study was approved by the Committee for the Protection of Human Subjects (CPHS) at the University of Texas Health Science Center at Houston's Institutional Review Board (Appendix C). The primary study data was collected between August 2015 and May

2018 from a purposive sample of student nurses (n=153) recruited from UTHealth undergraduate public health nursing (PHN) clinical courses.

The manuscript outlines the analyses, results for both aims of the project, and discussion of study findings. Appendices A-C contain supplemental information from the studies including the conceptual framework, CPHS approval from the University of Texas Health Science Center, and FTT+HPV Student Nurse Survey.

Proposal

Human Papillomavirus (HPV), is the most widespread sexually transmitted infection (STI) worldwide (Markowitz et al., 2014). An estimated 80 million Americans are currently infected with HPV (Owusu-Edusei et al., 2013), and nearly 42,700 new cases of HPV-associated cancers are expected to develop yearly (Satterwhite et al., 2013). HPV, which has more than 150 types, causes nearly all cervical cancers and many cancers of the vagina, vulva, penis, anus, rectum, and oropharynx; in addition to genital warts and recurrent respiratory papillomatosis (de Villiers, Fauquet, Broker, Bernard, & Zur Hausen, 2004).

The HPV vaccine is a cost-effective prevention strategy to provide protection against associated cancers and genital warts, and yet it remains one of the most underutilized vaccines in the United States (McRee, Gilkey, & Dempsey, 2014). The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization practices (ACIP) recommends administration of the HPV vaccine to 11-to 12-year old adolescents with a "catch-up" vaccination for those aged 13- 45 years (Allison et al., 2016; McRee, Gilkey, & Dempsey, 2014; U.S. Food and Drug Administration, 2018). Despite the potential severity of health outcomes associated with HPV, the national vaccination coverage rates continue to demonstrate low vaccine uptake and completion among adolescents and young adults (Markowitz et al., 2014).

Although HPV vaccination correlates have been discovered, little is known about the relationship between demographic factors and HPV vaccination status among student nurses. Understanding and increasing vaccine uptake among 18-26-year-old adults is particularly important, as these individuals are among the age group with the highest rates

of newly acquired HPV infections yearly (Satterwhite et al., 2013). Moreover, student nurses represent the next generation of healthcare providers and are in a position to influence vaccine uptake through their own personal and professional health choices, decision regarding future children and patients, and willingness to provide vaccine counseling and endorsements. As HPV- associated cancers rates steadily rise and vaccine uptake remains low, it is necessary to identify factors that could influence HPV vaccine uptake among this population.

Our *long-term goal* is to develop useful educational interventions to address factors that influence vaccination attitudes and behaviors that maximize HPV vaccine endorsement among student nurses. The *overall objectives* of this proposal are to (1) identify modifiable factors that may influence HPV vaccination status in student nurses and (2) explore their perceptions of parental vaccine hesitancy, intentions to counsel, and strategies that may assist with counseling vaccine-hesitant parents on the HPV vaccination among student nurses. Our goal is to better understand factors that may contribute to HPV vaccine uptake and endorsement among emerging healthcare providers and to inform development of educational tools and strategies to address those factors to improve suboptimal vaccination rates. The *rationale* for this project is that identifying student nurses' personal and perceived parental barriers to vaccine uptake may assist with improving HPV vaccination rates and their counseling ability to provide a strong endorsement of CDC recommended vaccines. To attain the overall objectives, the following *aims* will be pursued:

1. To identify factors associated with HPV vaccination status among student nurses.

    RQ 1: What is the association between age, race/ethnicity, marital status,

religion, and HPV vaccination status among student nurses?

RQ 2: What do student nurses perceive as motivational factors to HPV vaccine uptake and completion?

2. To identify student nurses' perception of parental vaccine hesitancy, preferred counseling strategies, and factors associated with intention to counsel vaccine-hesitant parents on the HPV vaccination.

RQ 1: What do student nurses perceive as parental barriers to HPV vaccine uptake?

RQ 2: What is the association between students' HPV endorsement outcome expectations, vaccination status, and skills satisfaction as both a parent child communication counselor and adolescent sexual health educator on their intention to counsel parents about the HPV vaccination?

RQ 3: What are student nurses' perceptions of potential strategies that may assist with counseling vaccine-hesitant parents on the HPV vaccination?

At the completion of the proposed research, our ***expected outcomes*** are to have determined factors associated with vaccine uptake and completion among student nurses and to identify perceived parental barriers that may hinder their intentions to counsel parents among student nurses. Identifying these factors may assist with addressing discrepancy between nurses' perception of parental barriers and barriers often reported by parents. These results will assist in developing strategies to improve HPV vaccine uptake among adults, provider endorsement of the HPV vaccination, and provider-patient

communication, which in turn may influence evidence-based practices and health interventions, ultimately increasing vaccine recommendations, uptake, and completion.

Significance

Scientific Premise

Sexually active adolescents and young adults (ages 15-24) have the highest prevalence of new acquired HPV infections (Moscicki, 2007). Most infections are transient and asymptomatic; however, individuals who eventually clear the virus without developing cancer can still pass it on to others (Markowitz et al., 2014). High-risk HPV types cause nearly all cervical cancers and many cancers of the vagina, vulva, penis, anus, rectum, and oropharynx (de Villiers, Fauquet, Broker, Bernard, & Zur Hausen, 2004; Lowy& Schiller, 2012; Muñoz et al., 2003). Low-risk HPV types cause 90% of all genital warts; in addition to benign or low-grade cervical cell changes and recurrent respiratory papillomatosis (Lacey, Lowndes, & Shah, 2006).

HPV vaccines are more than 98% effective in reducing the incidence of HPV types that are responsible for genital warts and associated cancers (Braaten & Laufer, 2008). Despite proven benefits, HPV vaccination rates remain far below Healthy People 2020 goal of 80 percent coverage (Jain, Singleton, Montgomery, & Skalland, 2009). Of those aged 13 - 17 years of age, only 50% of girls and 38% of boys had received all doses of the HPV vaccine series (Walker et al., 2017). In 2016, coverage with at least one dose of the HPV vaccine was 48.5% among females and 13.5% among males aged 19 to 26 (Lewis & Markowitz, 2018).

While coverage rates for routinely recommended vaccines continue to rise, HPV vaccination rates have increased minimally. This may suggest that the factors

surrounding healthcare providers, parents and young adults' attitudes about the HPV vaccine are different from other vaccines. Increasing vaccination coverage to 80%, could prevent 90% or 31,200 cases of cancers caused by HPV each year (Gargano et al., 2017; Hariri et al., 2011). Administering the HPV vaccination at the recommended age will help to reduce risk of contracting HPV as well as infections. But for this to occur, healthcare providers, parents, and young adults must be willing to accept the HPV vaccine.

Nurses are often sought out by patients to assist with health-related concerns (Johnson-Mallard et al., 2014). An essential component of nursing involves advocating for patients by supporting causes that help to promote optimal health such as health education and immunizations. Nurses play a central role in fostering vaccine uptake and completion by providing strong vaccine recommendation; educating individuals and families about when to begin the vaccine series; and by addressing concerns related to vaccine myths, safety, and hesitancy (Gustavo da Silva Fagundes, Frota, & Silva, 2018). Parents who changed their minds after delaying or refusing vaccination for their child cited information or assurances from healthcare provider as the main reason (Dube et al., 2013; Leask et al., 2008). One study revealed that the most trusted source of health information among parents came from their local nurse or family physician; however, few reported receiving vaccine information or advice from their healthcare provider (La Vincente et al., 2015). A nurses' knowledge and attitudes toward vaccination have been cited as important determinants of their own personal vaccine uptake, intention to promote vaccinations, and the uptake of vaccination among their patients (Dube et al., 2013; Zhang, While, & Norman, 2010).

Personal beliefs, perceived sexual health risk, and self-confidence to address questions or engage in uncomfortable conversations with those who are reluctant to be vaccinated have been strongly associated with vaccine uptake, intentions to counsel, and recommendation practices among nurses (Duval et al., 2009; Paterson et al., 2016; Wamai et al., 2013). Anticipated parental hesitancy, lack of preparedness for advising patients and lack of training may play a role in nurses' willingness to recommend vaccination (Ildarabadi, Moonaghi, Heydari, Taghipour, & Abdollahimohammad, 2015). Failure to discuss vaccination may result in missed clinical opportunities for receipt of the HPV vaccination, which may lead to the development of more HPV-related cancers each year.

Overall Scientific Premise

A nurses' direct involvement in vaccine endorsement has been associated with increased vaccine uptake (Miller et al., 2015). Nurses are often sought out by parents and students for their expertise regarding the safety and efficacy of vaccinations (Johnson-Mallard et al., 2014). Due to their regular contact with patients, nurses are well-positioned to address patients' concerns that may influence vaccine uptake and completion among patients (Johnson-Mallard et al., 2014). Studies suggest that a nurses' willingness to recommend vaccination may be influenced by personal knowledge and beliefs toward HPV (Perkins & Clark, 2012; Holman et al., 2014). Vaccinated nurses and those who express a willingness to be vaccinated are more likely to recommend HPV vaccination to their patients (Askarian, Khazaeipour, & McLaws, 2011; Makwe & Anorlu, 2011; Lavela et al., 2004).

Scientific Premise for Aim #1

While the choice of whether or not to vaccinate adolescents is mainly placed upon parents, college aged youth are often able to make vaccine decision for themselves. Perceptions of vulnerability to HPV infection and HPV-related disease have been strongly associated with vaccination uptake among high-risk populations (Downs et al., 2010; Marchand, Glenn, & Bastani, 2012). Research posits vaccine acceptability may be linked to distrust in healthcare system, cultural or fatalistic beliefs, lack of access and utilization of healthcare; in addition to lack of provider recommendation among minority racial and ethnic groups (Holman et al., 2014; Jeudin et al., 2014; Tsui et al., 2014). Studies indicate that increased vaccine uptake among college students is strongly associated with being younger age; non-Hispanic; Caucasian; being unmarried; not practicing organized religion; receiving a doctors' recommendations; attitudes toward vaccination; supportive beliefs from peers and significant others; and vaccination costs (Barnard, George, Perryman, & Wolff, 2017; Cohen & Legg, 2014; LaJoie, Kerr, Clover, & Harper, 2018; Lefkowitz et al., 2014; Thompson et al., 2016a).

Many patients rely on their healthcare providers to assist with decisions concerning healthcare and well-being. Provider recommendation has been cited as one of the most influential factors in vaccine acceptability and uptake among young adults, adolescent and parents (Kahn et al., 2007; Reiter et al., 2013a; Duncan & Newman, 2015). Thus, healthcare providers are a critical component to successful provision of the HPV vaccine. Additionally, studies indicate that patients' intention to vaccinate against HPV relies heavily on their knowledge, beliefs, and attitudes toward the HPV disease and

the vaccine; in addition to the convenience of receiving the vaccine (Gamble et al., 2010; Holman et al., 2014).

The importance of the nurse's role in vaccine promotion, signifies the critical need to identify factors that contribute to vaccine uptake among the next generation of nurses, who will play a critical role in vaccine promotion and disease prevention. Additionally, this study may identify factors associated with vaccine uptake and completion among young adults, as many student nurses are within this age group and may also be undervaccinated. Research findings may provide empirical support for nurse educators and those responsible for vaccination delivery who may want to develop new education programs or reform vaccination training. In addition, this study will serve as the first step in developing strategies and education tools which are critically needed to improve provider-level vaccine intentions, vaccination practices, and completion.

At this time, to our knowledge, no investigators have reported on the factors associated with the HPV vaccination status of student nurses. For this group of adults, it is not too late to vaccinate against HPV. On October 5^{th,} 2018, the U.S. Food and Drug Administration (FDA) approved expanding the use of the Gardasil 9 HPV vaccine to include all women and men through 45 years of age (U.S. Food and Drug Administration, 2018). Therefore, identifying these factors will inform the development of a critically needed intervention that could improve patient and provider vaccine hesitancies, vaccine uptake and completion rates, and create an opportunity to help prevent HPV-related disease burdens in a broader age range. The significance of the study lies in its ability to identify factors associated with vaccine initiation, uptake, and completion among an

important population, who play an instrumental role in HPV vaccine promotion, adoption, and disease prevention.

Scientific Premise for Aim #2

Nurses represent the largest group of healthcare providers, who are usually in the age range for being at the highest risk of acquiring new HPV infections. Studies indicate that healthcare providers in the United States generally have positive attitudes toward the HPV vaccine (Allison et al., 2016; Hill & Okugo, 2014; Hofstetter et al., 2017; McRee, Gilkey, & Dempsey, 2014; Perkins & Clark, 2012). Interestingly, the majority of the studies report a high percentage of providers who do not recommend the vaccine for adolescent in the recommended age group (Allison et al., 2016; Hofstetter et al., 2017; McRee, Gilkey, & Dempsey, 2014; Perkins & Clark, 2012; Soon et al., 2015; Tom et al., 2016).

Healthcare providers often cite parental beliefs, financial concerns, and lack of time as barriers to vaccine promotion (McRee, Gilkey, & Dempsey, 2014; Tom et al., 2016). In terms of reasons for HPV vaccine delay or refusal, most providers overwhelmingly agreed that factors that contributed to parents' decisions included: belief that his/her child is not at risk, belief that their child is not sexually active, lack of parental education/understanding of HPV, as well as parental reluctance to discuss sex with their child (McRee, Gilkey, & Dempsey, 2014; Tom et al., 2016). Conversely, lack of provider endorsement was cited as the leading barrier to vaccination uptake among parents (Dorell, Yankey, & Strasser, 2011; Reiter, Katz, & Paskett, 2013b). Healthcare providers' perceptions of sexual health risk, parental vaccine hesitancy, importance of vaccination and counseling have been well documented as barriers to HPV counseling

intentions and vaccine uptake (Dube et al., 2013; McRee, Gilkey, & Dempsey, 2014). Barriers to vaccination and low vaccine coverage rates, point to the critical need to better understand providers' attitudes toward HPV vaccination, strategies to assist with vaccine endorsement, and barriers to HPV vaccination uptake from the point of view of student nurses.

In the case of HPV recommendation, a healthcare providers' perceived ideas of patient benefits and health risk, perceptions of parental barriers, personal beliefs, and past encounters with patients may influence their decisions to provide vaccine counseling (Hill & Okugo, 2014; Hofstetter et al., 2017; McRee, Gilkey, & Dempsey, 2014; Perkins & Clark, 2012; Soon et al., 2015). In addition, negative experiences with vaccine-hesitant parents may discourage providers from routinely recommending the HPV vaccine (McRee, Gilkey, & Dempsey, 2014). Importantly, these findings are concerning given that recent research suggest that parental concerns in regard to the HPV vaccine are overestimated by healthcare providers (Healy, Montesinos, & Middleman, 2014). A recent study reported that most healthcare providers rarely ask questions to explore parents' reasons for vaccine delay or refusal (McRee, Gilkey, & Dempsey, 2014). Furthermore, the study concluded that providers with low confidence in their ability to address parental concerns were less likely to recommend HPV vaccination according to national guidelines (McRee, Gilkey, & Dempsey, 2014).

Low self-confidence, lack of preparedness, and lack of training were found to be important barriers that impact vaccine recommendations among nurses (Paterson et al.,2016). Many nurses are in need of additional education to address parental vaccine hesitancy. As student nurses transition into the role of a professional nurse, it is vital that

we understand what factors may influence their intentions to counsel and recommend the HPV vaccine.

At this time, to our knowledge, there are no published studies that have reported on students' perception of parental vaccine hesitancy, preferred counseling strategies, factors associated with their intention to counsel parents on the HPV vaccination, or student nurses' intentions to vaccinate themselves. Identifying these factors would likely be a critical intervention that could improve vaccine hesitancy, counseling intentions, and overall vaccination rates. Effective and efficient ways of addressing perceived barriers and improving providers' self- efficacy are critically needed as these factors have been documented as key barriers to vaccine recommendation, uptake, and completion. The significance of this study lies in its ability to identify provider-level barriers associated with HPV vaccine recommendation. The study findings may also assist with designing and evaluating vaccine training programs and communication tools that may assist healthcare providers with addressing vaccine questions and difficult conversations with vaccine-hesitant parents.

Theoretical Framework

The Theory of Planned Behavior (TPB) will provide the framework for examining how student nurses' beliefs influence their intention to receive the HPV vaccine and their intentions to counsel parents on the HPV vaccination (Figure 1). The TPB identifies four concepts that can be used to explain factors that indirectly and directly influence an individual's intention and action toward vaccination. For the purpose of this study, contributing factors, beliefs, perception/attitudes, behavioral intentions, and behavioral outcomes will be examined among student nurses.

Nurses are a key source of information to parents, adolescents, and young adults. Many parents rely on nurses to assist with decisions concerning their adolescent's health and well-being. Evidence suggests that improving provider-parent communication through participatory (vs presumptive) communication formats to initiate vaccine recommendations may influence parent's likelihood to accept vaccination (Opel et al., 2013; Opel et al., 2015). In addition, studies suggest that healthcare provider willingness to recommend vaccination may be influenced by personal knowledge and beliefs toward HPV (Perkins & Clark, 2012; Holman et al., 2014). Thus, to improve vaccination rates of patients, it is vital that we fully understand factors associated HPV vaccination status and intentions to counsel among student nurses. The application of the TPB will assist in understanding the causal and correlational relationship among social influences, attitudes and beliefs, and behavior intentions/action toward vaccine recommendation and uptake.

Innovation

The research proposed in this proposal is innovative, because it focuses on identifying student nurses' perspectives on factors associated with HPV vaccine uptake and completion, perceived parental barriers to vaccine recommendation, and tools and strategies to assist with counseling parents on the HPV vaccination. While many studies have identified that provider-perceived parental barriers to vaccination exist, exploring factors that may contribute to vaccine uptake among student nurses is expected to allow us to overcome some current limitations of vaccine delivery. Thus, thereby opening new horizons for more effective strategies, vaccination training programs, and screening tools to facilitate better communication and self-efficacy to address vaccine hesitancy among young adults, healthcare providers, and parents.

Approach

Methods

Research Design, Sample and Setting

A secondary data analysis will be conducted from a randomized controlled trial (RCT) titled, "Efficacy Trial of a Brief Parent Based Adolescent Sexual Health Intervention" funded by the National Institute of Child Health and Human Development (NIH) conducted by the Principal investigator (PI) Dr. Diane Santa Maria, of The University of Texas Health Science Center at Houston Cizik School of Nursing (UTHealth) (NCT02600884). The study was a community-based RCT that used parent-child dyads (n= 513) from predominantly minority communities in the greater Houston area to determine the impact of a student nurse-as-educator program, Families Talking Together Plus (FTT + HPV), on minority parent and adolescent outcomes.

A purposive sample of student nurses (n=153) were recruited from UTHealth undergraduate public health nursing (PHN) clinical courses (15 sections containing approximately 10 students each). Students were deemed eligible for the study if: they were currently enrolled in the PHN clinical course and expressed willingness to complete baseline and end of semester anonymous surveys. Using a quasi-experimental design, students were non-randomly assigned to the intervention or control arm. The student nurses in the intervention arm (n=103) attended curriculum training of Families Talking Together (FTT) with an added HPV component (FTT+ HPV). FTT is a parent-based sexual health intervention to prevent and/or reduce sexual risk behavior by promoting effective communication skills, building parent-adolescent relationships and helping parents to develop successful monitoring strategies. Students in the control arm

completed a public health nursing clinical rotation that did not cover adolescent sexual health topics. Then the student nurses delivered brief face-to-face sessions, a manual, and booster calls to parents of youth 11- 14 years old as part of their community clinical experience.

The primary aim of this secondary analysis is to identify factors associated with the HPV vaccination status among student nurses and to identify students' perception of factors associated with parental vaccine hesitancy, intent to provide HPV vaccination counseling to parents, and preferences for counseling vaccine-hesitant parents using baseline survey data from the total sample (n=153). The initial study has been approved by the IRB. A request for approval to conduct this secondary analysis will be made. It is anticipated it will take up to 6 months to conduct the analysis and write the scientific manuscript.

Data Collection

For the purpose of this research and in order to achieve the objectives, a secondary analysis will be conducted. The primary study data was collected between August 2015 and May 2018. Before implementation of the intervention, a baseline investigator developed the Student Nurse Survey that was collected on 153 volunteer student nurses who attended UTHealth via tablet or internet hyperlink.

Sample Size and Power

For Aim 1.2, the power analysis for this secondary data analysis was conducted in G-POWER using an alpha of 0.05 and a sample size (n=155) for a two-tailed test. Based on this sample size, a logistic regression model will have 80% power when the effect size

is an odds ratio (OR) = .54. This equates to a 46% reduction in the odds of vaccine uptake for every one-point increase in age.

For Aim 2.2, the power analysis for this secondary data analysis was conducted in G-POWER using an alpha of 0.05 and a sample size (n=153) for a two-tailed test. Based on this sample size, a spearman's rho correlation model will have 80% power when the effect size is 0.22.

Instruments

The initial research team developed a self-administered survey (Appendix B). Survey items were drawn from measures used in prior published studies of HPV vaccination uptake and sexual health. The questionnaire was divided into three sections: (1) demographic characteristics, (2) outcome expectations and health-related beliefs, and (3) behavioral intentions. The first section consisted of demographic characteristics (11 items), in addition to the Sex Education Confidence Scale (SECS) (22 items). Demographics factors assessed included age, race/ethnicity, primary language, education level, marital status, religion, and the importance of religion to participant. The second section consisted of health-related beliefs investigating perceived stress (3 items, Cohen, Kamarak, & Mermelstein, 1994), safety of vaccination (1 item, Marlow, Waller & Wardle, 2007), parent-child communication about sexual health, perceived adolescent sexual health risk, sexual health parent-child communication outcome expectancies, skills satisfaction for parent sexual health counselor, skills satisfaction as adolescent sexual health educator, parental monitoring, and intentions to counsel parents on the HPV vaccination developed by Guilamo-Ramos et al. (2011) for use with parents and adolescents (45 items). HPV endorsement intentions and outcomes, experience providing

HPV vaccination counseling to parents, parents reactions to HPV vaccination recommendation, contributing factors to parental or refusal of HPV vaccination, actions taken when counseling HPV-vaccine hesitant parents, and helpfulness of tools when counseling HPV-vaccine hesitant parents were assessed using survey items developed by McRee, Gilkey, & Dempsey (2014) (57 items). In addition, likelihood of receiving HPV vaccination along with determining factors for HPV vaccine receipt, completion, or incompletion were assessed using three questions developed by Kessel et al. (2012) (4 items). The third section consisted of behavioral intentions investigating HPV initiation, continuation, and completion utilizing three questions developed by Widdice et al. (2011) for use with female patients (4items).

A 5-point Likert scale was used for questions regarding beliefs about sexual health, intentions to counsel, HPV, and HPV endorsement outcomes expectancies, with response options ranging from “strongly disagree” to “strongly agree”. A 5-point Likert scale was also used for questions about skills satisfaction, HPV endorsement, perceived stress, and experience providing HPV counseling. The questions regarding HPV vaccination initiation, continuation, and completion used dichotomized yes or no responses. The remaining questions regarding the HPV vaccination series used a 9-point Likert scale with answer choices ranging from (1) The doctor's recommendation, (2) it became common practice/It has been standard for years/I was comfortable with recommendation, (3) I knew enough about HPV disease and the vaccine, (4) I became sexually active, (5) My insurance covered the cost/No cost concerns, (6) I had enough information about vaccine safety, (7) It was convenient for me to get vaccinated/I found

the time to do so, (8) Other, please specify, and (9) Don't know. The survey was designed to be completed within 30 minutes on average.

For this secondary data analysis, the following scales and items will be used from the main questionnaire: demographic information (5 items: age, race/ethnicity, marital status, religion, importance of religion), HPV Endorsement Outcomes Expectancies Scale (8 items, HPV Endorsement Outcomes Expectancies Scale, McRee, Gilkey, & Dempsey, 2014), Outcome Expectancies (9 items, Sexual Health Parent-Child Communication Outcome Expectancies, Guilamo-Ramos et al., 2011b), Skills Satisfaction (12 items, Skills Satisfaction as a Communication Counselor and Sexual Health Educator, Guilamo-Ramos et al., 2011a), Intentions (2 items, Intentions to Counsel Parents on the HPV vaccination, Guilamo-Ramos et al., 2011b), Perceived Parental Barriers (13 items, Contributing Factors to Parental Delay or Refusal of HPV Vaccination, McRee, Gilkey, & Dempsey, 2014), Tools and Strategies for Counseling (8 items, Helpfulness of Tools when Counseling, McRee, Gilkey, & Dempsey, 2014), HPV vaccination initiation (1 item, HPV vaccination initiation, Widdice et al., 2011), HPV vaccination continuation (1 item, HPV vaccination continuation, Widdice et al., 2011), HPV vaccination completion (1 item, HPV vaccination completion, Widdice et al., 2011), factors for receiving HPV vaccination (1 item, factors for receiving HPV vaccination, Kessel et al., 2012), factors for determining factor for completing HPV vaccination (1 item, determining factor for completing HPV vaccination, Kessel et al., 2012), and reasons for incompletion of HPV vaccination series (reasons for incompletion of HPV vaccination series, Kessel et al., 2012).

Factors related to Student Nurses' HPV Vaccination Status

Factors associated with HPV vaccination were measured using 3 items developed from Kessel et al. (2012). Students were asked, "What was the most important factor that determined when you received the HPV shots?", with one possible response of: (1) The doctor's recommendation; (2) It became common practice/It has been standard for years/I was comfortable with recommendation; (3) I knew enough about HPV disease and the vaccine; (4) I became sexually active; (5) My insurance covered the cost/No cost concerns; (6) I had enough information about vaccine safety; (7) It was convenient for me to get vaccinated/I found the time to do so; (8) Other, please specify; and (9) Don't know. Students were then asked, "What is the most important factor that will determine when you will complete the HPV vaccination series?" with one possible response of (1) The doctor's recommendation; (2) If it becomes common practice/Been standard for years/Comfortable with recommendation; (3) When I know enough about HPV disease and the vaccine; (4) Becoming sexually active; (5) Insurance covering the cost/No cost concerns; (6) Having enough information about vaccine safety; (7) If it is convenient for me to get vaccinated/If I find the time to do so; (8) Other, please specify; and (9) Don't know. Lastly, students were asked, "What is main reason you will not/have completed the HPV series in the next 12 months?", with one possible response of: (1) My provider did not recommend it; (2) The vaccine is not available in provider's office; (3) I did not know about the vaccine/I did not know the vaccine was recommended for me; (4) I do not believe the vaccine is needed or necessary; (5) The school does not require; (6) I have safety concerns about it; (7) I am uninsured/My insurance does not fully cover shots/The insurance co-pay or other costs are too high (i.e., administration fees and/or office visit

charges); (8) The shot could be painful; (9) I have had difficulty making or getting an appointment/I have had transportation problems; (10) I intend to complete the HPV series but have not yet/Already planned; (11) I am not sexually active; (12)Other, please specify ; and (13) Don't know.

Factors related to Student Nurses' Intention to Counsel

Sexual Health Parent Child Communication Outcome Expectancies were assessed using nine items developed by Guilamo-Ramos et al. (2011a) using a 5-point Likert scale. Students were asked about the barriers and facilitators to parent child communication with statements such as "I don't know what to say to parents about how to talk with youth about sex", "I'm too embarrassed to talk to parents about how to talk with youth about sex", and "Talking to youth about sex won't make a difference", and "Talking to youth about sex will lead to them having sex." Response options included "strongly disagree", "moderately disagree" "neither agree nor disagree", "moderately agree" and "strongly agree".

Skills Satisfaction was assessed using eight items developed by Guilamo-Ramos et al. (2011a). Students were asked to rate their level of satisfaction as both a parent communication counselor and adolescent health educator. Students responded to items such as, "At this moment in time how satisfied do you feel with the amount of control you have over being able to counsel a parent on how to talk with youth about sex?" and "At this moment in time, how satisfied do you feel with your ability to discuss prevention

of sexually transmitted infections (STIs)?" Responses were coded on a 5-point Likert scale (1= Not at all satisfied to 5= very satisfied).

HPV Endorsement Outcomes Expectancies Scale was used to measured students' outcome expectations when counseling parents about HPV vaccination utilizing survey items developed from McRee, Gilkey, & Dempsey (2014). Students were asked, "When parents wish to delay or refuse HPV vaccination, there is not much I can say to change their minds?" and I am confident that I can address parental HPV vaccine concerns about adolescent sexual activity?" Responses were coded on a 5-point Likert scale (1= Strongly agree to 5 = I have no experience with this).

Perceived Parental Barriers Scale were used to measured students' opinions on factors associated with parental vaccine delay or refusal utilizing survey items developed by McRee, Gilkey, & Dempsey (2014). Students were asked a series of 13 items related to their perception of parental barriers to HPV vaccine uptake. Specifically, students were asked, "Based on your experience in the past year, how much do each of the following contribute to parents' decisions to delay or refuse HPV vaccination?" Students responded

to items such as “Belief that HPV is not severe enough to warrant vaccination.” Responses ranged from 1 (not at all) to 4 (a lot).

Helpfulness of tools was measured using 8 investigator developed items from McRee, Gilkey, & Dempsey (2014). Students were asked, “How much would the following strategies and tools help you when counseling parents who are hesitant to get HPV vaccine for their adolescent children?” An example of an item is “Providing information about HPV vaccine to parents before the clinical visit.” Responses were on a 4 –point Likert scale ranging from 1 (not at all) to 4 (a lot).

Students’ intention to counsel parents on HPV vaccination were assessed with two items developed by Guilamo-Ramos et al. (2011b). Students were asked to respond to the following statements, “I plan to counsel parents about the importance of vaccinating youth against HPV.” and “I plan to counsel youth about the importance of getting the HPV vaccine at the recommended age.” Responses were coded on a 5-point Likert scale (1= Strongly disagree to 5 = strongly agree).

Outcome Variables

The primary outcome measures for the study is HPV vaccination status. Vaccination status including both uptake/initiation and series completion will be assessed through students’ self -report. HPV vaccine uptake was defined as having one or two doses of the HPV vaccine. HPV vaccine uptake was measured using two investigator developed items from Widdice et al. (2011). Students were asked to respond to the following questions: (1) Did you receive dose 1 of the three dose HPV series? and (2) “Did you receive dose 2 of the three dose HPV series?”. Responses were coded 1 (yes) and 2 (no).

The study's secondary outcome variable was HPV vaccine completion. Defined as having all three doses of the HPV vaccine series. HPV vaccine completion was measured using one investigator developed question from Widdice et al. (2011). Students were asked to respond to the following question: Did you receive dose 3 of the three dose HPV series? Responses were coded 1 (yes) and 2 (no). Students who obtained all three doses of the vaccine will be included in the "Vaccine Completers" category, whereas students who obtained < three doses were included in the "Vaccine Initiator" category. Non-initiators will be defined as students who had not received any dose of the HPV vaccine series.

Specific Aim 1: To identify factors associated with HPV vaccination status among student nurses.

Introduction

Nurses are at the frontline to educate patients, families, and communities about vaccine- preventable diseases. Research has shown that shifting vaccine promotion to nurses is an effective strategy that promotes vaccination, influences vaccine uptake and reduce the number of exemptions among families when compared with other healthcare providers (Chan et al., 2011, Salmon et al., 2004). However, factors that may influence vaccination status within this population have not been explored. The ***objective*** for this aim is to gain a better understanding of factors influencing vaccination uptake among student nurses by addressing the following research questions:

RQ 1: What is the association between age, race/ethnicity, marital status, religion, and HPV vaccine uptake and completion among student nurses?

RQ 2: What do student nurses perceive as motivational factors to HPV vaccine uptake and completion?

The *rationale* for this aim is that its successful completion is likely to contribute more insight on factors influencing HPV vaccine intent and uptake among student nurses, who are transitioning into the nurse role, where they will have the opportunity to promote the HPV vaccination and reduce missed opportunities for HPV prevention. Upon completion of the aim, it is our *expectation* that we will have identified critical factors that influenced vaccine uptake among student nurses.

Data analysis

The analysis of this secondary data will be conducted using baseline FTT + HPV student survey data to assess demographic information and factors associated with HPV vaccination status among student nurses. All of the statistical analyses will be done using SPSS for Mac 25 software (Statistical Package for Social Sciences, IL, USA). We expect missing data to be minimal. Obvious errors will be corrected; those that cannot be corrected will be set to missing and replaced using average imputation (i.e. using the average value of the responses from the other participants to fill in the missing value (Fox-Wasylyshyn & El-Masri, 2005).

Analysis for **Aim 1.1-1.2** will be based on descriptive statistics. Descriptive statistics will be calculated for the correlates: age, race/ethnicity, marital status, religion, and factors affecting HPV vaccination status (doctor's recommendation, it became

common practice/It has been standard for years/I was comfortable with recommendation, I know enough about HPV disease and the vaccine, I became sexually active, My insurance covered the cost/No cost concerns, I had enough information about vaccine safety, it was convenient for me to get vaccinated/I found the time to do so, Other, please specify:, and don't know), across the total sample by the outcome variable (vaccination status). For descriptive analysis, mean, range, standard deviation (age), and percentage for categorical variables will be calculated. Frequency tables will be created to summarize demographic variables, including age, race/ethnicity, religion, importance of religion, current marital status, and whether participants had received any dose of HPV vaccination. Chi-square test will be used to test association between age, race/ethnicity, religion, importance of religion, marital status, and whether participants had received any dose of HPV vaccination. Statistical significance will be assessed by two-tailed tests with α level of 0.05.

Data from Aim 1.1 will then be analyzed by multivariable logistic regression to identify the associations between correlates (age, race/ethnicity, marital status, religion, importance of religion) and vaccination status. Bivariate analyses with p-value < 0.05 will be used criterion to select variables for multivariable analyses. Results of the logistic regression will be presented by the odds ratios (OR) and associated 95% confidence intervals (CI).

Expected Outcome

In terms of scientific contribution, the expected results of aim 1, will seek to understand factors associated with HPV vaccination status from a student perspective. Acknowledging barriers to HPV vaccination has the potential to inform educators and

health promoters in designing strategies specific to college students and future healthcare providers. The results of the study will aid in the advancement of theoretical understanding of factors that may influence vaccine initiation, uptake, and completion of the three-dose HPV vaccine series in young adult healthcare providers, which is relevant to disease promotion and prevention. The study may increase our understanding about the factors associated with vaccine uptake, which in turn, may allow clinicians, researchers, and policy makers to develop multilevel interventions to improve vaccine uptake. In addition, this study may assist with development of strategies to improve HPV vaccine series completion and practices recommendations among young healthcare providers.

H1. There is a relationship between age, race/ethnicity, marital status, religion, and HPV vaccine uptake among student nurses.

Specific Aim 2: To identify students' perception of factors associated with parental vaccine hesitancy, intent to provide sexual health and HPV counseling to parents, and preferences for counseling.

Introduction

Healthcare providers, parents, and adolescents are critical components in the successful provision of the HPV vaccine. Nurses serve as one of the main sources of information to parents and adolescents. Families with children rely on nurses for counseling and guidance regarding their health and wellbeing (Rosen, Ashwood, & Richardson, 2016). Evidence suggests that effective communication and vaccine delivery by healthcare provider may increase vaccine acceptance among parents (Opel et al., 2015). However, studies have found that perceived vaccine hesitancy among nurse may hinder strong vaccine recommendation (Dube et al., 2013; McRee, Gilkey, & Dempsey,

2014). Thus, it is important to identify factors that may influence provider intention to recommend vaccination as this has been associated with parental vaccine uptake. The *objective* for this aim is to gain a better understanding of students' perception of factors associated with parental vaccine hesitancy, intent to provide HPV vaccination counseling, and preferences for counseling parents using the following research questions:

RQ 1: What do student nurses perceive as parental barriers to HPV vaccine uptake?

RQ 2: What is the association between students' HPV endorsement outcome expectations, vaccination status, skills satisfaction, and intention to counsel parents about the HPV vaccination?

RQ 3: What are student nurses' perceptions of potential strategies that may assist with counseling vaccine-hesitant parents?

The *rationale* for this aim is that it may contribute more insight into how provider-focused communication can best be promoted. Equally, it is important to identify and address perceived-parental vaccine hesitancy that influence nurses' intention to counsel parents. Upon completion of the aim, it is our *expectation* that we will have identified critical factors that influenced perceived-parental HPV barriers, intentions to provide HPV vaccination counseling, and preferences for counseling vaccine-hesitant parents.

Data analysis

Statistical analyses will be performed using SPSS for Windows 25 software (Statistical Package for Social Sciences, IL, USA). We expect missing data to be minimal. Obvious errors will be corrected; those that cannot be corrected will be set to

missing and replaced using average imputation (i.e. using the average value of the responses from the other participants to fill in the missing value (Fox-Wasylyshyn & El-Masri, 2005).

Analysis for Aim 2.1-2.3 will be based on descriptive statistics. Descriptive statistics will be calculated for correlates (perceived reasons for delay or refusal, potential strategies for counseling, intentions to counsel, HPV endorsement outcome expectations, and skills satisfaction) across the total sample by the outcome variable (HPV vaccination status). For descriptive analysis, frequencies, mean, and percentages will be calculated. Frequency tables will be created to summarize correlate variables of perceived reasons for delay or refusal, potential strategies for counseling, skills satisfaction, HPV endorsement outcome expectations, intention to counsel parents on HPV vaccination.

Data from Aim 2.2-2.3 will be analyzed by Independent Sample *t* test to determine the associations between categorial data (HPV endorsement outcome expectations, vaccination status, skills satisfaction) and the Mann-Whitney *U* test for ordinal, discrete, and continuous data (intention to counsel parents on the HPV vaccination) among groups (non-initiators vs initiators and initiators vs completers). Statistical significance will be assessed by two-tailed tests with α level of 0.05.

Expected Outcomes

The expected results of this aim will aid in the advancement of theoretical understanding of factors that may alter students' intention to counsel parents on the HPV vaccination. The results of the study may offer insights on how student nurses perceive parental vaccine hesitancy and their role as health educators. In addition, information learned may assist with development of educational tools to improve HPV knowledge,

education, and support nurses' self-efficacy to disseminate HPV information to parents. This analysis may assist with addressing parental concerns and help to promote HPV vaccine recommendations in accordance with national guidelines.

H1. There is an association between students' HPV endorsement outcome expectations, vaccination status, skills satisfaction, sexual health parent child communication outcome expectations, and intention to counsel parents on the HPV vaccination.

Table 1

Timeline

TIMETABLE							
AIMS/TASKS	**Aug 01**	**Sept 02**	**Oct 03**	**Nov 04**	**Dec 05**	**Jan 06**	**Feb 07**
Specific Aim #1	←						→
Benchmark #1.1 **Meet with committee to discuss project goals**	⊗	⊗	⊗	⊗	⊗		
Benchmark #1.2 **Literature Review**	⊗	⊗	⊗	⊗			
Benchmark #1.3 **Research Questions Finalized**	⊗	⊗					

Benchmark #1.4 **Meet with dissertation committee for proposal defense**	⊗	⊗					
Benchmark #1.5 **Obtain IRB approval from CPHS**		⊗	⊗				
Benchmark #1.6 **Data Management and cleaning**		⊗	⊗				
Benchmark #1. 7 Quantitative analysis of survey		⊗	⊗	⊗	⊗		
Benchmark #1.8 **Documentation of results**					⊗	⊗	⊗
Specific Aim #2	←						→
Benchmark # 2.1 **Meet with committee to discuss project goals**	⊗	⊗	⊗	⊗	⊗		
Benchmark # 2.2	⊗	⊗	⊗	⊗			

Literature Review							
Benchmark # 2.3 **Research Questions Finalized**	⊗	⊗					
Benchmark # 2.4 **Meet with dissertation committee for proposal defense**	⊗	⊗					
Benchmark # 2.5 **Obtain IRB approval from CPHS**		⊗	⊗				
Benchmark # 2.6 **Data Management and Cleaning**		⊗	⊗				
Benchmark # 2. 7 Quantitative analysis of survey		⊗	⊗	⊗	⊗		
Benchmark # 2.8 **Documentation of results**					⊗	⊗	⊗

Potential Problems and Alternative Strategies

Potential limitations of the study include the use of previously collected data which resulted in a lack of control over data collection. Participants were recruited using a purposive sample of student nurses from one Bachelor of Science Nursing school in an urban area which may limit the generalizability of findings. In addition, the sample may not represent overall HPV vaccine uptake and completion rates among student nurses. Second, it is possible that those students who were most interested in parent-child sexual health may have been more likely to participate resulting in potential selection bias. Lastly, the use of a self-reported questionnaire may over- or underestimate responses since students may answer in a socially acceptable manner.

Protection of Human Subjects

Institutional Review Board (IRB) approval for the primary study is attached as Appendix C. A separate IRB form will be submitted to The University of Texas Health Science Center at Houston IRB for an expedited review, as all of the data for this secondary analysis was completely de-identified. There is low risk involved in this study for the research participants. Data will be stored on a secure, password protected flash memory external device, stored in a locked file cabinet, and locked office when not in use. All necessary firewall and password protection will be implemented to limit access to and ensure confidentiality of data. The data will be managed by the PI using a secure database, computer, and locked storage file cabinet at the UTHealth Cizik School of Nursing.

Future Directions

This study will seek to understand factors associated with HPV vaccine uptake, provider-perceived parental vaccine hesitancy, counseling strategies, and intentions to

counsel from a nursing perspective. The study will provide insight into factors associated with HPV vaccine uptake and completion among young adult healthcare providers. Findings from this study may guide educational interventions to improve vaccine training, uptake and completion. In addition, the study findings may provide a better understanding of perceived adult health risk in this population which may inform the development of strategies to increase awareness, HPV vaccine recommendation, uptake and completion. The study findings may provide implications for interventions targeted toward provider and parental vaccination concerns which may increase vaccine uptake. This research may guide development of strategies, vaccination training programs and screening tools to facilitate better communication and self-efficacy to address vaccine hesitancy among young adults, healthcare providers and parents.

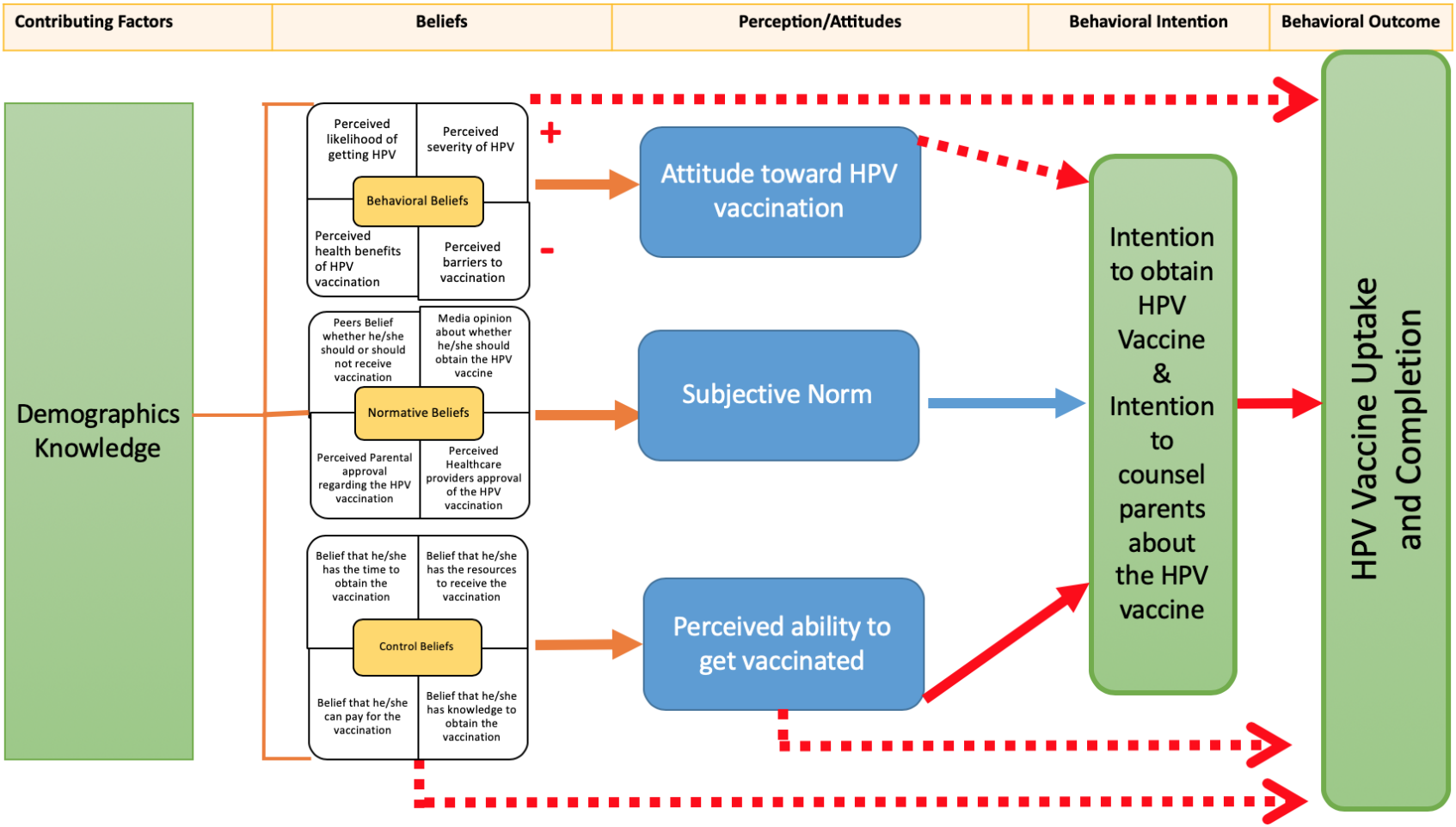

Figure 1. The Theory of Planned Behavior (TPB)

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Manuscript

HPV Vaccination Status and Endorsement among Undergraduate Nursing Students

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Introduction

Human papillomavirus (HPV) infection is the most prevalent sexually transmitted infection (STI) (Markowitz et al., 2014), with approximatively 79 million people currently infected (Owusu-Edusei et al., 2013). An estimated 20 million new HPV infections will occur yearly with nearly half of these among persons aged 15–24 (Satterwhite et al., 2013). Although most infections are transient and asymptomatic; persistent infection with high risk HPV types may result in cancers of the cervix, vagina, vulva, penis, anus, rectum, and oropharynx; in addition to genital warts and recurrent respiratory papillomatosis (Markowitz et al., 2014). HPV- associated cancers have drastically increased, contributing to about 43,000 cases annually in both men and women (Centers for Disease Control and Prevention [CDC], 2018a).

Sexually active adolescents and young adults have the highest prevalence of HPV infection with 50 - 80% of cases occurring within 2-3 years of sexual debut (Moscicki, 2007). The Advisory Committee on Immunization practices (ACIP) recommends administration of the HPV vaccine to 11-to 12-year old adolescents with a “catch-up” vaccination for those aged 13-26 years (U.S. Food and Drug Administration, 2018). The HPV vaccine is a cost-effective prevention strategy to provide protection against HPV-related health burdens; however, it remains one of the most underutilized recommended vaccines (McRee, Gilkey, & Dempsey, 2014).

Background

While HPV affects individuals of all ages, college students are at substantially greater risk than older adults of developing HPV-related disease, yet many remain unvaccinated (Markowitz et al., 2014). In 2016, coverage with at least one dose of the HPV vaccine was 48.5% among women and 13.5% among men aged 19 to 26 (Lewis & Markowitz, 2018). Studies indicate that vaccine uptake among college students is strongly associated with being younger age (LaJoie, Kerr, Clover, & Harper, 2018), non-Hispanic (Lefkowitz et al., 2014), Caucasian (LaJoie, Kerr, Clover, & Harper, 2018), being unmarried (Thompson et al., 2016a), and not practicing organized religion (Lefkowitz et al., 2014). Past studies have shown that receiving a doctors' recommendation (Barnard, George, Perryman, & Wolff, 2017), supportive beliefs from peers and significant others regarding the HPV vaccine (LaJoie, Kerr, Clover, & Harper, 2018), and low vaccination costs (Cohen & Legg, 2014) are key determinants in vaccine uptake among college students.

College students represent an important population for HPV vaccination as these individuals are among the age group with the highest prevalence of HPV infections (Moscicki, 2007) and are a priority group for HPV catch-up vaccinations (Sharma & Nahar, 2017). Existing research among 18 to 26 years old adults has focused on investigating the determinants of vaccine uptake, however, the primary focus has been on HPV-vaccine knowledge, attitudes and beliefs, social approval, provider recommendation, and young women (Marchand et al., 2013). Since HPV vaccination recommendations were established, few studies have examined factors associated with

HPV vaccination status among college students and no research to date on HPV vaccine uptake has focused specifically on student nurses.

Student nurses, as future professionals in the healthcare system, will take part in providing vaccine education, addressing parental concerns, and providing strong vaccine endorsements. Research has shown that shifting vaccine promotion to nurses is an effective strategy that promotes vaccination and influences vaccine uptake among families (Chan et al., 2011, Salmon et al., 2004). Studies suggest that vaccinated nurses and those who express a willingness to be vaccinated are more likely to recommend HPV vaccinations to their patients (Askarian, Khazaeipour, & McLaws, 2011; Makwe & Anorlu, 2011). Identifying factors associated with HPV vaccine uptake may assist with understanding and improving student nurses' personal HPV vaccine uptake and completion, as well as their intention to counsel and provide a strong HPV vaccine endorsement to parents, adolescents, and adult patients.

Conceptual Framework

The Theory of Planned Behavior (TPB) posits that an individual's intention is a direct antecedent to behavior. The TPB describes how an individual's intention is derived from their attitudes toward performing the behavior, perceptions about whether significant others think they should engage in the behavior (subjective norms), and their perception of the ease or difficulty of performing the behavior (perceived behavioral control). This research study applied the TPB in an effort to identify factors that influence student nurses' intention to receive and complete the HPV vaccine, as well as their intention to counsel parents on the HPV vaccination. Figure 1 presents the conceptual framework that framed this study.

Aims

The primary aim of this study was to identify factors associated with the HPV vaccination status among student nurses. A secondary aim of the study was to identify student nurses' perception of parental vaccine hesitancy, preferred counseling strategies, and to identify factors associated with their intention to counsel parents. Additionally, the study sought to identify factors associated with the student nurses' personal vaccine non-initiation, initiation, and completion. To accomplish these aims, we assessed HPV vaccination status (non-initiation, initiation, and completion) among student nurses. We also assessed potential correlates of vaccination including demographic factors (age, race/ethnicity, marital status, religion) and factors associated with vaccine non-initiation, initiation, and completion in a diverse sample of student nurses recruited from a large urban nursing school in the southwestern U.S.

Methods

The data from this study is a subset of data from a larger NIH-funded randomized controlled trial titled, "Efficacy Trial of a Brief Parent Based Adolescent Sexual Health Intervention" (NCT02600884**).** In the parent study, student nurses were recruited from an undergraduate public health nursing course between August 2015 and May 2018. The primary aim of the parent study was to evaluate an enhanced version of Families Talking Together (FTT), a parent-based adolescent sexual health intervention with additional modules on HPV and adolescent vaccinations (herein called FTT+HPV) using student nurses as sexual health educators. In that study, student nurses delivered the FTT+HPV intervention to parents of 11-14-year old youth. For the purpose of this study, baseline student nurse data was used to avoid intervention effects from the training program.

Ethics and Participants Recruitment

The University Institutional Review Board approved the study protocol. Students were deemed eligible for the study if: they were currently enrolled in an undergraduate public health nursing clinical course and expressed willingness to complete baseline and end of semester surveys. The research team recruited participants in person with information sessions provided during regularly scheduled classes. Interested students self-selected to participate in the study and were then trained to become interventionists for the program.

Data Collection

After providing written informed consent, participants were assigned study IDs. Participants completed a pre-and post-intervention web-based survey on a computer or tablet prior to the intervention and 6 months post intervention. The survey used skip logic to administer only relevant questions based on participants' response. The baseline survey took approximately 30 minutes to complete and assessed demographics such as age, race/ethnicity, marital status, religion, HPV vaccination status, HPV endorsement outcome expectancies, skills satisfaction and intentions to counsel parents on the HPV vaccination. No compensation was provided for participation.

Survey Instrument

The research team developed a self-administered survey. The Student Nurse Survey items were drawn from measures used in prior published studies of HPV vaccination uptake (Widdice et al., 2011; Kessel et al., 2012), skills satisfaction (Guilamo-Ramos et al., 2011a), and HPV endorsement outcome expectancies (McRee, Gilkey, & Dempsey, 2014). The survey included sections on demographics, students'

vaccination status, intent to receive vaccination, intent to counsel parents on the HPV vaccine, skills satisfaction as both a parent sexual health communication counselor and adolescent sexual health educator, HPV endorsement outcome expectancies, and factors associated with vaccine initiation and completion.

Demographics

To assess race/ethnicity, students were asked if they identified as Hispanic, Caucasian, African-American, Asian, American Indian or Native American, Multiracial, and something else. We created a category called "Other" that included those who identified as American Indian, multiracial, or something else. Marital status was measured by asking students if they were single/no partner, single/living with partner, married, divorced, separated/living in different households, widowed with no partner, or other. This variable was collapsed into two categories: single with no partner vs. living with partner/married due to low frequencies of the other response options. Religion was assessed by asking students if they identified as Atheist or Agnostic, Buddhist, Christian, Hindu, Jewish, Muslim, and other. However, due to low frequencies of many of these options, the variables were collapsed into two categories: Christian and Other.

Vaccination Status

Students' vaccination status including vaccine non-initiation, initiation, and completion were assessed through students' self -report. Non-initiation was defined as an individual who had not received any dose of the HPV vaccine series. Initiation of HPV vaccination was defined as whether an individual had ever received at least one dose of the three-dose series. Completion of HPV vaccination series was defined as whether an individual had completed all three doses of HPV vaccination series.

The primary outcome variable was HPV vaccination status. To assess this, students were asked: (1) Did you receive dose one of the three dose HPV series?, (2) Did you receive dose two of the three dose HPV series?, and (3) Did you receive dose three of the three dose HPV series?. Responses were coded 1 (yes) and 2 (no). Students who had not received any dose of the HPV vaccine series were included in the "Non-Initiators" category. All students who obtained at least one HPV vaccination were included in the "Initiators" category. Among initiators, students who did not complete the series were categorized as "Non-Completing Initiators" and those that obtained all three doses of the vaccine were categorized as "Completers".

Factors Influencing Personal Vaccination

Factors associated with vaccination status were assessed using three questions with nine response options developed from Kessel et al. (2012). Students were asked: (1) What was the most important factor that determined when you received the HPV shots?; (2) What is the most important factor that will determine when you will complete the HPV vaccination series?; and (3) What is the main reason you have not completed the HPV series in the next 12 months?

Skills Satisfaction as both a Sexual Health Parent Communication Counselor and Adolescent Health Educator

Participants were asked about their current level of confidence in providing counseling and education using 14 items validated (α=0.65) in previous research from a comparative study of interventions for delaying the initiation of sexual intercourse among Latino and black youth developed by Guilamo-Ramos et al. (2011a). Students were asked to rate their level of satisfaction as both a parent communication counselor and

adolescent health educator prior to any training. Students responded to items that asked such things as: “At this moment in time how satisfied do you feel with your confidence in counseling parents on how to talk with youth about sex?” and “At this moment in time, how satisfied do you feel with your ability to discuss prevention of sexually transmitted infections (STIs)?” Responses were coded on a 5-point Likert scale (1= Not at all satisfied to 5= very satisfied).

HPV Endorsement Outcome Expectancies

The HPV endorsement outcome expectancies scale was used to assess students’ beliefs toward HPV vaccine endorsement using eight items from the Minnesota Health Care Provider Survey developed by McRee, Gilkey, & Dempsey (2014). The scale was validated in a previous study using cognitive interviews with five healthcare providers to identify potential sources of response error and to ensure the clarity of new survey items. Students reported their beliefs toward HPV vaccine endorsement with the following statements: “When parents wish to delay or refuse HPV vaccination, there is not much I can say to change their minds” and “I am confident that I can address parental HPV vaccine concerns about adolescent sexual activity” The response options used a 5-point Likert scale of “strongly agree”, “somewhat agree”, “somewhat disagree”, “strongly disagree”, and “I have no experience with this”.

Intentions to Counsel Parents on HPV Vaccination among Student Nurses

Students’ intention to counsel parents on HPV vaccination were assessed with two items developed by Guilamo-Ramos et al. (2011b) in their study a parent-based intervention to reduce sexual risk behavior in early adolescence: Building alliances between physicians, social workers, and parents. Students were asked to respond to the

following statements, “I plan to counsel parents about the importance of vaccinating youth against HPV.” and “I plan to counsel youth about the importance of getting the HPV vaccine at the recommended age.” Responses were coded on a 5-point Likert scale (1= Strongly disagree to 5 = strongly agree).

Students’ Perception of Parental Barriers to HPV Vaccine Uptake

Perceived parental barriers were assessed with items from the Minnesota Health Care Provider Survey developed by McRee, Gilkey, & Dempsey (2014). The scale was validated in a previous study using cognitive interviews with five healthcare providers to identify potential sources of response error and to ensure the clarity of new survey items. In this study students were asked one question with 13 items related to their perception of parental barriers to HPV vaccine uptake. Specifically, students were asked, “Based on your experience in the past year, how much do each of the following contribute to parents' decisions to delay or refuse HPV vaccination?” with responses such as “Belief that HPV is not severe enough to warrant vaccination.” Responses ranged from 1 (not at all) to 4 (a lot).

Tools and Strategies for Counseling HPV Vaccine-Hesitant Parents

Helpfulness of tools when counseling was assessed using one question with eight items from the Minnesota Health Care Provider Survey developed by McRee, Gilkey, & Dempsey (2014). The scale was validated in a previous study using cognitive interviews with five healthcare providers to identify potential sources of response error and to ensure the clarity of new survey items. Students were asked, “How much would the following strategies and tools help you when counseling parents who are hesitant to get HPV vaccine for their adolescent children?” An example of an item for evaluation is

"Providing information about HPV vaccine to parents before the clinical visit." Responses were on a 4 –point Likert scale ranging from 1 (not at all) to 4 (a lot).

Statistical Analysis

Survey data was analyzed using IBM SPSS Statistical Package for Social Sciences (version 25) for Mac. First, descriptive statistics were used to analyze the distribution of demographic variables (mean, standard deviation, frequencies and/or percentages) and stratify participants based on vaccination status (non-initiators, initiators, and completers) (Table 1). *P* values less than 0.05 were considered statistically significant for all analyses.

Bivariate frequencies and chi-squared test were then calculated to compare each independent variable (age, race, ethnicity, marital status, and religion) to the outcome variables, HPV vaccine initiation and completion. The variables considered for the final multivariable were statistically significant at the bivariate level ($p<0.05$) with HPV vaccine initiation and completion were included in a multivariable logistic regression model to predict vaccine initiation and completion.

Bivariate associations of age and marital status with HPV vaccination completion were examined using logistic regression model, expressed as unadjusted odds rations (OR) and 95% confidence intervals (CI) (Table 2). For logistic regression analyses, HPV vaccination completion was categorized as a dichotomous (yes/no) dependent variable. Age and marital status with HPV vaccine completion were then examined using multivariable logistic regression model, as these two factors were significantly associated with HPV vaccine completion in bivariate analyses ($p<0.05$). The quality of the model was assessed using Hosmer-Lemeshow fit statistics.

Univariate descriptive statistics (mean, standard deviation, frequencies and/or percentages) were computed to analyze the distribution of each variable (HPV endorsement, skills satisfaction as a sexual health parent communication counselor and adolescent sexual health educator, intentions to counsel, perception of parental vaccine hesitancy, and helpful tools to assist with counseling). Next, independent sample *t*-tests were used to assess for mean differences between non-initiators vs. initiators and initiators vs. completers in HPV endorsement outcome expectations, skills satisfaction as a parent sexual health communication counselor, and skills satisfaction as an adolescent sexual health educator (Table 3). We examined intentions to counsel parents on HPV differences between non-initiators vs. initiators and initiators vs. completers using Mann-Whitney U test, due to a non-normal distribution of the data (Table 4).

Results

Sample Characteristics

Data were collected from a total of 153 student nurses. The mean age of all students was 24.5 (SD=5.95), with 73% (n=112) aged between 18 and 26 years. The majority of participants were non-Hispanic (n=111, 73%) and self-identified their race as either Caucasian (n=97, 63.4%), Asian (n=23, 15%), African-American (n=15, 9.8%) or other race (n=18, 11.8%). Nearly, three-fourths of participants (n=107, 70%) were single, with 30% (n=46) stating they were married or living with a partner. The vast majority of participants declared they were religious (n=133, 87%); among them, 73% (n=111) self-identified as Christian (Table 1).

HPV Vaccination Status

Forty-two percent (n=64) of students reported that they had not received any doses of the HPV vaccine (Table 1). More than half (n=89, 58%) of students reported that they had received at least one dose of the HPV vaccine series. Of students who had initiated the vaccine series, 42% (n=65) reported that they had received all three doses of the HPV vaccine. Caucasians (n=56, 62.9%) and Hispanics (n=29, 32.5%) were more likely to initiate the HPV vaccine when compared with Asian (n=13, 14.6%), African-American (n=10, 11.2%), and those who identified as other (n=10, 11.2%). Caucasian and Hispanic students had higher rates of HPV vaccine completion (n=40, 61.5%; and n= 19, 29% respectively) when compared with Asian (n=9, 13.8%), and African-American students (n=9, 13.8%), and students who identified as other race (n=7, 10.8%).

Factors Associated with Three Dose HPV Vaccine Completion

Chi-squared tests indicated a significant relationship between HPV vaccine completion and marital status, X^2 (3, N = 153) = 20.11, $p < .000$ among those who had received at least one dose of HPV vaccine (initiators). In addition, the relationship between vaccine completion and age was significant, (t (151) = 4.36, $p = .00$) among completers and non-completers. The percentage of students who were vaccine non-completers and completers did not differ by race (X^2 (4, N = 147) = 3.55, $p > .47$), ethnicity (X^2 (1, N = 153) = .18, $p > .67$), or religion (X^2 (8, N = 152) = 7.83, $p > .45$) (data not shown). Therefore, only age and marital status were included the logistic regression.

To further explore vaccination completion, a binary logistic regression model was conducted among non-completers and completers. In the regression model, marital status

was significantly associated with vaccination completion as well as age. Students who identified as single (OR: 2.65; 95% CI: 1.09-6.42, *p*= .031) were almost three times more likely to complete the HPV vaccine series than those who were married. Age (OR: 0.86; CI: 0.78-0.95; *p*=.003) was significantly associated with a decreased likelihood of vaccine completion; an increase of one year in age was associated with a 14% reduction in the odds of vaccine completion. The Hosmer-Lemeshow fit statistics indicated acceptable model fit (χ^2=8.50, *p*=.39) (Table 2).

Factors Influencing Personal Vaccination Status

Among those who had received at least one dose of the vaccine series (n=89), students reported that the most important factors that influenced vaccine initiation were having a doctor's recommendation (*n*=25, 39%), confidence in the HPV vaccine (n=24, 27%), having a parent who recommended the vaccine (*n*=9, 14%), and having enough knowledge about HPV disease and the vaccine (n=9, 14%). The most commonly cited factors that influenced vaccine completion were: age (<26) (n=21, 24%), receiving a doctor's recommendation (n=17, 19%), and convenience of receiving the vaccine (n=15, 17%). The most common reasons for not completing the HPV series among non-initiators and non-completing initiators were age eligibility (>26 years of age) (n=17, 26%), lack of provider recommendation (n=14, 16%), intention to complete the HPV series but have not yet (n=12, 14%), and not being sexually active (n=7, 8%).

Next, we assessed for differences in factors that may influence student nurses' role as a parent child communication counselor, sexual health educator, and provider of HPV vaccination endorsement. We compared non-initiators vs. initiators and initiators

vs. completers on their HPV endorsement, counseling outcomes, skills, and intentions to counsel parents on HPV vaccination.

Skills Satisfaction as a Parent Sexual Health Communication Counselor

There were no significant differences in skills satisfaction as a parent sexual health communication counselor score between non-initiators vs. initiators, as well as initiators and completers (Table 3). An independent sample *t* test indicated that initiators (M=9.62, SD=3.95) scored higher on the skills satisfaction as a parent sexual health communication counselor than non-initiators (M=8.94, SD= 3.98), (t (151) = 1.047, *p* = .297). Initiators had higher skills satisfaction as a parent sexual health communication counselor scores (M=9.50, SD=4.28) when compared with completers (M=9.11, SD=3.51), (t (151) = .603, *p*= .547).

Skills Satisfaction as an Adolescent Sexual Health Educator

There were no significant differences in skills satisfaction as an adolescent sexual health educator score between non-initiators vs. initiators, as well as initiators and completers (Table 3). An independent sample *t* test indicated that initiators (M=27.30, SD=8.74) scored higher on the skills satisfaction as an adolescent sexual health educator than non-initiators (M=25.70, SD=8.29), (t (151) =1.140, *p*=.256). Initiators had higher skills satisfactions scores as an adolescent sexual health educator (M=26.99, SD=8.88) than completers (M=26.15, SD=8.17), (t (151) =.594, p= .553).

HPV Endorsement Outcome Expectancies

Independent sample *t* tests found no statistically significant differences in mean HPV endorsement outcome expectancies scores between non-initiators vs. initiators, as well as initiators vs. completers (Table 3). Initiators had higher HPV endorsement

outcome expectancies scores (M =17.44, SD =3.96) than non-initiators (M=17.23, SD=4.13), (t (151) =.288, *p*=.774). Additionally, when we compared initiators to completers, completers reported higher levels of HPV endorsement outcome expectancies scores (M=17.39, SD=4.10) than initiators (M=17.32, SD=3.99), (t (151) =-.087, *p*=.931).

Intentions to Counsel Parents on HPV Vaccination among Student Nurses

For intention to counsel parents on HPV, scores were higher for initiators (mean rank = 79.10) than non-initiators (mean rank =74.08) (Table 4). A Mann-Whitney *U* test indicated that there was no difference in intentions to counsel parents on the HPV vaccination (*U* = 2661, *Z*= -.952, *p*=.341) between non-initiators and initiators. In addition, vaccine completers scored higher (mean rank =78.27) on intention to counsel parents on HPV vaccine than initiators (mean rank =76.06). However, a Mann-Whitney *U t*est showed that this difference was not significant, (U = 2777.50, Z= -.419, p= .675).

Students' Perception of Parental Barriers to HPV Vaccine Uptake

In terms of reasons for HPV vaccine delay or refusal, most students perceived factors that contributed to parents' decisions were: the belief that their child is not sexually active (n=73, 57%) and discomfort talking with their child about sex (n=64, 53.1%). Among students who provided data (n=128), perceived factors that contributed "a little" or "not at all" to parental decision to delay or refuse HPV vaccination for their child included the belief that HPV vaccine is not very effective (n=99, 77.3%), parent's let their children decide and the child refused the vaccine (n=99, 77.3%), and child was sick at the time of visit (n=101, 78.9%). In addition, students perceived that concern that their child will suffer immediate short-term effects (n=94, 73.4%) and/or long-term

complications from HPV vaccine (n=94, 73.4) also contributed “a little” or “not at all” to parental delay or refusal of the HPV vaccine.

Tools and Strategies for Counseling HPV Vaccine- Hesitant Parents

Student nurses (n=140) reported a range of attitudes about strategies and tools for counseling vaccine-hesitant parents. The strategies and tools that student nurses perceived would be most helpful (i.e., “a lot” or “somewhat”) for counseling parents who are hesitant to get their adolescent children vaccinated against HPV were: information tailored to patients’ cultural background (n=122, 87%), or specific to parent concerns (n=125, 89%), and providing information for parents and adolescents separately (n=106, 76%). Students nurses perceived that providing information about the HPV vaccine to parents prior to the clinical visit (n=102, 73%) and giving interactive decisional aids to prioritize their health values (n=113, 81%) would also beneficial to counsel parents.

Discussion

There are many concerns about reaching high rates of vaccine uptake and completion among young adults. Student nurses represent the next generation of healthcare providers and are in a position to influence vaccine uptake through their own personal and professional health choices, decision regarding future children and patients, and willingness to provide vaccine counseling and endorsements. As HPV- associated cancers rates steadily rise and vaccine uptake remains low, it is necessary to identify factors that could influence HPV vaccine uptake among this population.

The findings from this analysis indicate that student nurses had low rates of HPV vaccine initiation (n=89, 57%). Additionally, completion rates were far below Healthy People 2020 goal of 80 percent coverage (n=65, 42%). We found that the vaccination

prevalence in this study was comparable to previous studies in college students which have ranged from 25% to 62.8% for initiation (Licht et al., 2010; Marchand et al., 2012; Marchand et al., 2013; Rahman, Laz, McGrath, & Berenson, 2014; Wilson et al., 2016) and 27% to 60.7% for completion (Canfell et al., 2015; LaJoie et al., 2018; Rahman, Laz, McGrath, & Berenson, 2014; Wilson et al., 2016). These proportions are also parallel to recent national estimates that 48.5% of eligible women and 13.5% of men 19 to 26-year-old adults have initiated the HPV vaccine (Lewis & Markowitz, 2018). These findings indicate that continued efforts to improve catch-up vaccination and eliminate missed vaccination opportunities among young adults are urgently needed.

The majority of participants in the study were under the age of 26 (n=113, 72.4%). At the time of the study, the HPV vaccine was recommended for young women through age 26; young men through age 21; and through age 26 for young men who have sex with men, young men who identify as gay or bisexual or who intend to have sex with men, young adults who are transgender, and young adults with certain immunocompromising conditions (including HIV) (CDC, 2018b). Of those over the age eligibility requirements at the time of the study (n=41, 25.8%), many expressed interests in receiving the vaccine. For this group of adults, it is not too late to vaccinate against HPV as the FDA recently approved expanding the use of the Gardasil 9 HPV vaccine to include all women and men through 45 years of age (U.S. Food and Drug Administration, 2018).

The proportions of students who initiated the vaccine in the current sample differed by race/ethnicity. We found that Caucasians were more likely to report initiation and completion of the three-dose series when compared with other racial/ethnic groups.

These findings are similar to national estimates, which recently showed that Caucasian (adults aged >19) (48.5%) are more likely to initiate the HPV vaccine when compared with African-American (37.7%) and young Hispanic adults (33%) (Williams et al., 2017). Studies report ethnic minority populations are willing to accept vaccination; however cultural differences may create barriers to vaccine uptake (Holman et al., 2014). Therefore, it is important to develop culturally relevant educational programs that could potentially increase HPV vaccine uptake and completion among minority racial and ethnic groups.

In our study, we found that higher vaccination completion was associated with being unmarried. This might be related to a greater perceived risk for HPV infection among unmarried student nurses. Students who reported being married or single but living with a partner were less likely to have completed the HPV vaccination series, possibly because these students may not believe they are at risk of contracting STIs and therefore, may be less likely to get vaccinated. These findings are consistent with previous research indicating that women who were single were significantly more likely than married women to be interested in the HPV vaccine (Thompson, Sappenfield, Straub, & Daley, 2016b). These findings suggest that relationship status may influence HPV vaccination uptake, by impacting risk perceptions and perceived need for the HPV vaccine. Additionally, efforts aimed at improving HPV vaccination rates should focus on highlighting lifetime risk for acquiring HPV among young adults in relationships.

Our findings revealed that having a doctor's recommendation was the most influential factor associated with vaccine initiation and completion among student nurses. One study found that those who received a doctor's recommendation were over 35 times

more likely to receive at least one dose of HPV vaccine when compared to those who did not receive a recommendation (Gerend, Shepherd, Lustria, & Shepherd, 2015). Our study highlights that young adults consider the role that healthcare providers play in health promotion and disease prevention to be important. This is of particular concern because a lack of doctor recommendation was cited as a reason for non-initiation and completion of the HPV vaccine series among undervaccinated students. One probable reason for low HPV vaccination rates is that young adults are not receiving routine vaccine recommendations. Failure to discuss vaccination may result in missed clinical opportunities for receipt of the HPV vaccination, which may ultimately lead to the development of more HPV-related cancers each year.

In this study, we attempted to identify whether differences existed in students' intentions to counsel, outcome expectations, skills satisfaction as both a sexual health parent communication counselor and adolescent sexual health educator by vaccination status. There was no significant difference between the two groups (non-initiators vs. initiators and initiators vs. completers). These findings suggest that vaccination status did not substantially impact students' beliefs about counseling, skills satisfaction, outcome expectations, or intentions to counsel parents about the HPV vaccination.

Overall, all scores were high indicating that students had high levels of confidence in their ability to provide communication counseling, sexual health education, and overcome HPV vaccine hesitancies. Studies indicates that a nurses' personal beliefs and self-confidence to address vaccine concerns often drive their vaccine endorsement practices (Paterson et al., 2016; Wamai et al., 2013). Unvaccinated students had high mean intentions to counsel scores, despite being unvaccinated. These findings suggest

that students' intention to counsel may also be influenced by their personal attitudes toward the HPV vaccination. Among the student nurses who participated in our study, those who initiated and completed the vaccine series had higher mean intentions to counsel scores. Our findings suggest that personal HPV vaccine uptake among student nurses may influence their vaccine endorsement practices. These findings are consistent with previous research that suggest vaccinated nurses and those who express a willingness to be vaccinated are more likely to recommend the HPV vaccination (Paterson et al., 2016). Moreover, findings suggest that the influences of their own vaccine confidence, outcome expectancies, and vaccination uptake play a key role in their HPV vaccine endorsement practices. Improving providers' vaccination uptake and confidence to address parental concerns may be important for promoting HPV vaccine recommendations and ultimately improving HPV vaccine completion rates, in a broader age range.

Our findings indicate that student nurses perceived parental barriers such as the belief that their child is not sexually active, discomfort talking with their child about sex, and belief that their child was unlikely to get an HPV-related disease, as contributing factors impacting HPV vaccination rates. This is consistent with previous literature which suggest that factors such as reluctance to discuss sexual health, child's age, and low perception of risk as common barriers to HPV vaccine endorsement, uptake, and completion among patients and providers (McRee, Gilkey, & Dempsey, 2014; Mills et al., 2016). Differences in risk perception between healthcare providers and patients, may also pose increase risk to health. Further studies are needed to raise awareness about HPV risk among parents, patients, and healthcare providers, followed by development of

tailored educational tools and strategies to facilitate better communication between parents, patients, and healthcare providers.

Limitations and Strengths

Limitations of the study included the use of previously collected data and self-reported measures. Additionally, participants were recruited using a purposive sample of student nurses from one Bachelor of Science Nursing school in an urban area which may limit the generalizability of findings. Additionally, while we did not assess gender, student nurses are majority female; this may be seen as a limitation since vaccination rates differ by gender have been well-documented (Daniel-Ulloa, Gilbert, & Parker, 2016).

Despite these limitations, the focus on student nurses is an innovative approach for HPV vaccine research. This research will provide insight on young adults as student nurses, who are transitioning into the nurse role, where they will have the opportunity to promote the HPV vaccination and reduce missed opportunities for HPV prevention. The study findings will provide direction for interventions and programs targeted toward young adults and healthcare providers vaccination concerns which may increase awareness, HPV vaccine recommendations, uptake, and completion.

Conclusion

Given the growing epidemic of HPV infection, more research is needed, particularly for high risk populations and future healthcare providers which may increase vaccine promoting behaviors and impact clinical practice. Although, acceptance of HPV vaccination is promising, uptake and completion rates remain low among young adults that are at highest risk for HPV- related disease burdens. Our findings suggest that low

HPV vaccination rates persist among college students, specifically student nurses. Additionally, our findings indicate that student nurses who had initiated and/or completed the HPV vaccine series had higher intentions to recommend vaccination to parents. Therefore, it is important to develop targeted interventions to increase vaccination rates among student nurses, not only to protect them from HPV but also because of the impact that their vaccination status has on their intention to counsel parents.

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Table 1

Sample Characteristics by HPV vaccination status among student nurses (n=153)

Variables	Non-initiators (n=64)	Initiators (n=89)		Total (n=153)
Demographics		Non-Completing Initiators (n=24)	Completers (n=65)	
Age in years, M (SD)				24.5 (5.95)
≤ 26, n (%)	36 (56)	20 (83)	56 (86)	112 (73.2)
>26, n (%)	28 (44)	4 (17)	9 (14)	41 (26.8)
Ethnicity, n (%)				
Hispanic	13 (20)	10 (42)	19 (29)	42 (27.4)
non-Hispanic	51 (80)	14 (58)	46 (71)	111 (72.6)
Race, n (%)				
Caucasian	41 (64)	16 (66.6)	40 (61.5)	97 (63.4)
Asian	10 (15.6)	4 (16.6)	9 (13.8)	23 (15)
African-American	5 (7.8)	1 (4.1)	9 (13.8)	15 (9.8)
Other[a]	8 (12.5)	3 (12.5)	7 (10.8)	18 (11.8)
Marital Status, n (%)				
Single/Not in a relationship	33 (52)	18 (75)	56 (86)	107 (70)
Married /Living with partner	31 (48)	6 (25)	9 (14)	46 (30)
Religion, n (%)				
Christian	45 (70)	17 (70.8)	49 (75.3)	111 (72.6)
Other[b]	19 (30)	7 (29)	16 (25)	42 (27.4)

Note. [a]Other: American Indian or Native American; Multiracial; Something else

[b]Other: Atheist, Buddhist, Hindu, Jewish, Muslim, None of the above, Refuse to answer

Table 2

Factors associated with vaccination completion (completers vs. all other groups) among student nurses.

	Coefficient B	**SE**	**OR**	***p***	**95% CI of OR**
Age	-.149	.050	0.86	.003	0.78-0.95
Marital Status	.975	.452	2.65	.031	1.09-6.42

*CI=confidence interval

Table 3

Independent Sample t test comparing non-initiators and initiators

Variable	Group	N	Mean	Std. Deviation	Std. Error Mean	t	Sig. (2-tailed)
Skills Satisfaction as a Sexual Health Parent Communication Counselor	non-initiators	64	8.94	3.984	.498	1.047	.297
	initiators	89	9.62	3.956	.419		
Skills Satisfaction as Adolescent Sexual Health Educator	non-initiators	64	25.70	8.295	1.037	1.140	.256
	initiators	89	27.30	8.748	.927		
HPV Endorsement Outcome Expectancies	non-initiators	56	17.23	4.138	.553	.288	.774
	initiators	78	17.44	3.966	.449		
Independent Sample *t* test comparing initiators and completers							
Skills Satisfaction as a Sexual Health Parent Communication Counselor	initiators	88	9.50	4.283	.457	.603	.547
	completers	65	9.11	3.518	.436		
Skills Satisfaction as Adolescent Sexual Health Educator	initiators	88	26.99	8.880	.947	.594	.553
	completers	65	26.15	8.176	1.014		
HPV Endorsement Outcome Expectancies	initiators	77	17.32	3.995	.455	-0.87	.931
	completers	57	17.39	4.100	.543		

Table 4

Mann-Whitney U comparing non-initiators and initiators

Variable	Group	N	Mean Rank	Sum of Ranks	*U*	*Z*	*p*
Intentions to Counsel Parents on HPV vaccination	non-initiator	64	74.08	4741	2661	-.952	.341
	initiator	89	79.10	7040			
	Total	153					

Mann-Whitney *U* comparing initiators and completers

Variable	Group	N	Mean Rank	Sum of Ranks	U	Z	*p*
Intentions to Counsel Parents on HPV vaccination	Initiator	88	76.06	6693.50	2777.500	-.419	.675
	Completer	65	78.27	5087.50			
	Total	153					

Table 5
Determining factors for HPV vaccination status among student nurses.

		Initiators		Total (n)	%
	NI	I	C		
What is the most important factor that will determine when you will complete the HPV vaccination series?					
Other, please specify	17	4		21	24
The doctor's recommendation	11	6		17	19
If it is convenient for me to get vaccinated/ If I find the time to do so	8	7		15	17
Don't Know	13	0		13	15
Insurance covering the cost/No cost concerns	4	4		8	9
If it becomes common practice/ Been standard for years/Comfortable with recommendation	5	2		7	8
When I know enough about HPV disease and the vaccine	3	0		3	3
Becoming sexually active	2	0		2	2
Having enough information about vaccine safety	1	1		2	2
What was the most important factor that determined when you received the HPV shot?					
The doctor's recommendation			25	25	39
It became common practice/It has been standard for years/I was comfortable with recommendation			13	13	20
Other, please specify			9	9	14
I knew enough about HPV disease and the vaccine			8	8	12
Don't Know			6	6	9
I became sexually active			2	2	3
My insurance covered the cost/No cost concerns			1	1	2
I had enough information about vaccine safety			1	1	2
What is the main reason you will not/have not completed the HPV series in the next 12 months?					
Other, please specify: age eligibility	14	8		22	25
My provider did not recommend it	13	1		14	16
I intend to complete the HPV series but have not yet/Already planned	4	8		12	14
Don't know	8	3		11	13
I am not sexually active	7	0		7	8
The school does not require	5	1		6	7
I am uninsured/My insurance does not fully cover shots/The insurance co-pay or other costs are too high (i.e., administration fees and/or office visit charges)	5	1		6	7
I did not know about the vaccine/I did not know the vaccine was recommended for me	3	0		3	3
I do not believe the vaccine is needed or necessary	3	0		3	3

Table 6

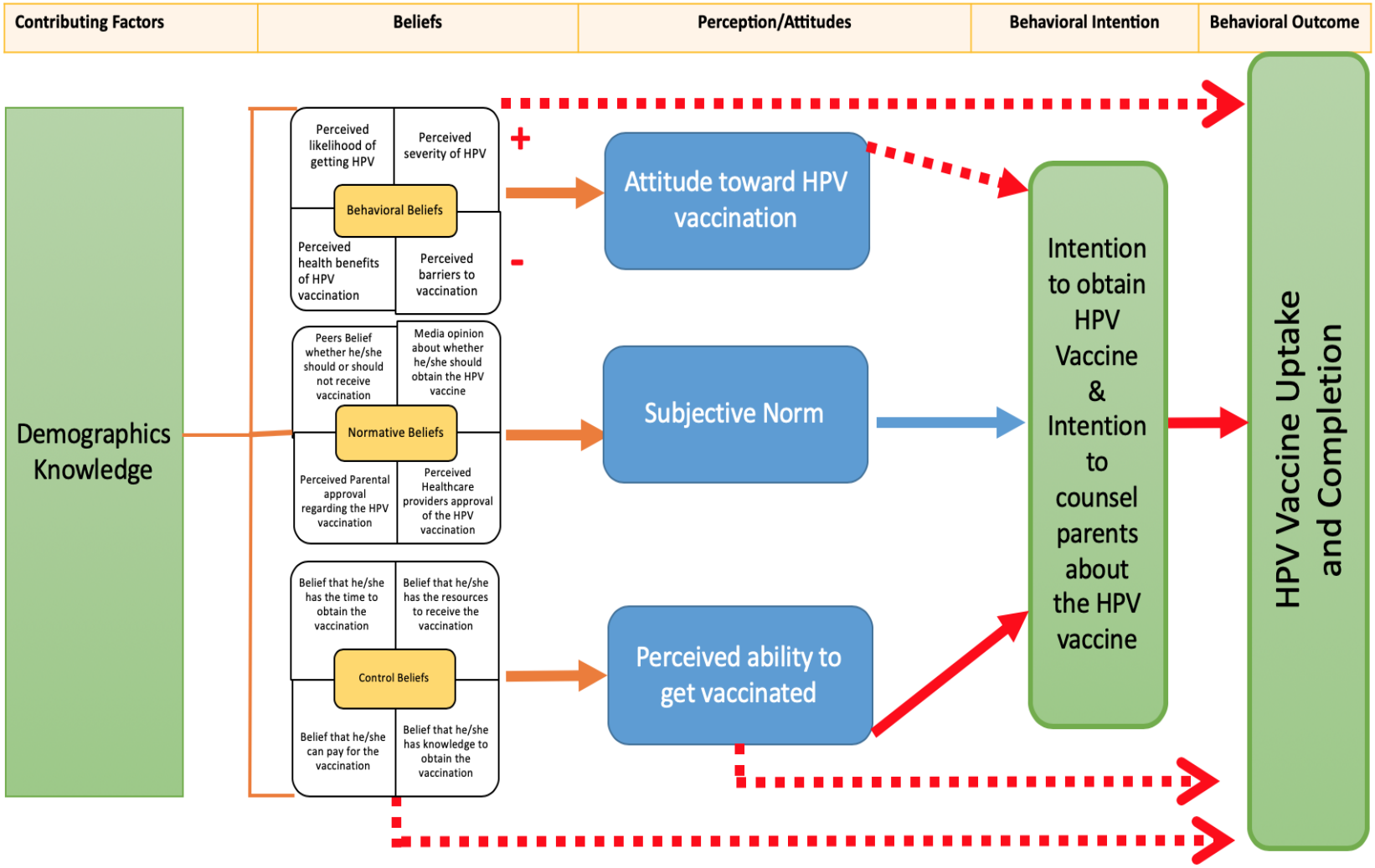
Students' perceptions of reasons for parental HPV vaccine hesitancy and helpfulness of potential tools

	A lot %	**Some %**	**A little %**	**Not at all %**
Perceived reasons for parental delay or refusal of HPV vaccine for their child				
Belief that their child is not sexually active	44	29	17	38
Discomfort talking with their child about sex.	37	31	17	43
Belief that their child is unlikely to get an HPV-related disease.	25	31	29	43
Concerns about vaccines in general.	14	36	27	50
Belief that HPV is not severe enough to warrant vaccination.	13	28	30	58
Concern about the cost of HPV vaccine.	10	35	23	59
Concern about getting multiple vaccines at the same visit.	10	25	37	53
Belief that HPV vaccine recommendations are driven by profit considerations of drug companies.	9	25	23	71
Concern that their child will suffer immediate, short-term effects (such as fever, pain)	8	26	34	60
Concern that their child will suffer long-term complications from HPV vaccine.	7	38	21	61
Parents let their children decide and the child refused the vaccine.	5	22	22	77
Belief that HPV vaccine is not very effective.	4	25	26	73
Child was sick at the time of visit.	3	22	27	74
Helpfulness of potential tools of counseling HPV-vaccine hesitant parents				
Written information for parents that is tailored to their cultural background.	90	32	13	5
Information sheets or brochures tailored to specific parent concerns.	84	41	9	6
A screener to identify specific parent concerns.	72	40	22	6
Providing information about HPV vaccine to parents before the clinical visit.	65	37	29	9
A discussion guide or script for health care professionals.	64	51	18	7
Interactive decision aids that help parents prioritize their health values in relation to HPV vaccination.	64	49	20	7
Providing information for parents and adolescents separately.	63	43	26	8
More attractive/accessible version of standard Vaccine Information Sheets.	61	48	24	7

Note. Presented in descending order by variable mea

APPENDIX A

THEORY OF PLANNED BEHAVIOR (TPB)


Contributing Factors
Beliefs
Perception/Attitudes
Behavioral Intention
Behavioral Outcome
Demographics Knowledge
Perceived likelihood of getting HPV
Perceived severity of HPV
Behavioral Beliefs
Perceived health benefits of HPV vaccination
Perceived barriers to vaccination
+
-
Attitude toward HPV vaccination
Peers Belief whether he/she should or should not receive vaccination
Media opinion about whether he/she should obtain the HPV vaccine
Normative Beliefs
Perceived Parental approval regarding the HPV vaccination
Perceived Healthcare providers approval of the HPV vaccination
Subjective Norm
Belief that he/she has the time to obtain the vaccination
Belief that he/she has the resources to receive the vaccination
Control Beliefs
Belief that he/she can pay for the vaccination
Belief that he/she has knowledge to obtain the vaccination
Perceived ability to get vaccinated
Intention to obtain HPV Vaccine & Intention to counsel parents about the HPV vaccine
HPV Vaccine Uptake and Completion

APPENDIX B

STUDENT NURSE SURVEY

FTT+HPV Student Nurse Survey (Pre-Test)

Start of Block: Study ID

Q167 Current Year:
- 2015 (1)
- 2016 (2)
- 2017 (3)

Q168 Current Semester:
- Fall (1)
- Spring (2)
- Summer (3)

Q169 Please enter Study ID in the box below:

_____

End of Block: Study ID

Start of Block: Demographics

Q69 How old are you?

_____

Q70 Are you Hispanic or Latino?
- Yes (1)
- No (2)

Skip To: Q72 If Are you Hispanic or Latino? = No

Q71 Which category best describes your Hispanic or Latino background?

- Puerto Rican (1)
- Dominican or Dominican American (2)
- Mexican or Mexican American (3)
- Cuban or Cuban American (4)
- Central American (5)
- South American (6)

Q72 What is your race or ethnicity?

- White (1)
- Black or African American (2)
- Asian or Pacific Islander (3)
- American Indian or Native American (4)
- Other, please specify: (5)

  _____

Q238 What language do you predominately speak at home?

- English (1)
- Spansih (2)
- Other (3)

Q77 How much schooling have you completed?

- Up to 8th grade (1)
- Some High School (2)
- Completed High School (3)
- Completed my GED (4)
- Some College (5)
- Bachelors Degree (6)
- Some Graduate School (7)
- Master's Degree (8)

Q78 What is your current marital status?

- Single/ Living with No Partner (1)
- Single/Living with Partner (2)
- Married/ Living with Husband (3)
- Divorced or Separated/Living in Different Households (4)
- Widowed with no partner (5)
- Other (6) _____

Q79 What is your current religion?

- Atheist or Agnostic (1)
- Buddhist (2)
- Chrisitian (for example Baptist, Catholic, Episcopal, Lutheran, Methodist, Pentecostal, Presbyterian) (3)
- Hindu (4)
- Jewish (5)
- Muslim or Moslem (6)
- Other, please specify: (7)
  _____
- None of the above (8)
- Refuse to answer (9)

Q80 How important is religion to you?

- Not at all important (1)
- Somewhat important (2)
- Quite important (3)
- Very important (4)

End of Block: Demographics

Start of Block: Block 10

Q194 How confident are you in your ability to teach on the following topics:

Q171 a) The physiology of the sex organs

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q172 b) Pregnancy and birth

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q173 c) Taking care of sexual health

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q174 d) HIV/AIDS

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q175 e) Pregnancy prevention methods

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q176 f) Buying and using contraceptives

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q177 g) Abstinence

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q178 h) Getting tested for STIs/STDs

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q179 i) Emotional issues related to sex

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q180 j) Discussing sex with a partner

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q181 k) Talking to parents about sex

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q182 l) Abortion

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q183 m) Adoption

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q184 n) Homosexuality

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q185 o) Sex in other cultures

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q186 p) Sexual choices based on values

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q187 q) Oral sex

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q188 r) Masturbation

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q189 s) Anal sex

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q190 t) Heavy petting

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

Q191 u) Kissing

- Prefer not to answer (1)
- Do not think it is an appropriate topic (2)
- Would not want to teach it (3)
- Not sure I could do it (4)
- Confident, with a little time for preparation (5)
- Confident, may need to use lecture style (6)
- Very confident, including leading discussion and answer questions (7)

End of Block: Block 10

Start of Block: Beliefs

Q58
This section asks you questions about your beliefs. We want you to tell us your impressions about what happens when parents talk to their teens about sexual intercourse or monitor their social activities.

Please indicate how strongly you agree or disagree with the following statements regarding 11-14 year old youth and their parents.

Q1 By talking to youth about NOT having sex, parents would definitely LESSEN the chances that their child will experience a negative sexual health outcome.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q2 By setting clear rules and expectations about not engaging in sexual activity, parents would definitely LESSEN the chances that their child will experience a negative sexual health outcome.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q3 By keeping track of where youth are, parents would NOT LESSEN the chances that their child will experience a negative sexual health outcome.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q4 By discouraging youth from dating an older teen, parents would definitely LESSEN the chances that their child will experience a negative sexual health outcome.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q5 By encouraging youth to have friendships rather than serious dating relationships, parents would NOT LESSEN the likelihood that their child will experience a negative sexual health outcome.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

End of Block: Beliefs

Start of Block: Block 1

Q59
Now we are going to ask you about your opinions about health-related behaviors and outcomes among teens in general. Please indicate whether you agree or disagree with the following statements.

Q7 Given that a child is between the ages of 11 and 14, I realize that there is a chance s/he could start having sex soon.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q8 Given that more than 50% of minority youth get pregnant before the age of 20, I should be concerned about teen pregnancy in youth.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q9 Because almost half of all sexually transmitted infections (STIs) occur among youth ages 15 to 24, I recognize that youth are at high risk for acquiring an STI.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q10 African Americans or Latino families living in an urban setting face more challenges than most parents of other ethnic groups in trying to prevent youth from getting HIV.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q11 As teen parenthood is a leading cause of school drop-out, I am deeply concerned about teen pregnancy in youth.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

End of Block: Block 1

Start of Block: Block 2

Q60
People have different opinions about why some parents talk to their teens about sexual intercourse while others do not. This section explores your opinions about things that might happen if a parent talks with their youth about sex between ages 11-14. Please indicate whether you agree or disagree with the following statements.

Q12 Talking to youth about sex won't make a difference.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q13 Talking to youth about sex will lead to them having sex.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q14 I'm too embarrassed to talk to parents about how to talk with youth about sex.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q15 I'm too embarrassed to talk to youth about how to talk with their parents about sex.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q16 I don't know what to say to parents about how to talk with youth about sex.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q17 I don’t know what to say to youth about how to talk with their parents about sex.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q18 I don't know what to tell a parent who had sex as a teen and doesn't know how to address that with their youth.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q19 Teens get enough information about sex at school and they don't need to hear it from a parent.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q20 Teens get enough information about sex at school and they don't need to hear it from a nurse.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

End of Block: Block 2

Start of Block: Block 3

Q161 For the next set of questions, we want to know your level of satisfaction with your skills to educate parents about adolescent sexual health.

Q21 At this moment in time, how satisfied do you feel with your confidence in counseling parents on how to talk with youth about sex?

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q22 At this moment in time, how satisfied do you feel with your confidence in counseling youth on how to talk with their parent about sex?

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q23 At this moment in time, how satisfied do you feel with the amount of control you have over being able to counsel a parent on how to talk with youth about sex?

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q24 At this moment in time, how satisfied do you feel with the amount of control you have over being able to counsel youth on how to talk with their parents about sex?

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

End of Block: Block 3

Start of Block: Block 4

Q61
For the next set of questions, we want to know your level of satisfaction with your skills as an adolescent sexual health educator.

Q25 At this moment in time, how satisfied do you feel with your ability to discuss prevention of HIV/AIDS.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q26 At this moment in time, how satisfied do you feel with your ability to discuss prevention of sexually transmitted infections (STIs)

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q27 At this moment in time, how satisfied do you feel with your ability to discuss prevention of teen pregnancy.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q28 At this moment in time, how satisfied do you feel with your ability to increase parent-child sexual health communication.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q29 At this moment in time, how satisfied do you feel with your ability to increase parental monitoring.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q30 At this moment in time, how satisfied do you feel with your ability to increase parents' beliefs that they can make a difference.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q31 At this moment in time, how satisfied do you feel with your ability to increase focus of parental communication on social reasons for decision making.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q32 At this moment in time, how satisfied do you feel with your ability to counsel parents on overcoming communication barriers.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q33 At this moment in time, how satisfied do you feel with your ability to motivate parent-child communication using health outcomes.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

Q34 At this moment in time, how satisfied do you feel with your ability to counsel parents on getting the sexual health conversation started.

- Not at all satisfied (1)
- A little satisfied (2)
- Somewhat satisfied (3)
- Mostly satisfied (4)
- Very satisfied (5)

End of Block: Block 4

Start of Block: Block 5

Q62 We now want to find out some of your general feelings about parental monitoring of youth sexual behavior and social activities. Remember that when we say “social activities”, we mean the things teens do for fun when they have free time, such as hanging out with friends, going to parties, or going out on dates.

Q35 When youth go out at night, parents should know where they are.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q36 Parents should talk with youth about the plans they have with friends.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q37 Youth should let parents know who they are going to be with before they go out.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q38 Parents should ask youth where they will be when they go out.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q39 Parents should know where youth are after school.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q40 Youth should call parents to let them know if they are going to be home late.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q41 Parents should set clear expectations for how they expect youth to behave when it comes to having sexual intercourse at this time in their lives.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q42 Parents should follow through if youth break rules or agreements at this time in their lives.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

Q43 Parents should check in with youth about what is currently going on in their lives.

- Almost never (1)
- Sometimes (2)
- A moderate amount of time (3)
- Most of the time (4)
- All of the time (5)

End of Block: Block 5

Start of Block: Block 6

Q63 We now want to find out some of your general feelings about talking to parents and youth about sexual activity. Remember that when we say "sexual intercourse", we mean "going all the way" or the "act by which babies are made." Sexual intercourse is when a male inserts his penis into a female's vagina.

Q44 I plan to counsel parents about the importance of talking with youth about not having sexual intercourse at this time in his/her life.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q45 I plan to counsel parents about the importance of talking with youth about protecting him/herself if s/he chooses to have sexual intercourse at this time in his/her life.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither agree nor disagree (3)
- Moderately agree (4)
- Strongly agree (5)

Q66 I plan to counsel parents about the importance of vaccinating youth against HPV.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither Agree nor Disagree (3)
- Moderately agree (4)
- Strongly Agree (5)

Q67 I plan to counsel youth about the importance of getting the HPV vaccine at the recommended age.

- Strongly disagree (1)
- Moderately disagree (2)
- Neither Agree nor Disagree (3)
- Moderately agree (4)
- Strongly Agree (5)

End of Block: Block 6

Start of Block: Behavior

Q64 This next set of questions ask about your communication with parents in the past three months.

Q46 In the past 3 months, have you ever talked with parents about how to talk with youth about NOT having sexual intercourse at this time in their lives?

- Yes (1)
- No (2)

Q47 In the past 3 months, how often did you talk with parents about how to talk with youth about not having sexual intercourse at this time in their lives?

- Once (1)
- More than once, but less than once per month (2)
- About once per month (3)
- A few times per month (4)
- About once per week (5)
- About two or more times per week (6)
- Never (8)

Q48 In the past 3 months, have you ever talked with parents about how to talk with youth about why social reasons for having sex are not good reasons?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q49 In the past 3 months, have you ever talked with parents about how to talk with youth about the qualities of a healthy relationship between two people?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q50 In the past 3 months, have you ever talked with parents about how to talk with youth about ways to resist peer pressure for having sex?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q51 In the past 3 months, have you ever talked with parents about how to talk with youth about their beliefs on when sex should or shouldn't take place?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q52 In the past 3 months, have you ever talked with parents about how to talk with youth about their rules about dating?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q53 In the past 3 months, have you ever talked with parents about how to talk with youth about sexually transmitted diseases, such as HIV?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q54 In the past 3 months, have you ever talked with parents about how to talk with youth about using methods of contraception, such as condoms or the pill?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

Q170 In the past 3 months, have you ever talked with parents about the importance of getting the HPV vaccination for youth?

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- A moderate amount (4)
- A great deal (5)

End of Block: Behavior

Start of Block: Block 11

Q82 In the last month, how often have you felt that you were unable to control the important things in your life?

- Never (1)
- Almost never (2)
- Sometimes (3)
- Fairly Often (4)
- Very Often (5)

Q83 In the last month, how often have you felt confident about your ability to handle your personal problems?

- Never (1)
- Almost never (2)
- Sometimes (3)
- Fairly Often (4)
- Very Often (5)

Q84 In the last month, how often have you felt that things were going your way?

- Never (1)
- Almost never (2)
- Sometimes (3)
- Fairly Often (4)
- Very often (5)

Q85 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

- Never (1)
- Almost never (2)
- Sometimes (3)
- Fairly Often (4)
- Very often (5)

End of Block: Block 11

Start of Block: Block 13

Q163
We would now like to ask about your experience in the past 3 months of providing HPV vaccination counseling to parents.

Q92
How often will you recommend HPV vaccine to 11-12 year old girls as part of their routine care?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q90 I prefer to recommend HPV vaccine as an optional vaccine for girls ages 11-12.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q91 I will recommend HPV vaccine for girls ages 11-12 as strongly as other adolescent vaccines such as Tdap and meningococcal vaccine.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q93
How often will you recommend HPV vaccine to 11-12 year old boys as part of their routine care?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q94
I prefer to recommend HPV vaccine as an optional vaccine for boys ages 11-12.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q95 I will recommend HPV vaccine for boys ages 11-12 as strongly as other adolescent vaccines such as Tdap and meningococcal vaccine.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q96
Please think about times during the past year that you have recommended HPV vaccine to parents of boys and girls 11-12 years old. How often did parents react in the following ways?

Q97 Accepted the recommendation for HPV vaccination without question.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q98 Requested to delay HPV vaccination until a future visit.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)
- Not applicable (6)

Q99 Refused HPV vaccination for their child.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q100 Expressed concerns about HPV vaccination.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q101 Appeared offended or angry that you brought up the topic.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q102 Based on your experience in the past year, how much do each of the following contribute to parents' decisions to delay or refuse HPV vaccination?

Q103 Concern that their child will suffer long-term complications from HPV vaccine.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q104 Belief that their child is unlikely to get an HPV-related disease.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q105 Belief that HPV is not severe enough to warrant vaccination.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q106 Concern that their child will suffer immediate, short-term effects (such as fever, pain).

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q107 Belief that HPV vaccine recommendations are driven by profit considerations of drug companies.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q108 Belief that HPV vaccine is not very effective.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q109 Child was sick at the time of visit.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q110 Concerns about vaccines in general.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q111 Concern about getting multiple vaccines at the same visit.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q112 Belief that their child is not sexually active.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q113 Discomfort talking with their child about sex.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q114 Parents let their children decide and the child refused the vaccine.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q115 Concern about the cost of HPV vaccine.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q117
Please think about times during the past year that parents of 11-12 year olds have responded to your recommendation of HPV vaccine with concern or hesitancy.

When it comes counseling HPV-vaccine hesitant parents, how often did you do the following?

Q118 Strongly urge parents to initiate the HPV vaccine series at the present time.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q119 Suggest delaying HPV vaccination until an older age, even when eligible for vaccination.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q120 Ask questions to explore parents' concerns.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q121 Provide written materials, such as vaccine Information Sheets, to inform parents.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q122 Offer reassurance that HPV vaccine is safe.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q123 Tell parents that you have vaccinated (or would vaccinate) your own child with HPV vaccine.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Most of the time (5)

Q125 How much you agree or disagree with the following statements?

Q126 I am usually able to convince hesitant parents to get HPV vaccine.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- I have no experience with this (5)

Q127 When parents wish to delay or refuse HPV vaccination, there is not much I can say to change their minds.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q128 I am confident that I can overcome parental concerns about HPV vaccine safety.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q129 I am confident that I can address parental HPV vaccine concerns about adolescent sexual activity.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q130 I feel I have enough time during appointments to probe parents about their reasons for wanting to refuse or delay HPV vaccine for their adolescent child.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- I have no experience with this (5)

Q131 I am influential in parents' decision about whether or not to get HPV vaccine for their adolescent child.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- I have no experience with this (5)

Q132 I am confident I can address specific parental concerns and questions about HPV vaccine for boys.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q133 I am more likely to probe about parents' reasons for hesitancy with other adolescent vaccines (e.g., Tdap) than with HPV vaccine.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q134 How much would the following strategies and tools help you when counseling parents who are hesitant to get HPV vaccine for their adolescent children?

Q135 A discussion guide or script for health care professionals.

- Not at all (1)
- A little (2)
- Some (3)
- A lot (4)

Q136 A screener to identify specific parent concerns.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q137 More attractive/accessible version of standard Vaccine Information Sheets.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q138 Information sheets or brochures tailored to specific parent concerns.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q139 Written information for parents that is tailored to their cultural background.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q140 Providing information about HPV vaccine to parents before the clinical visit.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q141 Interactive decision aids that help parents prioritize their health values in relation to HPV vaccination.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q142 Providing information for parents and adolescents separately.

- Not at all (1)
- A little (2)
- Frequently (3)
- A lot (4)

Q149 Adolescent visits for HPV vaccine are a good opportunity to provide health education and anticipatory guidance to adolescent patients and their parents.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q150 HPV vaccination is a good opportunity to talk with adolescent patients or parents about sexual health.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q151 Discussing sex during visits for HPV vaccine may discourage parents from getting their child vaccinated.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q152 HPV vaccination is a good opportunity to encourage parents to talk with their children about sex.

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

End of Block: Block 13

Start of Block: Block 13

Q158 Did you receive dose 1 of the three dose HPV series?

- Yes (1)
- No (2)

Skip To: Q164 If Did you receive dose 1 of the three dose HPV series? = No

Q159 Did you receive dose 2 of the three dose HPV series?

- Yes (1)
- No (2)

Skip To: Q164 If Did you receive dose 2 of the three dose HPV series? = No

Q160 Did you receive dose 3 of the three dose HPV series?

- Yes (1)
- No (2)

Skip To: Q164 If Did you receive dose 3 of the three dose HPV series? = No

Q157 What was the most important factor that determined when you received the HPV shots?

- The doctor's recommendation (1)
  - It became common practice/It has been standard for years/I was comfortable with recommendation (2)
- I knew enough about HPV disease and the vaccine (3)
- I became sexually acitve (4)
- My insurance covered the cost/No cost concerns (5)
- I had enough information about vaccine safety (6)
- It was convenient for me to get vaccinated/I found the time to do so (7)
- Other, please specify: (8)

  _____

- Don't know (9)

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = The doctor's recommendation

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = It became common practice/It has been standard for years/I was comfortable with recommendation

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = I knew enough about HPV disease and the vaccine

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = I became sexually acitve

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = My insurance covered the cost/No cost concerns

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = I had enough information about vaccine safety

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = It was convenient for me to get vaccinated/I found the time to do so

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = Other, please specify:

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots?(Other, please specify:) Is Not Empty

Skip To: End of Survey If What was the most important factor that determined when you received the HPV shots? = Don't know

Q164 Are you planning to receive all 3 doses of the HPV series?

- Yes (1)
- No (2)
- I am unsure (3)

Q165 What is the most important factor that will determine when you will complete the HPV vaccination series?

- The doctor's recommendation (1)
- If it becomes common practice/Been standard for years/Comfortable with recommendation (2)
- When I know enough about HPV disease and the vaccine (3)
- Becoming sexually acitve (4)
- Insurance covering the cost/No cost concerns (5)
- Having enough information about vaccine safety (6)
- If it is convenient for me to get vaccinated/If I find the time to do so (7)
- Other, please specify: (8) _____
- Don't know (9)

Q153 What is the main reason you will not/have not completed the HPV series in the next 12 months?

- My provider did not recommend it (1)
- The vaccine is not available in provider's office (2)
- I did not know about the vaccine/I did not know the vaccine was recommended for me (3)
- I do not believe the vaccine is needed or neccesary (4)
- The school does not require (5)
- I have safety concerns about it (6)
- I am uninsured/My insurance does not fully cover shots/The insurance co-pay or other costs are too high (i.e., administration fees and/or office visit charges) (7)
- The shot could be painful (8)
- I have had difficulty making or getting an appointment/I have had transportation problems (9)
- I intend to complete the HPV series but have not yet/Already planned 10)
- I am not sexually active (11)
- Other, please specify (12) _____
- Don't know (13)

Q155 On a scale of 0 to 10, with “0” being “strongly disagree” and 10 being “strongly agree,” please tell how much you disagree or agree with the following statements. The HPV vaccine is safe.

- 0 (1)
- 1 (2)
- 2 (3)
- 3 (4)
- 4 (5)
- 5 (6)
- 6 (7)
- 7 (8)
- 8 (9)
- 9 (10)
- 10 (11)
- Don't Know (12)

Q154 How likely is it that you will receive HPV shots in the next 12 months?

- Very Unlikely (1)
- Somewhat Unlikely (2)
- Neutral (3)
- Somewhat Likely (4)
- Very Likely (5)

Q156 At what age do you plan to receive the HPV shot?

_____

Q65 We now want to ask you some questions about some other activities you might have done.

Q55 In the past 3 months, have you participated in any other adolescent sexual health trainings or educational programs outside of this one?

- Yes (1)
- No (2)

Q56 Please list the names of all the health programs that you have participated in during the past 3 months.

_____

Q57 What was the focus of these programs?

_____

Q195 I am confident in my ability to counsel families about the following topics:

Q196 a) Their child's weight.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q197 b) Making changes in the home environment related to their child's snacking behavior.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q198 c) Making changes in the home environment related to their child's intake of sugar-sweetened beverages.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q199 d) Making changes in the home environment related to their child's screen-time.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q200 e) Making changes in the home environment related to their child's involvement in physical activity.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q201 f) Making changes in the home environment to limit snacking in front of the television.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q202 After behavioral counseling, parents will be more likely to do the following:

Q203 a) Increase their own fruit and vegetable intake.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q204 b) Limit their own screen-time to 2 hours per day or less (outside of work).

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q205 c) Increase their own physical activity.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q206 d) Decrease their own intake of sugar-sweetened beverages.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q207 e) Refrain from snacking in front of the television.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q208 f) Decrease the availability of sugar-sweetened beverages in the home.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q209 g) Limit snacking in front of the television.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q210 h) Increase fruits and vegetables available in the home.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q211 i) Set household rules limiting screen-time (outside of school work).

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q212 j) Decrease sugar-sweetened beverages available in the home.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q213 k) Make healthier snack options available in the home.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q214 l) Encourage their child to participate in physical activity.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q215 m) Believe that fruits and vegetables are important to health.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q216 n) Believe that decreasing sugar-sweetened beverages is important to health.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q217 o) Believe that the relationship between physical activity and health is important.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q218 p) Believe that limiting screentime is important to health.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q219 q) Believe that snacking behavior is related to health.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q220 To what degree do you agree or disagree with the following statements about counseling parents?

Q221 a) I invite parents to talk about behavior change related to their child's weight.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q222 b) Parents perceive my sensitivity when talking about their child's weight.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q223 c) I ask questions about what they think about their child's weight.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q224 d) I understand challenges that parents face in making changes in their child's weight-related behavior.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q225 e) I provide information that is sensitive to their concerns.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q226 f) I convey respect for their choices about behavior change.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q227 g) I feel comfortable talking to the parents about behavior change.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q228 h) I understand the parent's concerns about the HPV vaccine.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q229 i) I feel comfortable talking to parents about the HPV vaccine.

- Strongly Disagree (1)
- Disagree (2)
- Neutral (3)
- Agree (4)
- Strongly Agree (5)

Q230 To what degree do you agree with the following statements?

Q231 a) I know how to use Motivational Interviewing to help patients make behavioral changes.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q232 b) I can easily incorporate Motivational Interviewing skills into my nursing practice.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q233 c) Motivational Interviewing will have an impact on my practice behavior.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q234 d) I am likely to use motivational interviewing techniques when I counsel patients and their families about weight.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q235 e) Motivational Interviewing takes too much time.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q236 f) Motivational Interviewing is a valuable tool to us in my practice.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

Q237 g) I would like to get more training in motivational interviewing techniques for counseling patients and their families about healthy eating and activity behaviors.

- Strongly Disagree (1)
- Disagree (2)
- Agree (3)
- Strongly Agree (4)

APPENDIX C

UTHSC CPHS APPROVAL

UTHSC CPHS Approval

Protocol Title:	Efficacy Trial of a Brief Parent-Based Adolescent Sexual Health Intervention HSC-SN-15-0091
Principal Investigator:	Diane Santa Maria, DrPH, MSN, RN, APHN-BC
Co-Investigators:	Christine Markham, Sanghamitra Misra, Kelli Drenner, Cristina Barroso
Study Coordinator:	Deidra Carroll
Population:	RCT=1060 (530 parents and 530 youth); 90 nursing students; Focus Groups = 60 parents, 32 youth 11-14 yrs old (16 males, 16 females) in Houston metropolitan area
Number of Sites:	UT Houston is lead on this single site study being conducted in 10 Boys and Girls Clubs in the Houston metropolitan area
Study Duration:	3 years
Subject Duration:	6 months

This Academic Research Enhancement Award (AREA) study proposes a randomized controlled trial (RCT) of an innovative model using student nurses as sexual health educators to provide an effective parent-based adolescent sexual health (P-ASH) intervention (Families Talking Together = FTT) to parents of underserved minority youth. Student nurses are a critical, untapped resource to extend the accessibility of evidence-based adolescent sexual health programs to hard-to-reach populations. Adolescents experience the largest burden of sexually transmitted infections (STIs), HIV, and unplanned pregnancy in the U.S. (1-3). One third of 9th graders report being sexually active (3). Early sexual debut is associated with inconsistent and nonuse of contraceptives and is a risk factor for STIs and pregnancy (4, 5). Each year, adolescents account for 48% of new STI cases (costing $6.5 billion) and experience about 750,000 pregnancies (costing $11 billion) (2, 6-9). Human papillomavirus (HPV) is the most common STI (up to 82%) in adolescents, (10, 11). Despite vaccination guidelines and free vaccination programs, uptake is low among early adolescents (12).

Parents play a pivotal role in adolescent sexual behaviors, including early sexual debut, number of sexual partners, condom and contraceptive use, and HPV vaccination (5, 13-17). Parent-child communication is a well-documented protective factor for adolescent sexual health outcomes and is associated with a delay in sexual debut and an increase in condom and contraceptive use (5, 18, 19). However, studies have found racial and ethnic differences in protective parenting practices. Minority youth reporting low parent-child communication are more likely to engage in risk behaviors than white youth (18). P-ASH interventions bolster parental protective factors and reduce adolescent sexual risk behaviors (20-23) but are often lengthy with multiple barriers to participant recruitment, retention, and dissemination in underserved communities (24).

We will enhance and evaluate FTT, a P-ASH program that has demonstrated success in delaying sexual debut in Latino and African American youth when implemented in the clinic and school setting (23, 25). We will build on the curriculum (herein called FTT+) by adding modules on HPV and evaluate the efficacy of student nurse delivery using a community-based RCT. This novel and cost-effective approach will reach large numbers of underserved parents and youth and introduces student nurses to public health intervention research, development, implementation, and evaluation. FTT+ will be delivered to parents of minority youth 11-14 years old recruited from after-school and community programs such as the Boys and Girls Clubs (BGC) to help parents increase sexual health communication, delay adolescent sexual debut, and increase HPV vaccination. BGC reaches ~10,000 Latino and African American inner-city youth 7-17 years old in Houston, TX, each year.

Specific Aim 1: Build on FTT to include modules on HPV and vaccination

1.1 Form a Community Action Board (CAB) of parents and youth to develop HPV module and facilitate program implementation, evaluation, and dissemination of findings

1.2 Conduct focus groups in target communities with parents and youth to obtain input on new HPV module

1.3 Develop additional FTT modules, e.g., HPV vaccine, from CAB/focus group input feedback
1.4 [Pilot test additional FTT modules] in target communities with parents and youth

Specific Aim 2: Conduct RCT of FTT+ in the community setting to evaluate the impact on parent and adolescent outcomes at 1- and 6-months post-intervention

2.1 Examine effects of FTT+ on parent outcomes (psychosocial factors, communication, monitoring, connectedness)
2.2 Examine effects of FTT+ on adolescent outcomes (psychosocial factors, sexual behaviors, HPV vaccination)
2.3 Examine relation between parent and adolescent outcomes

Specific Aim 3: Determine the impact of study participation on student nurse outcomes (knowledge, attitude, and intention for adolescent sexual health education and research)

This RCT is **significant** in its capacity to reach large numbers of parents of minority youth, a high-risk group for teen pregnancy and STIs, with an evidence-based adolescent sexual health intervention that has demonstrated success in delaying sexual activity and was developed specifically for minorities. This RCT is **innovative** in its use of student nurses, a cost-effective model to disseminating evidence-based interventions in underserved and hard-to-reach communities while enhancing the research capacity of public health nursing students and faculty. [This study builds on past research to determine if a low dose parent-based adolescent sexual health intervention that draws on naturally existing community structures can be successfully implemented using the student nurse facilitator model and tests the nurse as navigator role to improve HPV vaccination uptake using a sustainable cost effective model.] This study will serve as a model for equipping the next generation of nurses, who are the largest group of health care providers, to assume leadership roles in health promotion, disease prevention, and public health program delivery.

I. Significance

Importance of Public Health Nurses

Nurses are on the frontlines of healthcare, in a unique position of being highly trained to care for complex health conditions in individuals and being uniquely qualified to bridge the gap between health promotion science, practice, and adoption in communities. A core function of nursing is teaching and coaching. Nurses are prepared to assume the teaching-coaching role with various patient populations and in various acute care and community settings. Nurses are well equipped to and often called upon to deliver sex education to parents (26). But while RNs are the largest group of public health workers who deliver essential public health services in the community and public health settings (approximately 97,210 RNs), only 1.3% of RNs are currently working in public health (27, 28). The HRSA Public Health Workforce study of districts and local health offices reported a need for training public health nurses in core public health concepts and practical applications (29). Student nurses receive little hands-on health promotion experience in a public health setting outside of typical didactic courses. The shift in health care toward primary health care delivery systems requires that nurses learn to collaborate with various populations and work in community settings (30). Engaging student nurses in public health research is an innovative model for teaching community practice and research and increases both research knowledge and skills (31, 32). [This study will examine the efficacy of a brief student nurse led intervention, inform how student nurses can facilitate dissemination of adolescent sexual health and HPV vaccination uptake in a community setting, and provide a model to prepare nurses to assume leadership roles in public health nursing practice and research. Involvement in mentored research at the undergraduate level has been shown to lead to pursuit of graduate studies and may address critical nurse faculty shortages by increasing the number of faculty nurses (33). Our student nurses will also be prepared as adolescent sexual health educators, an essential task for nurses working with youth and parents in community, clinic, and hospital-based care (34, 35).]

Role of Nurses as Parent-Based Sexual Health Educators in Underserved Communities

A nationally representative sample of 5th-12th graders most frequently identified nurses and doctors as the first person asked about health issues and wanted providers to address STIs (61%) (36). Yet only 26% reported discussing sexual health with their providers. Many youth [said they would be embarrassed to do so. Nurse-initiated conversations about sexual health are essential to provide information in a comfortable way that addresses commons barriers such as adolescent embarrassment. Additionally, this study draws on the nurse as a healthcare navigator and tests the impact of student nurse navigation on HPV vaccination update.]

Importance of Targeting Minority Youth in Harris County, TX

Harris County, which houses Houston, is the largest Texas county and the 3rd most populous in the nation, with over 4 million residents, of whom over 1 million are under age 18 (37). It is one of the nation's most

diverse and disadvantaged counties. Over 50% of its residents are Hispanic (42%) or African American (19%) (vs. 17% and 13% nationally) (38) and 24% of children live in poverty, 49% (vs. 45% nationally) live in low-income families, and over 25% of residents are uninsured (37). Twenty-three percent of all adults and 57% of Hispanics have less than a high school education. About 52% of Harris County students were at risk of high school drop-out in 2011 (39). Harris County is a prototype for what other large urban centers may look like in the future. By testing the efficacy of a student nurse led P-ASH program here, we can develop a model for adolescent sexual health initiatives for other large, diverse urban centers.

Sexual Behaviors, Teenage Pregnancy, Sexually Transmitted Infections, and HPV Vaccination

Adolescents have the largest burden of unplanned pregnancy, STIs, and HIV in the U.S. and are at significant risk of early sexual debut with both immediate and long-term health consequences (1-3).

Sexual Behaviors. Nationally, one third of 9th graders (33%) are sexually active (3, 40). Early age of sexual debut is associated with inconsistent and nonuse of contraceptives and is a risk factor for STIs and teenage pregnancy (4, 5). Despite efforts targeting adolescent sexual health outcomes, racial and ethnic disparities persist. African American and Hispanic high schoolers have higher rates of nearly all sexual behaviors than white youth (3). In a recent study of 1,258 predominantly Hispanic and black youth in Houston, TX, about 15% of 7th graders, 30% of 8th graders, and 41% of 9th graders were sexually experienced (41). This demonstrates the added sexual health risk of minority youth in Houston. Compared with their peers at the state (7%) and national levels (6%), Houston high school students are significantly more likely to initiate sex before 13 (3).

Teenage Pregnancy. Adolescents experience about 750,000 pregnancies each year, with related annual medical costs of $11 billion (2, 8, 9). The birth rate for U.S. teenagers aged 15–19 years fell 6% in 2009, to 39.1 per 1,000, the lowest level reported in the U.S. since the 1960's, 37% below the recent peak in 1991 (1). The decline was reflected across subgroups by age and race/ethnicity (10-19 year olds and all race and Hispanic origin groups). While the trend is positive, the percentage of nonmarital births increased slightly to 41% with teenagers under age 20 accounting for 21% of all nonmarital births in 2009 (1). Most areas in Harris County have teen birth rates higher than the Texas rate (46.9 per 1,000 teen girls), and many areas have teen birth rates >70 per 1,000 teen girls (42). Additionally, Texas has a significant problem with repeat births, the 2nd pregnancy ending in a live birth before age 20. Nationally,18% of the 367,000 births to teens 15-19 years old is a repeat birth (43). Texas has the highest prevalence in the nation with 22% of teen births being a repeat birth. Additionally disparities by race/ethnicity persist; 20.9% of Hispanics and 20.4% of non-Hispanic blacks report experiencing a repeat teen pregnancy compared with 14.8% of non-Hispanic whites (43).

STIs. Adolescents account for 48% of new STI cases, with annual medical costs of $6.5 billion (6, 7). Of all females aged 14-19, 24% have STIs and nearly 38% of sexually experienced girls have an STI (10). Harris County (H) has higher rates per 100,000 than Texas (T) and the U.S. for adolescent cases of syphilis (H=37, T= 25, U.S.=5.3), chlamydia (H=2334, T=2041, U.S.=2083), and gonorrhea (H=650, T=475, U.S.=400) (44-46). HPV is the most common STI in the U.S., infecting 50-82% of sexually active individuals (10, 11, 47). Persistent HPV infection causes genital warts and is a main risk factor for cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers (47-49). HPV prevalence and HPV-related cancer incidence and mortality rates are disproportionately higher among blacks and Hispanics than non-Hispanic whites (12).

HPV Vaccination. In 2005, the Advisory Committee on Immunization Practices recommended HPV vaccination at 11-12 years based on the need to develop immunity prior to HPV exposure. However, uptake and completion rates of the 3-dose HPV vaccine series are significantly lower among females aged 13-years (63%) versus those aged 14-17 years (72%-74%) and are lowest (32%) in males aged 13 years (50). The estimated percentage of adolescents aged 13–17 years receiving 1 or more HPV vaccines is lower in females in Houston (27%) than Texas (32%) and the U.S. (53%) (50). Despite low vaccine uptake, the vaccine-targeted HPV type prevalence decreased among females aged 14-19 years within 4 years of vaccine introduction, demonstrating high vaccine effectiveness (51). A recent survey in Houston found that of 1,571 predominantly Hispanic and African American 8th grade students, only 13% had heard of HPV and 33% had heard of the HPV vaccine (52). Among those who had heard of the vaccine, 3% had received 1 dose of the 3-dose HPV vaccine series and 4% had completed the 3-dose series. Among those who had not completed the series, 6% reported it was somewhat or very likely that they would get the HPV vaccine in the next 12 months (52). Barriers to vaccination include low youth and parental knowledge about HPV and the vaccine (53, 54), parental fears about vaccine safety (55-57) or increased sexual promiscuity (53, 57-59), lack of provider referral (60), and beliefs that their child is not sexually active (61) or is too young for a vaccine against STIs (55). Nationally, healthcare providers have recommended HPV vaccination to 35% of 11-12 year olds compared to 53% of 13-17 year olds (62). However, African American and Hispanic parents are significantly less likely to be aware of the vaccine than white parents (57). Given that African American and Hispanic youth

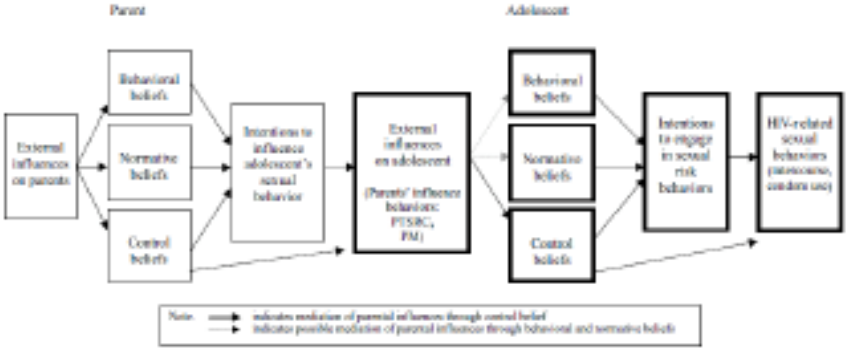
are more likely to initiate sex before age 13 than non-Hispanic whites (3) and the high prevalence of minority youth in Harris County, targeted efforts to increase HPV vaccination among minority preadolescents could greatly diminish disparities in HPV-related cancers.

There is an urgent need for effective adolescent sexual health programs for preadolescent youth. While school–based sex education can reduce adolescent sexual risk behaviors when provided before sexual initiation, the programs may begin after a child has become sexually active (63). While 72% of fifth- and sixth-grade teachers report that sex education was taught in their schools, that may indicate that ~30% of youth are not receiving sex education (64). Parents are a well-supported protective factor for adolescent sexual health outcomes and can provide early sexual health education (65, 66). Adolescent sexual health programs targeting parents increase protective parental practices (communication and monitoring) and improve adolescent sexual health outcomes (delay in sexual debut and increased condom and contraceptive use) (67-71).

Parental Influence on Adolescent Sexual Health Outcomes

Programs targeting parents improve on traditional adolescent sexual health education (14). P-ASH interventions aim to reduce adolescent sexual risk behaviors by bolstering parental protective factors as demonstrated by Hutchinson's parent-based expansion of the theory of planned behavior (PETPB) (Figure 1) (113, 20-22) and the analytic frameworks of Burrus et al. (68). [By using a low-dose parent-based adolescent sexual health intervention and a low-cost and sustainable student nurse facilitator model in a community setting, our proposed study employs PETPB and builds on other interventions that focus on parental attachment, communication, and monitoring to reduce sexual risk-taking.]

Figure 1. Hutchinson's parent-based expansion of the theory of planned behavior (PETPB)



This framework posits that parents are more likely to discuss sexual risk topics with children if they intend to do so (intentions), view parent-child communication positively (behavioral beliefs), believe that important others would approve of sexual health communication (normative beliefs), and believe that they have the skills necessary (control beliefs) to communicate about sexual health topics effectively.

Parent-Based Adolescent Sexual Health Interventions

Previous systematic reviews of P-ASH interventions showed significant parent and adolescent outcomes (67, 69-73). A recent systematic review (k=28) and meta-analysis (k=11) found that the average length of a P-ASH program was 7 contact hours and that there was a 68% probability for an increase in parent-child sexual health communication and a 74% probability for an increase in parental comfort with sexual health communication for participants in a P-ASH intervention compared with control groups (74, 75). All 28 P-ASH programs reported a positive impact on one or more parental practice outcomes (e.g. communication) or adolescent sexual health outcomes (e.g., delayed sexual debut). While dose-heavy, intensive, face-to-face P-ASH interventions have been successful in influencing parent and adolescent behaviors (76-81), brief interventions have also demonstrated success on parent and adolescent outcomes (20, 21, 23, 82, 83). Providing brief but effective P-ASH programs with flexible delivery modality would address the challenges of recruitment and retention in community-based interventions (24, 84). Additionally, many P-ASH programs solely focus on parent-child communication (67) despite evidence that other parenting practices are protective for adolescent sexual health outcomes such as connectedness, parental monitoring, and supervision (5).

Targeted Parental Protective Factors

This study focuses on 3 well-supported protective parenting practices that influence adolescent sexual health behaviors: parent-child connectedness, parent-child communication, and parent monitoring/supervision.

Parent-Child Connectedness. Parent-child connectedness, both maternal and paternal, has been found to be a protective factor for adolescent sexual health outcomes (13, 85, 86[illegible]

emotional attachment and commitment a child feels for their parents, is associated with greater self-efficacy for condom use, less permissive sexual attitudes, less unprotected sex, and fewer sexual partners in urban African American males (87). Conversely, adolescents' perceptions of low parental caring, difficulty talking to their parents about problems, and valuing their friends' opinions for serious decisions were significantly associated with compromised behavioral and emotional health outcomes (88).

Parent-Child Communication. Parent-child communication is a well-documented protective factor for adolescent sexual health outcomes and is associated with a delay in sexual debut and an increase in condom and contraceptive use both during adolescence and into early adulthood (5, 18, 19, 87). Some studies have found that parent-child sexual health communication is associated with decreased sexual intercourse and pre-coital sexual behaviors in adolescents (83, 89, 90). Longitudinal studies have found that >40% of youth engage in sexual activity prior to parent-child sexual health communication and that communication often occurs around the same time that the child initiates genital touching (91). One longitudinal study reported that as parent-child communication decreased there was an increase in moderate pre-coital behaviors (laying together) across race/ethnicity (92). However, racial and ethnic disparities exist. Huebner and Howell (18) found that minority youth reporting low parent-child communication were more likely to engage in sexual risk behaviors than like-aged Caucasian youth. Additionally, parent-child conversations about HPV vaccine may provide opportunities for parental influence on adolescent sexual health behaviors and STI prevention. One study found 65% of mothers reported talking with their daughters about HPV vaccine and 41% of those mothers believed that doing so led to a positive conversation about sex (93). Mothers who talked with their daughters about HPV vaccination were more likely to also talk with their daughters about sex (92% vs. 74%) than those who did not talk about HPV. Many mothers reported that the HPV vaccine provided a good reason to talk about sex (64%) and that it made it easier to start a conversation (33%) (93). Despite evidence of HPV vaccine effectiveness, significant barriers exist particularly in minority populations. Such barriers (knowledge, beliefs, and cues to action) can be addressed in a P-ASH intervention to improve vaccination through student nurse healthcare navigation.

Parent Monitoring/Supervision. Effective parental monitoring decreases risky sexual situations (19, 94). Parental monitoring is commonly described as knowledge of what your child is doing, who they are with, and where they are. By setting clear expectations and providing consistent parental solicitation and controls (rules and restrictions), parents can positively impact adolescent risk behaviors. Several studies have found that across race/ethnicity, young adolescents who report higher levels of parental monitoring, both maternal and paternal, report fewer sexual risk and problem behaviors (95-101). Parental monitoring has been shown to moderate the effect of adolescent attitude on sexual intention; adolescents who report successful parental monitoring have less favorable attitudes toward initiating intercourse (102). Evidence also suggests that parental monitoring is the most important parental asset in delaying sexual debut across race/ethnicity (103). Monitoring appears to work most effectively at protecting youth from risk behaviors when coupled with high parent-child connectedness (104) and communication (105). Concrete parental rules, such as limiting time home alone, are components of parental monitoring that are protective against adolescent sexual behaviors (106, 107).

Interactions between Connectedness, Communication, and Monitoring. Recent studies conducted in school-based samples of 7th graders and youth in psychiatric care suggest that parent-child communication is most effective at delaying sexual debut in early adolescents when coupled with high parental monitoring (108, 109). Parental monitoring may be the most important parental asset in predicting abstinence across race/ethnicity (103). Monitoring, a function of parental knowledge and child disclosure, is enhanced when parent-child communication is open and engaged (110). High monitoring and high communication have positive effects both individually and combined on minority youth (105, 111, 112). Tharp and Noonan (109) suggest that parental communication may be insufficient to reduce risk, but that in combination with parental monitoring, may have greater influence on youth risk-taking behaviors. In turn, parent-child communication may be an influential and critical factor for effective monitoring. Parental monitoring clearly benefits from parental knowledge, primarily gained through child disclosure, which may be affected by the level of open and honest communication between a parent and child. Parent-child communication may also be more effective at decreasing and delaying pre-coital sexual behaviors when coupled with effective parental monitoring. There is a need for effective P-ASH interventions that address connectedness, communication, and monitoring with parents. To date, no P-ASH program has been found that used the comprehensive frameworks set by Hutchinson and Wood (113) or Burrus et al (68) that encompass the breadth of parental practices that influence adolescent sexual behaviors to guide intervention development (75). This study will adapt these

theories (Figure 1) to guide development of additional modules on HPV and to facilitate the implementation of the clinic-to-community translation of FTT+.

Psychosocial and Demographic Factors. Parental knowledge, beliefs (behavior, normative, and control), outcomes expectations, and intentions for parental practices affect whether parents connect, communicate, and monitor their adolescents, which influences adolescent sexual health outcomes. For instance, when adolescents perceive that their parents strongly disapprove of sexual activity, they have lower levels of sexual intercourse and pregnancy (15, 114, 115). Additionally, family structure appears to influence adolescent sexual behaviors though previous studies of the effects of family structure on adolescent sexual behavior are mixed, pointing to the need for further investigation, particularly in minority populations with high prevalence of single-parent households (92, 116, 117). In this study we will collect and analyze information on known confounding factors to parental connectedness, communication, and monitoring; factors that influence parental impact on adolescent behavioral determinants (behavior, normative, and control, beliefs, and intention); and external factors (i.e., parent-child barriers) resulting from parental practices such as monitoring and supervision.

Families Talking Together

FTT (available in English and Spanish) has three main components: a brief face-to-face session, a manual, and booster calls. FTT has been successful in delaying sexual debut in minority youth at 9-months post intervention when implemented in clinics and schools (23, 25). This brief intervention is ideal for student nurse dissemination in an underserved community.

Significance of the Proposed AREA. This study includes student nurses as an integral part of the interprofessional team to facilitate the development, implementation, and evaluation of a parent-based, adolescent sexual health intervention while preparing the next generation of Public Health Nurses. It builds on previous research and contributes to our understanding of how to positively impact adolescent sexual health outcomes in hard-to-reach, underserved communities. Adolescent sexual behaviors, particularly early age of sexual debut, continue to put youth at risk for HIV, STIs, and pregnancy. Parents play a crucial protective role on adolescent sexual health outcomes.

II. Innovation

This study is innovative in 5 important ways: 1) it uses student nurses as emerging healthcare professionals to implement the program, enhancing target audience acceptability of the program and increasing health promotion skills of the public health workforce; [2) it is scalable to a large population of hard-to-reach youth using an evidence-based P-ASH intervention (EBI) in an existing community setting, increasing program reach (recruitment and retention) to increase parental protective practices and improve adolescent sexual health outcomes; 3) it integrates HPV vaccination efforts into an EBI, drawing upon the nurse as healthcare navigators to increase HPV vaccination]; 4) it examines the efficacy of a cost-effective student nurse-as-facilitator model of health promotion intervention delivery that can serve as a model in other large urban settings, and 5) it aligns with the goals of the Prevention and Public Health Fund of the Affordable Care Act (ACA) to address community prevention and public health infrastructure and training. The ACA provides our nation with an opportunity to broaden the scope of health promotion and disease prevention by including the training of the next generation of nurses as public health leaders while examining their role in creating positive change in adolescent sexual health outcomes in underserved communities.

III. Approach

Study Summary

This RCT will be conducted to determine the efficacy of a student nurse-as-educator implementation of a parent-based adolescent sexual health intervention (FTT+) in at-risk, predominantly minority communities. The **first aim** of the study is to build on FTT by adding a module on HPV and HPV vaccination using community-engaged research strategies. FTT+ will be enhanced using a community action board (CAB) and focus groups of youth and parents in the target community. The **second aim** is for student nurses from The University of Texas School of Nursing to provide FTT+ to parents of youth 11-14 years old who attend an after-school or community program in the greater Houston area. Five hundred thirty parent-child dyads will be recruited from community centers and participating after-school programs such as BGC (see letter of support). Participants will complete baseline and follow-up surveys at 1 and 6 months. The **third aim** will examine student nurse outcomes (knowledge, attitude, and intentions for adolescent sexual health education and research) using pre-post testing each semester to determine student level impact of participation in this study.

Intervention Description. In the *face-to-face session,* the parent and student nurse will meet for up to an hour to review the materials with the parent, motivate parents to talk with their children, and address specific components of the program. Student nurses will help parents designate a time to talk with their children and review information about the context of the present-day teen's world (ph[illegible]

emotions, and teen morals) and how a parent can help a teen through positive parenting (parenting styles, child discipline, parental monitoring, communication, relationship building, forming healthy relationships, self-esteem, refusal and negotiation skills, and risk reduction strategies). As part of the expansion of FTT+, the nurse will review information about HPV and the importance of the HPV vaccine, present local resource materials detailing where and when the child can get vaccinated, and help the parent make an appointment for the vaccination. Finally, participants will be shown the parent-child activities highlighted in the manual and be encouraged to work through the activities with their child in the following weeks. Each parent will receive a manual and 3 handouts to supplement the face-to-face session. The *manual* is divided into 9 sections: 1) health consequences of sexual risk behaviors; 2) positive parental influences on adolescent sexual behaviors; 3) barriers to sexual health communication and counterpoints to barriers; 4) how to say 'no' to sex and social reasons teens have sex; 5) common teen beliefs about sex; 6) specific monitoring and supervision strategies; 7) recommendations for parent-child relationship building; 8) conversation starters; and 9) communication tips. Two follow-up telephone-based *booster sessions*, at 1 and 3-months post-intervention, will be conducted by the student nurse. During the booster session call, the nurse will talk with the parent and ask about their progress communicating and monitoring their youth, use of the FTT+ manual, and discuss barriers they are facing to progressing through the manual. The student nurse will also inquire about the HPV vaccination status of the adolescent. The nursing students will discuss the importance of adolescent vaccinations including HPV with parents during the face-to-face session. The nursing student will counsel parents that the Texas Children's Hospital (TCH) Mobile Clinic will be coming to the Boys and Girls Club to provide adolescent vaccinations for those eligible to receive vaccinations through the Vaccine for Children (VFC) program. Adolescents who are eligible include those who are uninsured, on Medicaid, have private insurance that does not cover some or all vaccinations, or who are American Indian or Alaskan Native. Interested parents will be navigated by the student nurse through the vaccination consent forms. If the parent chooses to consent their child for the vaccination program, they will provide a copy of the child's vaccination record and/or permission for the nursing student to review the electronic vaccination records on IMMTRAC. The vaccination parental consent is active for one month. Therefore the TCH VFC mobile van will be scheduled to visit the BGC club within one month of the nursing student-parent face-to-face session. The student nurse will provide a reminder text message to parents participating in the TCH VFC program when the participating child is due for the next vaccination in the HPV series. As well, nursing students will discuss the vaccination that are due when the parent follow-up is completed at 1 and 6 months. If the child is due for the next shot in the HPV series, the nursing student will navigate the parent through the vaccination consent process at the 1 and 6 month follow-up. On the day of the TCH VFC mobile van visit to the BGC, the nursing student club coordinator will provide the signed vaccination parental consent form to the TCH Nurse Practitioner who will confirm consent, vaccinations due, and provide the needed vaccinations that parents have consented for their child to receive. Once the vaccines are received, the child will receive an updated vaccination record from the TCH Nurse Practitioner. As the child exits the mobile van, and if consented to do so by their parent, the child will show the up-to-date vaccine record with the nursing student who will record the vaccinations received on that day. This data sheet will be destroyed by shredding once the data is entered into the de-identified data set. This will be done within 48 hours of the vaccination event. For parents ineligible for the TCH VFC program or who are not interested in signing up their child for the mobile van vaccination program the student nurse will offer to make appointments to receive the 3-shot series when needed. When possible, participants and student nurses will be matched by gender to facilitate relationship and trust building. Additionally, bilingual students will be assigned to participants who prefer to receive the intervention and materials in Spanish. A bilingual research assistant will be hired to provide the intervention during semesters when no students are bilingual in English and Spanish. [The *control group* will receive standard services provided by after-school or community programs including invitations to parent involvement activities (e.g., movie night) and will receive an equal length face-to-face session led by nursing students. The 1-hr student nurse-led brief motivational interviewing (BMI) intervention is aimed at parents to modify the home environment to reduce risk and consequences of childhood overweight and obesity which can lead to early symptoms of type 2 diabetes in their children aged 11-14. BMI is a brief intervention based on motivational interviewing (MI), a promising evidence-based method of communication that engages the patient as a partner in the change process (Miller & Rollnick, 2012). Parents in the BMI condition will have one face-to-face session with the student nurse and two booster sessions via telephone. In each session, the parent will choose a behavior from a menu of topics related to lifestyle, including 1) decreasing "screen time" or hours engaged in electronic media-related sedentary behaviors; 2) decreasing frequency of fast food meals that are energy dense; 3) decreasing availability of sugar-sweetened beverages; and 4) increasing availability of fruit and vegetables. Once the nursing student and parent agree on a

behavioral focus, evoking the parent's own desire, ability, reason, and need for change (change talk) is the central task that culminates in a plan or goal to aim toward. The booster sessions will begin by following up on the goal set by the parent in the face-to-face session and then either assist in refining and problem-solving ways to meet their initial goal or focus on one of the other behaviors from the menu of options. Parents will also be offered educational information on all four of the lifestyle topics including recommendations and normative data, a variety of strategies for achieving behavior goals, self-monitoring tools, and encouragement for affirming and reinforcing behavior change in the home.

Research Team Expertise. The project team, led by Diane Santa Maria DrPH, MSN, RN (PI) and Christine Markham PhD (Co-I), will be responsible for the modification, implementation, and evaluation of FTT+. The PI will be responsible for the training and supervision of participating student nurses [in FTT+ and research methods]. **Dr. Santa Maria** is a board-certified Advanced Practice Public Health Nurse with 15 years of public health nursing experience and is committed to advancing the leadership role of nursing in parent-based sexual health initiatives. She has successfully developed, implemented, and evaluated nationally funded P-ASH programs in both community and school settings and has conducted extensive facilitator trainings nationally. Dr. Santa Maria has taught public health nursing for more than 5 years and facilitates the students' [public health nursing experience in a variety of community settings, including BGC. She has successfully involved baccalaureate and honors research students in her research on 3 funded projects.] **Dr. Markham** has more than 20 years' experience in health promotion and behavioral sciences research on adolescent sexual and reproductive health. She has served as PI, Co-PI, and Co-I on multiple CDC, NIH, and other federally funded teen pregnancy, HIV, and STI prevention studies. She is a faculty mentor on 3 pre- and post-doctoral training grants, including 1 funded by NCI. Two nationally recognized leaders in the field will serve as consultants providing additional expertise in community-based work, FTT+ implementation, and student led research initiatives. **Marianne Marcus** PhD has led an academic-community partnership to develop a federally-funded capacity expansion initiative for HIV/AIDS and substance abuse prevention services in an African American community. Using community-based participatory research, her team designed, implemented, and evaluated Project BRIDGE, a successful 3-year intervention for adolescents in a faith-based setting (118-120) and Project SMART, a culturally, and developmentally appropriate health promotion intervention for underserved African American youth (121, 122). **Vincent Guilamo-Ramos** PhD, a developer of FTT, has a strong history of mentoring junior investigators and doctoral and post-doc students. As a mentor to recipients of a doctoral fellowship funded by the Substance Abuse and Mental Health Services Administration, he prepares students in leadership, teaching, policy development, and research. Dr. Guilamo-Ramos is well equipped to foster the growth of new and early career investigators. The investigative team clearly has the required expertise to conduct all phases of this study. Kelli Drenner and Cristina Barroso will be Co-Investigators and will develop and facilitate evaluation of the 1-hr student nurse-led brief motivational interviewing (BMI) intervention. Dr. Sanghamitra Misra, the Texas Children's Hospital Mobile Clinic Medical Coordinator, will be a Co-Investigator and facilitate the vaccination program and co-author vaccine related outcomes publications.

Preliminary Studies

Work with the target population. This study builds on an existing relationship between the PI, student nurses, and the BGC that provides outreach services to the parents of youth who attend the after-school programs. [The PI is currently conducting a pilot of this study with positive results, demonstrating the strength of existing community relationships]. The PI has worked with student nurses in 5 of the 10 area BGCs during the public health nursing clinical course, providing health promotion and positive youth development programs to youth 6-17 years old. The PI has also successfully conducted qualitative research at BGCs on mother-son sexual health communication strategies in single, African American, female-headed households through semi-structured interviews (123). That study suggested that mothers of early adolescent boys are very interested in learning about adolescent sexual health and about parenting practices such as sexual health communication and monitoring. In addition, youth in that study expressed a desire to improve sexual health communication with their parents, to learn about sex and development from their parents, and to be able to approach their parents with questions related to sex and development. BGC leadership, club directors, and staff were instrumental in successful [recruitment for these studies]. *Preferred intervention modality.* Additional data on preferred intervention modalities of parents of early adolescents were collected by student nurses using a brief survey with 48 parents of youth at the BGC during June-July, 2013. The majority (62%) of parents said they would be interested in a brief session to learn ways to talk to their children about sex and relationships. Parents most frequently indicated that the BGC location would be a convenient place to hold the brief intervention session and that between 12 and 8pm would be a convenient time of day. Parents indicated that

they would like to receive a small incentive (e.g., gift card, grocery store, or gas card) and would like refreshments and childcare to be provided for younger siblings. Parents of 11-14 year olds also indicated interest in learning about HPV vaccination. *Acceptability of nurse educators.* Our preliminary data indicate acceptability of nurses as educators; of 45 parents surveyed, all reported that nurses are a trustworthy source of health information, and 75% agreed or strongly agreed that nurses can be effective adolescent sexual health educators for families and that they found it easy to talk with nurses about health issues.

Student Nurse Involvement

Undergraduate and graduate student nurses (N=90) will actively conduct preliminary research to enhance FTT based on community input, recruit and consent participants, facilitate interventions, collect and manage data, track participants, conduct booster session calls, collect follow-up surveys, and analyze and present findings. Research has shown that community participants favor health education delivered by students for interventions such as weight management (124). Student nurses will be recruited from our undergraduate honor's research program and public health nursing clinical course and by request based on their interest in adolescent health, community-based research, maternal-child health, health promotion, and public health nursing. The student nurses will participate for approximately 45 hours per semester for up to 3 semesters. The student nurses will receive extensive training on the implementation of the FTT+ program and the student nurse-led brief motivational interviewing (BMI) intervention with fidelity [and research methods and skills training from the PI]. They will receive Protection of Human Subjects certification and additional education on research and ethics and will be extensively trained to assume the role of parent-based adolescent sexual health educator as part of their public health nursing clinical education. Students will be assigned in pairs to 5-10 study participants (control and intervention) and will follow those participants through recruitment, implementation, and evaluation. A fidelity and quality control system will track program implementation and data collection. [The fidelity protocol includes extensive role playing, observed implementation with guided feedback, and a student-initiated fidelity checklist completed after each intervention implementation. Students will be mentored to develop and present abstracts of the data generated from this study to enhance hands-on research analysis, reporting, dissemination skills.]

Specific Aim 1: Modify FTT to include modules on HPV vaccination

Community Engaged Approach

Community engaged strategies will be used to modify the effective FTT intervention to be facilitated by student nurses and to include modules on HPV. Parents, adolescents, and representatives from youth serving organizations will be invited to participate in a CAB to review the proposed FTT project and provide information to adapt the program delivery modality and to develop the additional HPV module. Suggestions from the CAB will be used to adapt FTT+ for nurse-based implementation. To establish an active CAB, parent, adolescent, and youth serving leaders in the community will be approached to determine their level of interest, availability, and preferred modality of the CAB activities. The CAB will meet monthly for 6 months prior to the implementation of the FTT+ sessions to incorporate community-level suggestions into the design of recruitment, FTT implementation modality, and follow-up protocols. CAB meetings will take place in the community at a mutually convenient time, last approximately 1.5 hours, and have meeting objectives that promote partnership, power sharing, participation, and idea sharing (125, 126). Meeting minutes will be recorded and shared with the CAB members at follow-up meetings. The PI, study staff, and student nurses with participate in the CAB meetings. Additionally, [10] focus groups (6 parent, 2 male youth, and 2 female youth groups) will be conducted in groups of 5-8 participants to explore target audience beliefs and attitudes towards the FTT program materials. Focus group participants will be asked about their beliefs and intentions related to HPV vaccine, perceived barriers, and if other materials are needed to supplement the existing FTT program. Focus groups will last < 2 hrs, include refreshments, will take place in a community location convenient to the participants, and will be available separately in English and Spanish as necessary. Participants will receive a $20 gift card for their time. **Data analysis.** Analysis for Specific ***Aims 1.1-1.3*** will be conducted by the PI and student nurses by first coding all transcripts while bracketing personal biases that may impact analysis of the data (127). Consensus building processes will be used to merge differing interpretations of text and subsequent code differences between coders. ATLAS.ti software will be used for coding and analysis. Thematic content analysis will be used to deduce themes and subthemes from the data that describe the experience of participating in a student-nurse led FTT+ intervention as well as their thoughts and experience with the new HPV module. Codes will be categorized according to identified themes. Quotes, expressions, and patterns that describe the data will be arranged together by the theme they most reflect. The PETPB theory (113) and Burrus' analytic framework (68) will be used to structure the data (Figure 1). A data matrix will be created to provide information about the relationship between the themes and codes. Qualitative

comparative analysis will be used to develop a conceptual model depicting the relation between the themes that emerged. Focus group findings will be reported to the CAB and will be used to modify FTT+. For ***Aim 1,*** we will pilot test the newly developed HPV module with a group of 20 parents who will receive the face-to-face intervention from student nurses, and take a pre- and immediate post-test to measure basic psychosocial outcomes. We will also collect usability data post-intervention from parents (what they liked, didn't like, recommendations for revision) and debrief with student nurses (what went well, didn't go well, recommendations for revision). Pre/post data will be analyzed using descriptive statistics and the Wilcoxon signed-rank test. Activities will be revised, if needed, for the RCT.

Modifying an Effective Intervention [for Community-based Implementation]

In this study, we will build upon FTT by working with the developer (Dr. Guilamo-Ramos) to preserve the active ingredients of the intervention while modifying it for a new audience and setting. We will use intervention mapping (IM) (128) and the RE-AIM framework (129, 130) to determine how to modify FTT to include modules on HPV vaccination and modify implementation from social workers to nurses. [The PI will work with student nurses to use IM to develop the extension of FTT+ to include an HPV module, guided by theory, empirical data, and target population assessment. Dr. Santa Maria is trained in the application of RE-AIM and IM and will guide the assessment of reach, efficacy, adoption, and implementation of the intervention effects.] We will use 2 theories as a framework (Figure 1) for understanding how parents influence adolescent sexual health outcomes: the parent-based expansion of the theory of planned behavior (PETPB) (131) and Burrus' et al. (68) analytic framework. Research findings with minority early adolescents suggest that PETPB, which takes into consideration the influence of parent-child communication and parental monitoring on adolescent sexual risk behavior, may be applicable to minority early adolescent populations (113). Social Cognitive Theory and data from the focus groups will be used in the development of the expanded HPV program materials to target parents' and youths' behavioral capability, self-efficacy, and outcome expectations related to completing the 3-dose HPV vaccine series using modeling, skills training, and goal setting to influence behavior change (132).

***Expected Outcome* H1**. Parents will be more likely to participate in an intervention when they participate in its design and implementation is convenient, tailored to them, and it does not require multiple sessions

Specific Aim 2: Conduct RCT of FTT+ in the community setting to evaluate the impact on parent and adolescent outcomes at 1 and 6-months post-intervention

2.1 Examine effects of FTT+ and the BMI intervention on parent outcomes ([PETPB-based] psychosocial factors, communication, monitoring, connectedness)

2.2 Examine effects of FTT+ and the BMI intervention on adolescent outcomes (psychosocial factors, sexual behaviors, HPV vaccination)

2.3 Examine relation between parent and adolescent outcomes

Research Design

We will conduct a community-based RCT of the adapted FTT+ intervention to determine the impact of a student nurse-as-educator implementation of FTT+ on minority parent and adolescent outcomes. This RCT will recruit 530 parent-child dyads (N=1060 participants) from community-based organizations such as BGC in Greater Houston, TX. Undergraduate and graduate student nurses from The University of Texas School of Nursing will provide FTT+ program [or nutrition counseling (control condition)] to parents of youth 11-14 years old who attend an after-school program in predominantly minority communities in the greater Houston area. Parent-adolescent dyads will be recruited from community centers and participating after-school programs such as the BGC (Appendix A, letter of support), consented and parental permission obtained, assented, and randomized [at the dyad level] using a computerized random number generator to intervention (265 dyads) and standard care control (265 dyads) groups and complete the baseline survey. Parental consent for the child to join the study will take place face-to-face at the Boys and Girls Clubs at the same time the parents are consented to participate. Once parents have consented to participate and consented to have their child participate, they will be randomized to the intervention or control arm. The PI and student nurses will implement the intervention during routine public health nursing clinical course at the participant's home, the after-school program building, or local library as preferred by the participant. Intervention parents will attend a 1-hour intervention session and receive program materials to use with youth at home and 2 booster phone calls at 1 and 3 months post intervention. [Control parents will receive standard services provided by after-school or community programs including invitations to parent involvement activities (e.g., movie night), an equal length face-to-face session and 2 booster calls with student nurses and the student nurse-led brief motivational interviewing (BMI) intervention.

We will examine the effects of FTT+ on parent (parent-child communication, parental monitoring) and adolescent (vaginal, oral, anal sex, age of sexual debut, HPV vaccination) outcomes at 1- and 6-months post-

intervention. *Inclusion criteria:* Parents (1) residing with a child 11-14 years old who attends a participating community center, after-school program, or BGC; (2) are available for a face-to-face or small group session with the PI or student nurse within 2 months of consenting and assenting to participate in the study; and (3) who can read, write, and speak English or Spanish are eligible for the study. *Exclusion criteria:* Parents without primary custody, incarcerated, or unable to attend a face-to-face session within 2 months will be excluded.

Study setting. BGC of Greater Houston, a private, nonprofit organization, has been a leading youth development organization for 6 decades, providing creative youth engaging activities, educating and empowering low-income youth, and helping sustain academic and economic success. Long renowned as "The Positive Place for Kids," the BGCs serve nearly 10,000 children and teens ages 6-17 each year, many of whom have few positive relationships or dependable resources. BGC provides a safe haven for youth living in chaotic, dangerous neighborhoods and at-risk families and provides character-building programming, enhances academic performance, improves physical health and fitness, expands life skills, develops leadership potential, promotes civic engagement, and equips youth for rigorous postsecondary educations and productive careers.

Recruitment. Participants will be recruited primarily from after-school programs (e.g., BGC) and community centers in the greater Houston area through fliers, club rosters, and contact with student nurses in clinics. BGC staff will help identify parents who are eligible and disseminate flyer to inform parents about the study. To accrue our sample and avoid recruitment bias, student nurses will actively recruit parents at BGCs during drop-off and pick-up times and by using a club participant roster. Student nurses ask potential parent participants a few demographic questions (e.g,. age of child, self-reported race/ethnicity, and gender) and questions about challenges of parenting adolescents before inquiring about interest in taking part in the study. This will allow us to analyze recruitment bias by comparing demographics of participants and non-participants. Rosters from participating BGCs and community settings will also be used to recruit parents by phone. Parents interested in the study will also be able to provide contact information in a drop-box by the entrance of each participating location. Those parents will be contacted by phone. Within 1 week, those eligible will be scheduled for the intervention. The nurses will try to contact potential participants up to 3 times. Contacting parents about program opportunities by phone and during pick-up and drop-off times is common at after-school programs like BGC. [Our pilot findings suggest that this approach is effective for recruitment and bias analysis.]

Intervention delivery. Student nurses will implement the FTT+ session with the intervention group and and the student nurse-led brief motivational interviewing (BMI) intervention with the control group in pairs at the participating locations or the participant's home as part of their routine public health nursing clinical course activities. Parents will be given the program materials and instructed to go through the activities in the manual with their child over the next several weeks. At 1 and 3 months after the face-to-face session, the student nurse will make booster calls to both the intervention and control groups to ask about the progression through the manual activities and answer any questions or concerns.

Data collection. Pre-surveys will be completed in person immediately prior to the intervention. Both control and intervention group participants will complete the post surveys at BGC, during a home visit with the PI or student nurse, or over the phone at 1-month and 6-months post-intervention (see above for randomization).

Expected Outcomes

H2. Parents receiving FTT+ will report improved psychosocial factors (beliefs and intentions) and increased parent-child communication, parental monitoring, and parent-child connectedness compared to controls.
H3. Adolescents of parents receiving FTT+ will report improved psychosocial factors (beliefs and intentions for sexual behaviors), less sexual activity (delayed sexual initiation, reduced frequency of vaginal, oral, anal sex,) and increased HPV vaccination rates compared to controls.
H4. Adolescents of parents with high levels of parent-child communication and parental monitoring will report fewer sexual risk behaviors than adolescents of parents with low communication and monitoring levels.

Measures

Measures with good reliability (i.e., Cronbach's alpha > 0.70) will be incorporated from several established surveys including FTT; Talking Parents, Healthy Teens; Keepin' It R.E.A.L.; and It's Your Game survey questionnaires (76, 80, 133-135). HPV measures (i.e., knowledge, beliefs, acceptability) have been derived from a systematic review of HPV measures (136). All survey measures have been validated with minority youth. The survey will assess demographic characteristics (gender, race/ethnicity, age, income, marital status), psychosocial factors (beliefs, knowledge, intentions), adolescent sexual behaviors (vaginal, oral, anal sex, age of debut, condom and contraception use, HPV 3-dose vaccination series), and parenting behaviors (connectedness, communication, monitoring, supervision). Body mass indexes will be collected on all participating parents and adolescents. [Communication measures such as content, frequency, and comfort will

allow the team to identify the important constructs surrounding communication.] Demographic and baseline surveys will be administered after consent. Follow-up surveys will be administered 1- and 6-months post-intervention. An audio computer assisted self-interview (ACASI) method using a computer tablet with headphones will be used to protect confidentiality, increase comfort in answering sensitive questions, allow participants to choose to take the surveys in English or in Spanish, and to read or listen to the questions. Our team has extensive experience using ACASI-administered surveys for large longitudinal RCTs.

Youth Measures. [Primary outcomes] Behavioral outcomes (i.e., sexual activity, HPV vaccine uptake) will be assessed using previously tested measures (Table 1) (133, 137). [Secondary outcomes.] Psychosocial measures known to influence adolescent sexual behaviors (i.e., intention to have sex, knowledge of HPV vaccine) and adolescent-reported parental behaviors that influence adolescent sexual health outcomes (i.e., communication, connectedness, and monitoring) will be assessed using scales from FTT (23, 133). Exploratory outcomes related to the brief BMI intervention will also be analyzed including body mass indexes.

Parent Measures. Sociodemographic data will be collected using [previously validated items] and will include gender, parent age, grade/age of child, race/ethnicity, income, and family structure. [Primary outcomes.] Behavioral outcomes for parents (i.e., communication comfort, intent to vaccinate) will be assessed using scales [with high validity] (Table 2) (23, 76, 133, 136-139). [Secondary outcomes. PETPB-based] psychosocial measures for parents that influence parental practices (i.e., parental beliefs), sexual health communication and parental monitoring and HPV measures (i.e., vaccine knowledge, beliefs, acceptability, and intention to vaccinate their child) will also be measured (140-142). Exploratory outcomes related to the brief BMI intervention will also be analyzed.

Table 1. Youth measures [Primary measures are shaded]

Construct	Example Item	# Items	Response Format	Alpha
[Beliefs]***	"I believe it is okay for people my age to have sex with a steady boyfriend or girlfriend."	4	4-pt (strongly disagree to strongly agree)	0.78
Communication content*	"In the past 3 months, my mother has talked with me about her values as the when sex should or shouldn't take place."	8	4-pt scale (not at all to a great deal)	0.97
Communication frequency*	"Thinking of the past 3 months, how often did your parent talk with you about not having sexual intercourse at this time in your life?"	1	5-pt scale (once to about 2 or more times per week)	NA
Communication comfort**	"I feel comfortable talking about sex with my mother."	6	5-pt scale (strongly disagree to strongly agree)	0.71
Parent-child connectedness*	"At this moment in time, how satisfied do you feel with the degree of closeness between you and your parent(s)?"	8	5-pt scale (not at all satisfied to very satisfied)	NA
Parental monitoring*	"My mother knows where I am after school."	7	5-pt scale (almost never to almost all of the time)	0.80
Intentions***	"How likely is it that you will have sex (vaginal and oral) in the next year?"	3	5-pt scale (very unlikely to very likely)	NA
Sexual activity***	"Have you ever had sexual intercourse (vaginal and oral)?"	4	Yes, No	NA
HPV knowledge of risk factors	"If a women uses condoms, she is completely protected against HPV"	10	True-false	0.93
HPV vaccine beliefs	"The HPV vaccine will keep me from getting genital warts."	NA	NA	0.89
HPV vaccine acceptability	"How likely are you to obtain a free HPV vaccine that prevents HPV, cervical cancer, or genital warts?"	6	5-pt scale (very unlikely to very likely)	0.89
HPV vaccine received	"Did you receive the first vaccine for HPV?"	3	Yes, No (number of vaccine received in series)	NA
Reasons for HPV vaccine refusal	"I did not receive the HPV vaccine because my parents have not taken me to the clinic"	5	Check all that apply	NA

Table 2. Parent measures [Primary measures are shaded]

Construct	Example Item	# Items	Response Format	Alpha
[Beliefs]*	"I believe it is ok for adolescents to have sex with a serious boyfriend or girlfriend."	10	5-pt scale (strongly disagree to strongly agree)	NA
Communication Barriers*	"I'm too embarrassed to talk to my teen about sex."	4	5-pt scale (strongly disagree to strongly agree)	NA
Outcome	"Talking with my teen about sex won't make a	7	5-pt scale (strongly disagree	NA

expectations*	difference."		to strongly agree)	
Intentions	"I intend to talk with my child about sexual health topics in the next 2 weeks."	1	5-pt scale (strongly disagree to strongly agree)	NA
Communication content*	"In the past 3 months, have you ever talked to your teen about ways to resist peer pressure for having sex?"	7	5-pt scale (not at all to a great deal)	0.97
Communication frequency*	"Thinking of the past 3 months, how often did you talk with your teen about not having sexual intercourse at this time in his/her life?"	7	5-pt scale (once to about 2 or more times per week)	NA
Communication comfort**	"I feel comfortable talking about sex with my child."	6	5-pt scale (strongly disagree to strongly agree)	0.71
Parent-child connectedness*	"At this moment in time, how satisfied do you feel with the degree of closeness between you and your teen?"	8	5-pt scale (not at all satisfied to very satisfied)	NA
Parental monitoring*	"When my teen goes out at night, I know where s/he is."	7	5-pt scale (almost never to almost all of the time)	0.80
HPV knowledge of risk factors	If a women uses condoms, she is completely protected against HPV	10	True-False	0.93
HPV vaccine beliefs	"The HPV vaccine will keep my child from getting cervical cancer."	NA	NA	0.89
HPV vaccine acceptability	"How likely are you to obtain a free HPV vaccine for your child that prevents HPV, cervical cancer, or genital warts?"	6	5-pt scale (very unlikely to very likely)	0.89
HPV vaccine received	"Did your child receive the first vaccine for HPV?"	3	Yes, No (number of vaccine received in series)	NA
[HPV vaccine refusal reasons]	"My child did not receive the HPV vaccine because I do not believe in it."	5	Check all that apply	NA

*Measures from *FTT* (23); ** measures from *Keepin' It R.E.A.L.*(76); *** measures from *It's Your Game* (139)

Analysis Plan

Data Analysis. Descriptive statistics will be calculated for all measures at each time point. We expect missing data to be minimal. Obvious errors will be corrected; those that cannot will be set to missing and replaced using single imputation with case mean substitution, i.e., replacing a participant's missing items with that participant's mean item score (143). Reliability estimates of the study instruments will be computed with Cronbach's alpha (≥ .70 will be considered acceptable for internal consistency (144)).

Analysis for ***Aim 2.1-2.3*** will be based on the intention-to-treat principle (138). The chi-square test will be used to compare the groups for the dichotomous response questions on sexual behaviors and HPV vaccination at 1- and 6-month follow-ups. Repeated measures analysis with linear mixed models will be used to compare the intervention and control groups over time (pre, 1 and 6 months) with respect to instrument scores for parent-child connectedness, communication, and monitoring and [PETPB-based] psychosocial variables (145). The use of linear mixed models for repeated measures provides important advantages over the standard repeated measures analysis of variance (ANOVA). In mixed model analysis, missing data for a subject does not require the deletion of all data from that subject, which significantly improves power over traditional repeated measures ANOVA. Also, linear mixed models are better able to account for correlations between repeated measures by allowing for selection of the most appropriate covariance structure. For the linear mixed models, effects tested will include time, group, and the interaction of time and group.

Data from ***Aim 2.3*** will be analyzed by logistic regression to determine the effect of communication and monitoring on sexual behavior at 6 months. [Adolescent] responses to the sexual intercourse question at 6-months will be the outcome variable and [parent] communication and monitoring scores at 6 months the independent variables. Communication score X monitoring score will be included to test for interaction.

Sample Size [and Power.] The primary research question is the effectiveness of FTT+ in decreasing the proportion of students initiating sexual activity. The sample size (530 adolescent-parent dyads) was calculated to ensure adequate power to test for differences between the intervention and control groups in sexual activity at 6 months. We estimate a participation rate of [85-]90% or higher based on anticipated community support and the use of incentives. [Our pilot study has a 100% retention rate at 1-month post intervention.] Assuming an attrition rate of 10-15%, the final sample size will be at least 450. This attrition rate is approximately double the rate reported for FTT in a clinic setting (23) and accounts for added retention issues experienced in community-based studies (24). [Each enrolled dyad] will be randomly assigned to the intervention or control group using a blocked randomization scheme with a 1:1 allocation to ensure equal numbers in each group. For

450 dyads (225 in each group), a chi-square test for Specific Aim 2.1 will have 80% power to detect as significant an effect size as h = .27, which is a small effect as classified by Cohen (146). This effect size is based on previous research demonstrating that 12% of 7th graders and 22% of 9th graders have had sexual intercourse (23, 135). Therefore we expect the baseline rate of sexual intercourse to be approximately 12%, for that to increase toward 22% at 6 month follow-up, and for the control group to increase more than the intervention group. For ***Aims 2.1 and 2.2***, 225 per group in a repeated measures analysis model will have 80% power to detect as significant an effect size of f=.06 for the interaction of time and group, also a small effect size. For ***Aim 2.3***, a logistic regression analysis with a sample of 450 will have 80% power to detect an odds ratio of 0.71 or a 29% reduction in the odds of sexual intercourse at 6 months for every 1-point increase in parental communication or parental monitoring score. **Participant Tracking Methods**. We aim to maintain a retention level of [85-]90% at 6-month follow-up by collecting complete participant information at baseline, using [an aggressive follow-up] tracking system, periodic check-ins with participants, and participation-based incentives. During the consent interview, we will obtain key tracking contact information including home, cellular, and work phone numbers, postal and email addresses, [strategies successful in studies of high-risk runaway youth (147, 148)]. We also will collect contact information for 3 people who will always know how to reach the participant. Contact information will be updated at each post-survey and booster call. Also, incentives will be used to encourage participation. Each participant will each receive a $20 gift card after completing the face-to-face session and the 1- and 6-month post surveys ($60 total). [In the pilot, these methods resulted in 100% retention at 1-mo post intervention. Additionally, on average BGC youth attend the club 3 times a week for > 1 year increasing the feasibility of participant follow-up.]

Specific Aim 3: Determine the impact of study participation on student nurse outcomes (knowledge, attitude, and intention for adolescent sexual health education and research)

Students will complete pre- and post-semester surveys to measure their comfort as sexual health educators and public health nurses using the Sex Education Confidence Scale (SECS), which assesses knowledge, attitudes, and intention for sexual health education (α=.92-.97) (149). A qualitative debriefing (focus groups and exit interviews) will be conducted with a sample of student nurses to get their feedback on the research experience. [Data for ***Aim 3*** will be analyzed by t-test to identify changes in SECS measures.]

Expected Outcome H4. Student nurses will have improved post-test scores for knowledge, attitude, and intention for adolescent sexual health education and research

Figure 2. [Study Timeline]

Project Aims		Year 1						Year 2						Year 3					
Aim 1	Conduct Community Action Board meetings	■	■	■															
	Conduct exploratory focus groups		■	■															
	Design HPV vaccine module and implementation/evaluation protocol		■	■	■														
	Train student nurses		■	■	■	■	■	■	■	■	■	■	■	■	■				
Aim 2	Recruit participants		■	■	■	■	■	■	■	■									
	Conduct RCT student nurse led FTT			■	■	■	■	■	■	■	■								
	Parent and adolescent follow-up				■	■	■	■	■	■	■	■	■	■	■				
Aim 3	Analyze results					■	■	■	■	■	■	■	■	■	■				
	Report findings and apply for further funding						■				■	■	■	■	■	■	■	■	■

Potential Problems and Alternative Strategies. This study may have typical recruitment and follow-up challenges characteristic of community-based interventions in underserved communities. To reduce recruitment issues, we will recruit from after-school programs such as the BGC in the greater Houston area and, if that is not sufficient, from other community-based youth organizations working with adolescents. To address difficulties in follow-up data collection, each student nurse will work with the same intervention and control parents from recruitment to implementation and follow-up. This will facilitate a working relationship between the staff and participants that may improve retention and data collection. [To address the risk for contamination, we will ask participants to not share intervention materials with other parents or children. We will also measure exposure to the materials, measure the degree of contamination, and make statistical adjustments for it when modeling the effects of the intervention.]

Strengths and Limitations. There are several study limitations. Participants will experience some burden related to the surveys and follow-up. CAB and focus group feedback will be used to ensure that survey instruments are user-friendly and that tracking methods are non-intrusive. [During the pilot, participants were able to complete the survey in 25 minutes or less.] If FTT+ is effective, student nurses will offer FTT+ [with control participants after the conclusion of the study. Youth in BGC programs come from a larger area than a typical school zone, reducing the risk for contamination, but we will furth e the risk as described in the

previous section.] We feel the strengths of this study (e.g., innovative use of student nurses to implement evidence-based P-ASH programs, RCT design, training of Public Health Nurses in research) significantly outweigh any potential limitations. [Additionally, the success of our pilot supports the acceptability and feasibility of this study and suggests that this cost-effectives model of public health nursing education using evidence-based interventions may be applicable to other health promotion initiatives.]

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UTHSC CPHS Approval

UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES
HSC-SN-15-0091 - Efficacy Trial of a Brief Parent-Based Adolescent Sexual Health Intervention
PI: Dr. Diane Santa Maria
Reference Number: 172738
PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.
APPROVED: By Expedited Review and Approval
CHANGE APPROVED: Addition of Ashley Hollins to study team
APPROVAL DATE: 06/22/2018

CHAIRPERSON: Rebecca Lunstroth, JD
Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved at this meeting.
CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.
INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that if revisions to the informed consent form were made and approved, then old blank copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**
UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will
immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.
RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.

Curriculum Vitae

Ashley Hollins, PhD, MSN-ED., RN, FNP-BC

EDUCATION

University of Texas Health Science Center-Houston Cizik School of Nursing Nursing	2019	PhD
University of Texas Health Science Center -Houston Cizik School of Nursing Education	2018	MSN
Southern University and A&M College, Baton Rouge, LA Family Nurse Practitioner Role	2012	MSN
Southern University and A&M College, Baton Rouge, LA Nursing	2008	BSN

PROFESSIONAL POSITIONS:

Healthcare Clinics at Walgreens Katy, Texas Family Nurse Practitioner	2015 - present
University of Texas Health Science Center Houston, Texas Adjunct Faculty Nursing	2016 - present
Medical Clinics of Sealy Sealy, Texas Family Nurse Practitioner	2013 - 2015
Baton Rouge General Medical Center Baton Rouge, Louisiana Intensive Care Unit Nurse	2010 - 2013
Our Lady of Lourdes Medical Center Lafayette, Louisiana Intensive Care Unit Nurse	2008 - 2012

PROFESSIONAL MEMBERSHIP:

Sigma Theta Tau Honor Nursing Society Zeta Pi Chapter	2012 - present
The American Academy of Nurse Practitioners	2012 - present

American Nurses Association 2017 - present

Texas Nurses Associations 2017 - present

PRESENTATIONS:
"Predictors of Female Genital Mutilation/Cutting Among Young Girls in Egypt"
University of Texas Health Science Center
Houston, Texas