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The Influence of Relationship Status on HPV Vaccine Decision-Making among Young Adult Women

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The Influence of Relationship Status on HPV Vaccine Decision-Making
among Young Adult Women

by

Erika L. Thompson

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
Department of Community and Family Health
College of Public Health
University of South Florida

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DEDICATION

To all HPV vaccine-eligible persons, may they never have to face a preventable cancer diagnosis.

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ABSTRACT

Background: The HPV vaccine is a primary prevention method available to reduce the burden of HPV-related cancers and genital warts. The vaccine is currently approved for catch-up vaccination among women 18 to 26 years of age. Despite this recommendation, the rate of vaccine uptake among this group is considerably low (~34% uptake). One demographic characteristic that is consistently reported as a risk factor for non-vaccination is *relationship status*, specifically married or monogamous relationships. While the epidemiological data confirm this association, there is a lack of understanding how this risk factor operates. By elucidating the mechanism for this risk factor, HPV vaccine uptake among this consistently unvaccinated group could be improved.

Purpose: The purpose of this study was to understand how young adult women's relationship status influence informational needs, motivations, and behavioral skills related to HPV vaccination. This objective was achieved through the following specific aims: (1) assess how relationship status affects *primary reasons* for non-vaccination among 18 to 26 year old women; and (2) understand how relationship status frames HPV vaccine decision-making among 18 to 26 year old women.

Methods: To effectively achieve these specific aims, a concurrent mixed-methods study design was conducted. In Phase I, a secondary data analysis using the 2010 National Health Interview Survey was employed to determine if women in relationships are less likely to be *interested* in vaccination and identify the *primary reasons* (e.g., misinformation, motivations, behavioral skills) for non-vaccination among different relationship status categories. In Phase II, in-depth

interviews were conducted with a sample (N=50) of 18 to 26 year old women at the University of South Florida, stratified by relationship status and vaccination status. A comparative thematic analysis was conducted to determine if there were differences in informational needs, motivations, behavioral skills, and HPV vaccine decision-making between the groups.

Results: Using NHIS 2010 data, women who were living with a partner (PR 1.44 95%CI 1.07-1.87) and never married (PR 1.41 95%CI 1.12-1.73) were less likely to be interested in HPV vaccination compared women who were married. Moreover, primary reasons for non-vaccination differed significantly by relationship status group ($p<0.01$) Findings from the qualitative phase from the study indicated that women's risk perceptions for HPV were impacted by current relationship status. Women in long-term relationships reported that monogamy and number of sexual partners reduced their risk of HPV and perceived need of the HPV vaccine. Women in all relationship status groups reported similar HPV knowledge levels (e.g., recognition that HPV is sexually transmitted, less clarity on the outcomes associated with HPV), behavioral skills (e.g., procedural knowledge to get the HPV vaccine, perceived facilitators, perceived barriers), and influential macro factors (e.g., anti-vaccination culture, television advertisement) related to HPV vaccination.

Conclusion: This study found that relationship status impacts HPV vaccine decision-making among young adult women. Specifically, it operates by modifying risk perceptions for HPV, which serve as barriers to vaccination. Young adult women have the knowledge and behavioral skills necessary to access and understand the importance of HPV vaccination; however, women were unable to accurately perceive their risk for HPV, resulting in impaired motivation for vaccination. A potential approach to address this issue is the use of *health literacy*. Future research should integrate health literacy techniques with healthcare providers serving this

population to assist in the *evaluation* process for risk of HPV. This will facilitate shared decision-making and patient-provider communication surrounding the HPV vaccine. This can ultimately promote HPV vaccination among young adult women and reduce the morbidity and mortality of HPV-related diseases.

CHAPTER 1: INTRODUCTION

Background

Human papillomavirus (HPV) is the most incident and prevalent sexually transmitted infection (STI) in the United States; it is estimated there are nearly 14 million new cases and a total of 79 million cases a year (Satterwhite et al., 2013). The public health significance of this STI is highlighted by the fact that HPV is a *necessary cause* for some cancers. There are two grades of HPV infections: high-risk and low-risk. High-risk HPV, such as types 16 and 18, are known to cause cancers, including cervical, vulvar, vaginal, penile, anal, and oropharyngeal (Munoz et al., 2003; zur Hausen, 2002). While low-risk HPV, such as types 6 and 11, are known to cause genital warts and recurrent respiratory papillomatosis (Lacey, Lowndes, & Shah, 2006). HPV is transmitted primarily through genital sexual contact, but can also be transmitted via oral to genital contact or skin to skin genital contact (Burchell, Winer, de Sanjose, & Franco, 2006).

As a primary prevention strategy for HPV, in 2006, the United States' Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination for the 3-dose quadrivalent HPV vaccine series for females 11 to 12 years of age (Markowitz et al., 2007). Additionally, the quadrivalent vaccine, licensed as Gardasil®, was approved for use in females until age 26, if not previously vaccinated, as a “catch-up” group for vaccination. The quadrivalent HPV vaccine (HPV4) protects against four strains of HPV; low risk types 6 and 11, and high risk types 16 and 18 (Food and Drug Administration, 2014b). HPV4 serves as a primary prevention method against genital warts and HPV-related cancers (Lacey et al., 2006; Munoz et

al., 2003; zur Hausen, 2002). In 2009, this ACIP recommendation was expanded to include a bivalent HPV vaccine (HPV2), licensed as Cervarix ®, that protects against HPV strains 16 and 18 (Centers for Disease Control and Prevention, 2010a; Food and Drug Administration, 2014a). In 2015, the ACIP recommendation expanded to a third vaccine, Gardasil 9 ®, which protects against the four strains in Gardasil and five additional strains (31, 33, 45, 52, and 58). The recommendations were consistent with those currently in place for the Gardasil vaccine (Food and Drug Administration, 2015; Petrosky et al., 2015).

Table 1: HPV Vaccine Rates among Females 18-26 Years

Year	HPV Vaccine Uptake*
2008	11.6% (9.7, 13.6)
2009	19.0% (16.6, 21.4)
2010	21.5% (19.2, 23.8)
2011	29.7% (27.3, 32.2)
2012	34.1% (31.6, 36.7)

*Uptake is having received at least one HPV vaccine dose; **NHIS 2008-2010 data source

Given the earlier approval of the HPV vaccine for females, national public health priorities for HPV vaccination have focused primarily on females. Yet, current HPV vaccination statistics in the United States reveal vaccine completion rates (16.6%) below the target of 80% for females by the age of 13 to 15 years old (Healthy People 2020, 2015c). As a result, unvaccinated adolescent females transition into the catch-up age range of 18 to 26 years, and are consequently considered a priority population for vaccination. This time period is the last opportunity for females to receive the vaccine; therefore, intervening during young adulthood is essential for this primary preventive behavior and to ultimately decrease HPV-related disease.

Unfortunately, rates in the catch-up age range among young adult women are also low. Data from nationally-representative samples provide the most accurate and generalizable representation of the HPV vaccination coverage among females 18 to 26 years old. The National Health Interview Survey (NHIS) currently has data available from 2008 to 2012 for HPV vaccine uptake (reported as: *ever receiving at least one HPV vaccine dose*). Rates have significantly increased over time, and as of 2012 were at 34.1% (Table 1) (Schmidt & Parsons, 2014). The latest NHIS 2013 data indicate 36.9% of women 19 to 26 years old received at least one dose of the HPV vaccine; among these women, 27.6% received the first dose during this age range (Williams et al., 2015). Despite these increases, these rates are dramatically low given that the vaccine has been available for nine years.

Statement of Need

Young adulthood is a period for autonomous decision-making regarding sexual and reproductive health choices. As such, it is necessary to understand the complex factors that may contribute to these health decisions, such as receiving the HPV vaccine. Barriers and facilitators to HPV vaccination among young adult (18 to 26 year olds) females have been widely reported (e.g., low knowledge, perceived barriers, perceived benefits, self-efficacy, subjective norms, healthcare provider recommendation and risk perception) (Allen et al., 2009; Bendik, Mayo, & Parker, 2011; Bennett, Buchanan, & Adams, 2012; Bynum, Brandt, Sharpe, Williams, & Kerr, 2011; Daley, Vamos, et al., 2010; Dillard, 2011; Hodge, Itty, Cardoza, & Samuel-Nakamura, 2011; Joseph et al., 2014; Licht et al., 2010; Marchand, Glenn, & Bastani, 2012; Ratanasiripong, Cheng, & Enriquez, 2013; Rosenthal et al., 2011; Schaefer Ziemer & Hoffman, 2013; Zimet, Weiss, Rosenthal, Good, & Vichnin, 2010). Additionally, a limited number of interventions have

been developed targeting this age group to improve HPV vaccination uptake and completion (Fu, Bonhomme, Cooper, Joseph, & Zimet, 2014). One of the potential limitations with these studies is that the entire group of female 18 to 26 years olds is being regarded as the same (i.e., there is a lack of tailored health interventions or health research). This ignores the potential variability within sub-groups of this population (e.g., different stages of readiness or demographic characteristics) that may encounter different barriers or facilitators to vaccination. Thus, given the minimal improvements in HPV vaccination among this age category nine years post-vaccine licensure, research efforts should focus, not only on the broad population of 18 to 26 year olds, but rather on sub-groups who are consistently less likely to be vaccinated over this time period.

One of these demographic characteristics that is consistently reported as a risk factor for non-vaccination among young adult women is *relationship status*, specifically married or monogamous relationships (Anhang Price, Tiro, Saraiya, Meissner, & Breen, 2011; Bernat, Gerend, Chevallier, Zimmerman, & Bauermeister, 2013; Ford, 2011; Joseph et al., 2014; Laz, Rahman, & Berenson, 2013; Liddon, Hood, & Leichliter, 2012; Liddon, Leichliter, & Markowitz, 2012; Lindley, Elkind, Landi, & Brandt, 2013; Rahman, Laz, & Berenson, 2013; Schmidt & Parsons, 2014; Wei, Moore, & Green, 2013; Williams et al., 2013; Zimet et al., 2010). For example, according to 2010 NHIS data, unmarried or single women were significantly more likely to be vaccinated compared to married women (OR=3.10, 95% CI 1.71-5.60) (Laz et al., 2013). Moreover, this is a risk factor for non-HPV vaccination that is specific to female young adults, rather than young adult males (Bernat et al., 2013; Newman, Logie, Doukas, & Asakura, 2013).

Thus far, no research has been conducted to understand *why* this is occurring and how to remove this disparity. Women in long-term or monogamous relationships may be framing their

perceived risk of HPV according to their current relationship status and as a result declining vaccination. Interestingly, traditionally considered sexually high-risk women (e.g., more sexual partners, history of HPV, lower age at sexual debut) were more likely to be vaccinated for HPV compared to low-risk counterparts (Bednarczyk, Birkhead, Morse, Doleyres, & McNutt, 2011; Bendik et al., 2011; Bernat et al., 2013; Gerend & Shepherd, 2011; Lindley et al., 2013; Manhart et al., 2011; Mills, Vanderpool, & Crosby, 2011; Tiro et al., 2012). Moreover, healthcare providers may also have biases toward evaluating risk for HPV and perceived vaccine need based on relationship status of young adult women. Zimet et al., (2011) reported physicians giving a lower priority to vaccinating female patients who were married or in monogamous relationships compared to women who were single or dating. In contrast, these physicians surveyed did not alter priority perceptions based on women's sexual history (e.g., HPV infection, abnormal Pap test) (Zimet et al., 2011). Gaining a deeper understanding of how this unique risk factor, relationship status, operates will promote scientific advancement for HPV vaccination among young adult women. Targeting the informational needs, motivations, and behavioral skills required among women who are married or in long-term monogamous relationships through interventions will ultimately promote HPV vaccination among this historically un-vaccinated group.

While it is not disputed that monogamy is a protective factor for many sexual and reproductive health outcomes (e.g., unintended pregnancy, HIV), risk for HPV still exists among this group, even among persons engaging in serial monogamy (Burchell et al., 2006). Women who have only one sexual partner of the opposite sex have an average lifetime risk of 85% for HPV infection (Chesson, Dunne, Hariri, & Markowitz, 2014). Moreover, according to the National Study of Family Growth, the average number of lifetime sexual partners for women is

approximately 3.6 (Chandra, Mosher, & Copen, 2011). The average number of sexual partnerships compounds the lifetime risk for HPV. These statistics regarding risk of HPV transmission and sexual partnerships for women underscore the importance of HPV vaccination regardless of sexual relationships; however, this may contradict common heuristic beliefs among women that monogamous sex is safe sex. Furthermore, the ACIP guidelines do not provide any conditions for vaccination based on relationship status or sexual activity for women (Centers for Disease Control and Prevention, 2010a, 2010b, 2011). Therefore, being in a long-term, monogamous relationship should *not* preclude HPV vaccination.

Disentangling this complicated health message for dissemination and implementation into practice first requires a better understanding of the perspective of the target population to recognize how relationship status influences HPV vaccination decision-making. This must be considered within the context of other complex and evolving sexual and reproductive health guidelines (e.g., recommendations for Pap tests) that are also targeted at this population. Understanding why women may alter their risk perception for this particular health behavior will inform the type of shared decision-making and patient-provider communication that should occur surrounding this vaccine. Moreover, future interventions based on this research can tailor health information and messages specific to the unvaccinated sub-groups of interest (i.e., women in monogamous relationships) and reinforce messages to assist women in assessing risk for acquiring HPV infection (Williams et al., 2013).

Public Health Significance

Thus, the next step in the research trajectory for HPV vaccination uptake in young adult women is to understand how relationship status frames the HPV decision-making process. This

research is *timely* and *innovative* as it moves the current survey-based research forward to understand *why* this disparity in HPV vaccination exists among young adult women in long-term or monogamous relationships. This formative investigation will lay the groundwork for future research and interventions to improve HPV vaccination rates among young adult women.

Furthermore, this research responds to a number of national research priorities. The *National Institutes of Health, Office of Research on Women's Health (ORWH)* 2020 Strategic Plan recommended continued research to determine the best methods to improve adoption of prevention behaviors during adolescence and young adulthood, including HPV vaccine distribution (U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, & Office of Research on Women's Health, 2010). Moreover, the *Centers for Disease Control and Prevention* (CDC) calls for additional research to increase HPV vaccine coverage by engaging patients and providers to eliminate missed clinical opportunities (Markowitz et al., 2014). Finally, the research's long-term goals address multiple *Healthy People 2020* objectives, including (1) reduce the proportion of females with HPV; (2) reduce invasive uterine cervical cancer cases; and (3) reduce the death rate from uterine cervical cancer (Healthy People 2020, 2015a, 2015d). Therefore, the significance of this proposed research is underscored by these national research goals.

Finally, this research is *relevant* to emerging technologies (e.g., 9-valent vaccine; second-generation HPV vaccines) and changing vaccine dosing schedules (i.e., changing from two required doses rather than three required doses) (Markowitz et al., 2014). This evolution in HPV vaccination practices will expand protection against new HPV types and eliminate barriers to HPV vaccine completion (Joura et al., 2015). Therefore, it is critical to understand the sustained barriers to HPV vaccination among the unvaccinated young adult female population as health

messages surrounding the vaccine will become increasingly complicated with the evolving science.

Specific Aims and Research Questions

The long-term goal is to increase HPV vaccination rates among young adult women 18 to 26 years of age, ultimately decreasing HPV-related disease (i.e., HPV-associated cancers, genital warts). The purpose of this study was to understand how young adult women's relationship status influence informational needs, motivations, and behavioral skills related to HPV vaccination. This objective was achieved through the following *specific aims* and mixed-methods study design (Table 2).

To effectively achieve these specific aims, a concurrent mixed-methods study design was conducted. In Phase I, a secondary data analysis using the 2010 National Health Interview Survey was conducted to determine if women in relationships were less likely to be *interested* in vaccination and identify the *primary reasons* (e.g., misinformation, motivations, behavioral skills) for non-vaccination among different relationship status groups. In Phase II, in-depth interviews were conducted with a sample (N=50) of 18 to 26 year old women at the University of South Florida, stratified by relationship status and vaccination status. A comparative thematic analysis was conducted to determine if there are differences in informational needs, motivations, behavioral skills, and HPV vaccine decision-making attributed to relationship status.

Implications

This study used the Information, Motivation, and Behavioral Skills (IMB) Model approach for study design by beginning with the elicitation phase, which is conducted prior to

Table 2: Specific Aims of Dissertation Research

Specific Aims	Research Questions	Phase
1. Assess how relationship status affects <i>primary reasons</i> for non-vaccination among 18 to 26 year old women.	<ol style="list-style-type: none"> 1. Among unvaccinated 18 to 26 year old women, are married women less likely to be <i>interested</i> in the HPV vaccine compared to non-married women? 2. Among 18 to 26 year old women who are not interested in the HPV vaccine, does relationship status impact the <i>primary reason</i> for non-vaccination? 	1. Secondary data analysis of NHIS 2010
2. Understand how relationship status frames HPV vaccine informational needs, motivations, and behavioral skills among 18 to 26 year old women.	<ol style="list-style-type: none"> 3. How do HPV vaccine informational needs, motivations, and behavioral skills differ among <i>unvaccinated</i> 18 to 26 year old women <i>based on relationship status</i>? 4. How do HPV vaccine informational needs, motivations, and behavioral skills differ among <i>vaccinated</i> 18 to 26 year old women <i>based on relationship status</i>? 5. How do HPV vaccine informational needs, motivations, and behavioral skills differ among women 18 to 26 years old and <i>in relationships</i> (i.e., married, living with a partner, or in a long-term monogamous relationship) <i>based on vaccination status</i>? 6. How do HPV vaccine informational needs, motivations, and behavioral skills differ among women 18 to 26 years old and <i>not in relationships</i> (i.e., single or single and dating) <i>based on vaccination status</i>? 	2. In-depth interviews with college females 18 to 26 years old (N=50)

the intervention development and evaluation phases, to understand why young adult women are not getting vaccinated at the catch-up age range (Fisher & Fisher, 2002). Findings from this formative research will inform a quantitative survey utilizing the IMB Model to expand this research to a larger sample of women and increase the generalizability. Moreover, it will inform the types of health messages that should be tailored to different groups of young adult women

based on relationship status, ultimately improving patient-provider communication concerning actual risk for HPV and HPV vaccine shared decision-making. Future theory-based interventions developed from these findings will utilize the IMB Model approach for intervention design and intervention mapping methods (Bartholomew, Parcel, & Kok, 1998; Fisher & Fisher, 2002).

Moreover, future research should triangulate the findings from this study among young adult females with healthcare providers who administer the HPV vaccine to young adult women. While previous research indicates that these agents may have differential preferences for HPV vaccination based on relationship (Zimet et al., 2011), an understanding of how this bias operates, as well as the barriers that may need to be overcome is required.

This study has the potential to advance *theoretical methodology* and *public health practice*. Fisher (2012) has proposed the use of the IMB Model to understand HPV vaccination; however, no studies have used this theoretical model for HPV vaccination among young adult females and a limited number have used this model among other populations for the HPV vaccine (Fisher, 2012). Therefore, there is the potential to expand the utility and application of the IMB Model to new health behaviors and target populations. This study is the first step in the elicitation phase, while future research could expand upon these findings to develop and evaluate an intervention targeting HPV vaccination among young adult women.

Definition of Key Terms

HPV – Human papillomavirus

HPV4 – The quadrivalent HPV vaccine, which provides protection against HPV types 6, 11, 16, and 18. It is otherwise known and licensed as Gardasil ®.

HPV2 – The bivalent HPV vaccine, which provides protection against HPV types 16 and 18. It is otherwise known and licensed as Cervarix ®.

HPV9 – The 9-valent HPV vaccine, which provides protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. It is otherwise known and licensed as Gardasil 9 ®.

IMB Model – The Information, Motivation, and Behavioral Skills Model is a validated approach for predicting and promoting health behavior.

NHIS – The National Health Interview Study is a nationally-representative annual cross-sectional health survey in the United States.

CHAPTER 2: LITERATURE REVIEW

Human Papillomavirus

Human papillomavirus (HPV) is the most incident and prevalent sexually transmitted infection (STI) in the United States; it is estimated there are nearly 14 million incident cases and 79 million prevalent cases a year (Satterwhite et al., 2013). There are two grades of HPV infections: high-risk and low-risk. High-risk HPV, such as types 16 and 18, are known to cause cancers, including cervical, vulvar, vaginal, penile, anal, and oropharyngeal (Munoz et al., 2003; zur Hausen, 2002). While low-risk HPV, such as types 6 and 11, are known to cause genital warts and recurrent respiratory papillomatosis (Lacey et al., 2006). HPV is transmitted primarily through genital sexual contact, but can also be transmitted via oral to genital contact and skin to skin genital contact. Other routes of transmission exist, including nonsexual routes, such as mother to child transmission and oral-digital infection, but are less common (Burchell et al., 2006).

HPV Epidemiology

HPV infection prevalence varies based on study sample (e.g., population-based vs. clinical sample). The National Health and Nutrition Examination Survey (NHANES) estimated the prevalence of cervico-vaginal HPV among women in 2003-2006 to be 42.5% (95% CI 40.4-44.7%) and in 2007-2010 to be 39.8% (95% CI 37.7-42.0%). The prevalence was highest among women 20 to 24 years of age. Women in this age category had a prevalence of 19.9% (95% CI

15.5-25.2%) for vaccine-type HPV¹ and 16.2% (95% CI 12.2-21.4%) for high-risk vaccine-type HPV² (Markowitz et al., 2013). Among men, the prevalence of genital HPV was estimated to be 50%; the incidence of genital HPV was not associated with age among men (Giuliano et al., 2011). Moreover, it is estimated that the average lifetime probability of acquiring HPV among women with at least one male sexual partner is nearly 85% and among males with at least one female sexual partner is 91% (Chesson, Dunne, et al., 2014).

Health Outcomes Associated with HPV

Cancer. HPV is a causal agent for many cancers, including cervical, vulvar, vaginal, penile, anal, and oropharyngeal (Munoz et al., 2003; zur Hausen, 2002). Persistent HPV infections are primarily responsible for progressing to precancerous or cancerous conditions (Forman et al., 2012). According to the Centers for Disease Control and Prevention (CDC), an analysis of the National Program of Cancer Registries and the Surveillance, Epidemiology, and

Table 3: HPV-Associated Cancer Rates per 100,000

Anatomic Site	Females	Males
Cervical	7.7	--
Vulvar	1.8	--
Vaginal	0.4	--
Penile	--	0.8
Anal	1.8	1.2
Oropharyngeal	1.4	6.2

*Data source: NPCR, SEER 2004-2008

¹ Vaccine-type HPV refers to HPV types included in the vaccine; types 6, 11, 16 and 18

² High risk vaccine-type refers to HPV types included in the vaccine and considered high-risk; types 16 and 18

End Results program from 2004 to 2008 revealed an average of 33,369 HPV-associated cancer cases were diagnosed annually—this is a rate of 10.8 per 100,000 population. The rate was higher among females (13.2 per 100,000) compared to males (8.1 per 100,000) (Centers for Disease Control and Prevention, 2012). The rates of HPV-associated cancers depend upon anatomical site and sex (Table 3). HPV-associated cervical cancer has the highest rate (7.7 per 100,000), followed by oropharyngeal cancer in males (6.2 per 100,000). Additionally, cancers at these sites are largely attributable to HPV, with nearly 96% of cervical cancer cases attributable to HPV (Table 4) (Gillison, Chaturvedi, & Lowy, 2008). This translates to approximately 11,500 cervical cancer cases a year due to HPV (Centers for Disease Control and Prevention, 2012).

Table 4: Percentage and Number of Cases Attributable to HPV Annually

Anatomic Site	% (Range)	# (Range)
Cervical	96 (95-97)	11,500 (11,400-11,600)
Vulvar	51 (37-65)	1,600 (1,200-2,000)
Vaginal	64 (43-82)	500 (300-600)
Penile	36 (26-47)	400 (300-500)
Anal	93 (86-97)	2,900 (2,700-3,000) <i>Females</i> 1,600 (1,400-1,600) <i>Males</i>
Oropharyngeal	63 (50-75)	1,500 (1,200-1,800) <i>Females</i> 5,900 (4,700-7,000) <i>Males</i>

*Data source: NPCR, SEER 2004-2008, Gillison et al. (2008). *Cancer, 113*

There is also substantial mortality associated with these cancers. While data were not available on the proportion of cancer deaths attributable to HPV, the overall mortality rates for the cancers at the anatomical sites associated with HPV were available. For women, the age-

adjusted mortality rates annually using 2007-2011 data are as follows: cervical 2.3 per 100,000 women, vulvar 0.5 per 100,000 women, anal 0.3 per 100,000 women, and oral cavity/pharynx 1.4 per 100,000 women (vaginal cancer data are not available). For men, the age-adjusted mortality rates annually using 2007-2011 data are as follows: anal 0.2 per 100,000 men and oral cavity/pharynx 3.8 per 100,00 men (penile cancer data are not available) (National Cancer Institute, 2014).

Genital warts. HPV is also a cause of genital warts; HPV types 6 and 11 are associated with over 90% of genital warts cases (Lacey et al., 2006). According to NHANES 1999-2004 data, 5.6% of adults age 18 to 59 years report ever being diagnosed with genital warts. The proportion was higher for females (7.2%) compared to males (4.0%). Moreover, rates were highest among females 25 to 34 years of age and males 35 to 44 years of age (Dinh, Sternberg, Dunne, & Markowitz, 2008).

Recurrent respiratory papillomatosis. Recurrent respiratory papillomatosis is a rare disease caused by HPV types 6 and 11. This condition produces benign warts in the upper respiratory tract that can cause airway obstruction. This disease typically has a juvenile onset prior to 18 years (Markowitz et al., 2014).

HPV Vaccination

Three vaccines have been developed and approved for use to prevent HPV and ultimately reduce the impact of HPV-related health outcomes (i.e., cancer and genital warts). The quadrivalent HPV vaccine (HPV4) was developed by Merck and Co, Inc. and prevents HPV types 6, 11, 16, and 18 (Food and Drug Administration, 2014b). It has an efficacy rate of 98.2% for HPV types 6, 11, 16, and 18 for clinical endpoints adenocarcinoma in situ and cervical

intraepithelial neoplasia 2/3; 100.0% for HPV types 6, 11, 16, and 18 for clinical endpoints vulvar intraepithelial neoplasia and vaginal intraepithelial neoplasia; and 98.9% for HPV types 6 and 11 for genital warts as a clinical endpoint (Kjaer et al., 2009). The bivalent HPV vaccine (HPV2) was developed by GlaxoSmithKline and prevents HPV types 16 and 18 (Food and Drug Administration, 2014a). It has an efficacy rate of 94.9% for HPV types 16 and 18 for clinical endpoints adenocarcinoma in situ and cervical intraepithelial neoplasia 2/3 (Lehtinen et al., 2012). The 9-valent HPV vaccine (HPV9) was developed by Merck and Co, Inc. and prevents HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. It has an efficacy rate of 96.7% for types HPV 31, 33, 45, 52, and 58 for clinical endpoints cervical intraepithelial neoplasia 2/3, adenocarcinoma in situ, cervical cancer, vulvar intraepithelial neoplasia 2/3, vaginal intraepithelial neoplasia 2/3, vulvar cancer, and vaginal cancer (Food and Drug Administration, 2015).

HPV Vaccination Guidelines

The Advisory Committee on Immunization Practices (ACIP) is responsible for setting guidelines for immunizations in the United States. Table 5 describes the nine year timeline for HPV vaccination recommendations from ACIP, starting with the first recommendation for HPV4 among females (Markowitz et al., 2007). As of 2015, the current recommendations for HPV vaccination are: (1) HPV2, HPV4, and HPV9 for routine vaccination among females 11 to 12 years of age; (2) HPV2, HPV4, and HPV9 for catch-up vaccination among females 13 to 26 years of age; (3) HPV4 and HPV9 for routine vaccination among males 11 to 12 years of age; (4) HPV4 and HPV9 for catch-up vaccination among males 13 to 21 years of age; and (5) HPV4 and HPV9 for catch-up vaccination among male subpopulations until age 26, specifically men who

have sex with men (MSM) or men who are immunocompromised (Centers for Disease Control and Prevention, 2010a, 2010b, 2011; Petrosky et al., 2015).

HPV vaccination requires following a strict dosing schedule for vaccination completion. For all vaccines, three doses are required. The vaccine should be administered at 0, 1-2 months, and 6 months. Non-compliance with the schedule may offer limited immune response and protection (Widdice, Bernstein, Leonard, Marsolo, & Kahn, 2011). However, current research is dedicated to assessing the efficacy of only two doses of the vaccine in order to offer an alternative dosing schedule (Markowitz et al., 2014).

Table 5: ACIP Recommendations for HPV Vaccination

Time	Target Group	Recommendation
2006	Females, 11-12 years	Routine HPV4 vaccination
	Females, 13-26 years	Catch-up HPV4 vaccination
2009	Females, 11-12 years	Routine HPV2 vaccination
	Females, 13-26 years	Catch-up HPV2 vaccination
	Males 9-26 years	May receive HPV4 vaccination; not routine
2011	Males, 11-12 years	Routine HPV4 vaccination
	Males, 13-21 years	Catch-up HPV4 vaccination
	Males, 21-26 years, MSM or Immunocompromised	Catch-up HPV4 vaccination
2015	Females, 11-12 years	Routine HPV9 vaccination
	Females, 13-26 years	Catch-up HPV9 vaccination
	Males, 11-12 years	Routine HPV9 vaccination
	Males, 13-21 years	Catch-up HPV9 vaccination
	Males, 21-26 years, MSM or Immunocompromised	Catch-up HPV9 vaccination

Health Implications of the HPV Vaccine

HPV vaccination has the potential to *significantly reduce the morbidity and mortality associated with cancer*. According to a population-based HPV model, HPV vaccination would prevent 45,500 cervical cancer cases and 14,600 cervical cancer deaths at 30% vaccine coverage among females 12 years and younger. These estimates increase dramatically for a 80% coverage level (98,900 cervical cancer cases and 31,700 cervical cancer deaths) (Chesson, Markowitz, & Dunne, 2014). While these models only incorporate cervical cancer, additional prevention can be inferred for other HPV-associated cancers with higher HPV vaccination coverage. Moreover, according to epidemiological cancer data of HPV-associated cancers, it is estimated that HPV vaccination could prevent nearly 26,000 cancer cases a year (Centers for Disease Control and Prevention, 2012).

Additionally, ecological trends of genital warts in a public family planning clinic in California reveal decreases in genital warts rates among males and females since HPV vaccine approval (Bauer, Wright, & Chow, 2012). Similarly, evidence from Australia indicates a decrease in genital warts among young adult women attributable to the HPV vaccination program (Donovan et al., 2011). HPV vaccination has the potential to impact morbidity rates of genital warts; however, protection is only offered by the HPV4 and HPV9 vaccines that prevent low-risk HPV types 6 and 11 (Food and Drug Administration, 2014b).

Economic Implications of the HPV Vaccine

In addition to the potential morbidity and mortality implications associated with the HPV vaccine, economic evaluations are needed. The cost of the HPV vaccine series is estimated to be

\$500 (American Cancer Society, 2014a). The *cost-effectiveness* of the vaccine series must be considered in relation to the potential economic costs associated with HPV-related outcomes.

The majority of early studies examining the cost-effectiveness of the HPV vaccine examined female vaccination only. In these studies, HPV vaccination was considered cost-effective compared to cervical cancer screening alone (Chesson, Ekwueme, Saraiya, Dunne, & Markowitz, 2011; Kim & Goldie, 2008). One study compared coverage rates for female vaccination at age 12 in the US. At 30% coverage, the cost of a quality-adjusted life year (QALY)³ gained was \$2,000 compared to no vaccination. In a comparison of 45% coverage to the previously mentioned 30% coverage, the cost per QALY gained was \$8,200. There is no consensus regarding a threshold for “good value” for a QALY gained; however, \$50,000 per QALY is a commonly cited upper limit threshold (Eichler, Kong, Gerth, Mavros, & Jönsson, 2004; Kim & Goldie, 2008). Including males into this model increases the costs substantially, especially when female vaccination coverage is higher. For example, compared to female vaccine coverage of 45%, a model of male and female vaccination coverage at 30% was estimated to cost \$103,500 per QALY gained (Chesson et al., 2011). Furthermore, a systematic review of 29 studies examining HPV vaccine cost-effectiveness revealed that overall routine vaccination of females is cost-effective compared to traditional cervical cancer screening only; however, the value of adding males to vaccination programs is less clear (Seto, Marra, Raymakers, & Marra, 2012). This is likely due to the variability in estimate of female vaccination coverage; lower female vaccine coverage improves the estimated cost-effectiveness of including males in vaccine programs (Chesson & Markowitz, 2014). While the cost-effectiveness of vaccinating the entire male population may not be optimal, one study has

³ QALY refers to the incremental cost per quality-adjusted life year gained by HPV vaccination. The incremental cost per QALY is calculated as: (vaccination costs – medical costs averted from vaccination) / (number of QALYs gained by vaccination) (Chesson et al., 2011).

evaluated the effectiveness of vaccinating the MSM population and found it to be a cost-effective prevention method for anal cancer and genital warts (Kim, 2010).

An additional consideration that has been explored is extending the age limit for vaccinating young women. Studies have consistently shown that HPV vaccination of young women is less cost-effective as age increases compared to only vaccinating adolescents.⁴ Yet, there is no consensus on a specific threshold where cost-effectiveness becomes futile (Chesson & Markowitz, 2014; Kim & Goldie, 2008; Markowitz et al., 2014).

While these models currently provide the best estimates available for the cost-effectiveness of HPV vaccination, the majority studies typically focus on direct health effects and a limited range of cancer costs. This may significantly underestimate the cost-effectiveness of the HPV vaccine as it can affect a wider range of economic outcomes. Marsh et al. (2014) described the diversity of potential outcomes as extending beyond the individual, to family and caregivers, government (e.g., treatment costs), and societal costs (e.g., improved health equality). Moreover, the typically considered health-related costs exclude fertility impacts, out-of-pocket costs, loss of productivity, other sequelae, and a larger range of HPV-associated cancers (Marsh, Chapman, Baggaley, Llargeron, & Bresse, 2014).

As HPV vaccination guidelines change (e.g., two doses) and other technologies evolve (e.g., 9-valent vaccine), the estimated economic impact of the HPV vaccine will need to be updated. Initial estimates of the cost-effectiveness for HPV9 indicate that the expanded vaccine is more cost-saving compared to HPV4, especially for females (Brisson, 2014). The key messages taken from the literature indicate that HPV vaccination is *cost-effective* for females and

⁴ As the age range is extended in the cost-effectiveness vaccination models, the incremental cost per QALY gained increases to a level that may no longer be economically beneficial. For example, adding a catchup program to 26 years old increased the cost per QALY to \$152,700 compared to routine vaccination at 12 years old (Kim & Goldie, 2008)

the effectiveness declines with increasing age; however, no upper threshold has been established. In addition, the cost-effectiveness of vaccinating males is less clear and further studies are required to fully understand the economic implications.

HPV Vaccine Policies in the United States

While ACIP provides national guidelines for HPV vaccination in the United States, the implementation of these guidelines vary by state. Given that there is a lack of standardization at the national level, each state's policy must be evaluated as it may be the result of policy from state legislature or state executive branch (National Conference of State Legislatures, 2014).

Since 2006, 42 states and territories have introduced legislation to require the HPV vaccine, fund vaccination, or educate the public or parents of school children on HPV vaccination. Specifically, in the 2013-2014 legislative sessions, 10 states proposed legislation. Educational policies have been enacted in Iowa, Colorado, North Carolina, Texas, and North Dakota (Fernandez, Allen, Mistry, & Kahn, 2010). In 2007, Texas' governor mandated the HPV vaccination for school-aged children; however, this was overridden by the Texas legislature. Only the District of Columbia and Virginia have enacted a legislative school vaccine requirement with an opt-out policy for girls entering the sixth grade; both of which occurred in 2007 (Fernandez et al., 2010; National Conference of State Legislatures, 2014). As of 2014, Rhode Island has created executive legislation through the State Health Department to require the HPV vaccine for school entry for 7th grade starting in the 2015 school year (Gaito & North, 2014). No empirical evaluations have occurred to determine the effect of the Virginia and D.C. school vaccine mandates; however, National Immunization Survey-Teen (NIS-Teen) 2013 data

reveal that Virginia and D.C. are both below the national average for vaccine initiation and completion among females (National Center for Immunization and Respiratory Diseases, 2013).

An examination of HPV vaccine related bills enacted in the US between 2006 and 2010 indicated that only 23% were actually enacted. Among the 32 bills enacted, 44% involved policies, 25% provided education campaigns, 25% required insurance to cover vaccination, 13% included voluntary vaccination, and 9% mandated vaccination for school entry (Laugesen et al., 2014).

Other developed countries (e.g., United Kingdom, Australia, and Canada) have national programs that publically fund HPV vaccination (Markowitz et al., 2012). In the United States, this is not the case. Financing of the HPV vaccine is mainly the result of private insurance. However, there are public financing options, such as the Vaccines for Children program, Medicaid, or Children's Health Insurance Program (Kaiser Family Foundation, 2014). Alternatively, Merck and GlaxoSmithKline also offer assistance for vaccine payment (Kaiser Family Foundation, 2014). Since cost and insurance coverage are often cited as barriers to HPV vaccination in the United States by both target and catch-up age groups, consideration of alternative strategies for funding the vaccine is needed.

HPV Vaccination Rates

Despite the primary prevention benefits of HPV vaccination, the rates of uptake and completion remain low in the United States. As of 2013, using data from NIS-Teen, the rates of vaccination initiation was 57.3% for females and 34.6% for males ages 13-17 (Table 6) (Stokley et al., 2014). Fewer individuals received the second and third doses of the vaccine. In fact, the completion rates of the HPV 3-dose series among initiators is 70.4% for females and 48.3% for

Table 6: HPV Vaccination Rates Among 13-17 Year Olds

# Doses	Females	Males
≥1	57.3% ± 1.9%	34.6% ± 1.9%
≥2	47.7% ± 2.0%	23.5% ± 1.7%
≥3	37.6% ± 1.9%	13.9% ± 1.4%

*Data source: NIS-Teen 2013

males (Stokley et al., 2014). While these rates are increasing, the level of vaccination coverage is lower than other adolescent vaccines, such as Tdap (Tetanus, diphtheria, pertussis) and MenACWY (meningococcal). The Healthy People 2020 goals for teens 13 to 15 years in the US include coverage of 80% for at least one dose of Tdap, at least one dose of MenACWY, and three doses of HPV (males and females) (Healthy People 2020, 2015c). As of 2013, the goal was met for Tdap (87.5%) and close for MenACWY (78.1%) indicating these goals are achievable with current clinical encounters at this age range. However, HPV vaccination falls behind the current target (Stokley et al., 2014). If the HPV vaccine were administered during healthcare visits with other vaccine administration during this age range, then the rate of coverage for at least one HPV vaccine dose could be 92.6% (Centers for Disease Control and Prevention, 2013).

The NIS-Teen does not capture vaccination rates for persons 18 and older; therefore, other data sources are used for vaccination estimates. According to the National Health Interview Survey (NHIS), uptake⁵ of the HPV vaccine has increased among women 18 to 26 years of age from 11.6% (95% CI 9.7-13.6%) in 2008 to 34.1% (95% CI 31.6-36.7%) in 2012. Over the 2008-2012 timespan, overall 23.3% of women received at least one dose, 18.0% of women received at least two doses, and 13.6% of women received at least three doses. Rates were

⁵ Participants asked if they ever received the HPV vaccine; uptake defined as having received at least 1 HPV vaccine dose.

significantly higher for women 18 to 21 years of age (31.8%) compared to women 22 to 26 years of age (16.9%) (Schmidt & Parsons, 2014). According to NHIS 2013 data, approximately 36.9% of women 19 to 26 years old received at least one dose of the HPV vaccine; among these women 27.6% received the first dose during this age range (Williams et al., 2015).

Data regarding vaccination rates for young adult males are scarce. The latest data available are from the 2011-2012 NHANES dataset. The HPV vaccine uptake rate was only 5.5% (95% CI 3.1-9.5%) and completion of the vaccine series was reported to be 59.1% (95% CI 37.2-77.6%) (Pierre-Victor, Mukherjee, Bahelah, & Madhivanan, 2014). Alternatively, the National College Health Assessment (NCHA) data reported for the Fall 2013 survey, estimates the male, college student vaccination rate (at least one dose) to be 28.6% (American College Health Association, 2014). According to these data, the estimated proportion of college male HPV vaccination has ranged from 13.1% to 24.6% between 2008 and 2012. Despite these higher rates among college males, these rates are lower compared to college females (American College Health Association, 2010, 2011, 2012, 2013).

Factors Influencing HPV Vaccination

Macro level factors. Among the environmental factors at the organizational level, healthcare interaction and healthcare environment impact rates of vaccination (Tiro et al., 2012; Wei et al., 2013; Williams et al., 2013). Moreover, at the highest level of influence, health insurance, costs of vaccines, marketing of the vaccine, policies related to vaccination, and feminization of HPV have all influenced the ability to access and receive the HPV vaccine in the United States (Anhang Price et al., 2011; Daley, Buhi, Vamos, et al., 2012; Dempsey, Cohn,

Dalton, & Ruffin, 2011; Ford, 2011; Hodge et al., 2011; Jain et al., 2009; Laz et al., 2013; Lindley et al., 2013; Tiro et al., 2012; Wei et al., 2013; Zimet et al., 2010).

Provider recommendation. Key among all HPV vaccine target groups is the need for provider recommendation. Therefore, understanding the factors influencing a provider recommendation is necessary to consider. Characteristics of patients were a significant factor for provider recommendation, specifically, recommendation depended upon age (Vadaparampil, Murphy, Rodriguez, Malo, & Quinn, 2013), relationship status (Zimet et al., 2011), and gender (females more than males) (Vadaparampil et al., 2013). Additionally, perceived barriers included the anticipated parental response to the vaccine recommendation (Kahn et al., 2007), as well as logistical concerns (e.g., reimbursement, cost of vaccine) (Ko, Missmer, & Johnson, 2010). Practice environment also impacted providers; private practices and primary care practices were more likely to recommend the vaccine (Ko et al., 2010; Vadaparampil et al., 2014). Finally, practice guidelines are an external determinant to recommendation, especially given that the guidelines have changed multiple times since the vaccine has been introduced (Vadaparampil et al., 2013).

Factors among adolescents. Among adolescents, parents are the primary decision-making agents with regard to vaccination. As a result, the bulk of the literature has focused on parents' beliefs and attitudes toward HPV vaccination for their children (Fernandez et al., 2010). In a systematic review of parental factors influencing HPV vaccination of children, lack of knowledge or information, attitudes toward vaccination (e.g., vaccination in general, safety or side effects of vaccine), provider recommendation, risk perceptions, and outcome expectations with vaccination (e.g., belief child will engage in sexual activity) were reported as salient factors among parents (Trim, Nagji, Elit, & Roy, 2012). Additionally, perceived barriers are reported,

such as lack of insurance or funding for the vaccine (Donahue, Stupiansky, Alexander, & Zimet, 2014). Parental spousal agreement was also a predictor of intention to vaccinate (Rickert et al., 2014).

Factors among young adult males. As for young adult males, awareness, knowledge, perceived severity, perceived susceptibility, perceived barriers (e.g., cost, side effects), self-efficacy and provider recommendation were associated with HPV vaccination (Daley et al., 2011; Fontenot, Fantasia, Charyk, & Sutherland, 2014; Katz, Kam, Krieger, & Roberto, 2012; Newman et al., 2013). Additionally, rates of vaccination vary based on demographic characteristics, such as, poverty, race/ethnicity and education (Daley et al., 2011; Lu et al., 2013; Newman et al., 2013).

Factors Influencing HPV Vaccination among Young Adult Females

In order to assess the current state of HPV vaccination barriers and facilitators among young adult women in the United States, a systematic review of the literature was conducted. Articles were systematically selected from a search of PubMed and Web of Science databases, during a date range of June 1, 2006 to May 1, 2015. Search terms were organized into general categories of HPV (e.g., human papillomavirus, human papilloma virus, papillomavirus vaccines [MeSH], HPV, papillomavirus), immunization (e.g., immuniz*, vaccin*), female (e.g., female, women, woman, girl*), and young adult (e.g., college, catch-up, catch up, young adult). The search strategy in each database used the Boolean term of ‘AND’ for inclusion of each general category, and the Boolean term of ‘OR’ for inclusion of each search term within the category. Inclusion criteria applied were: (1) empirically-based; (2) published in a peer-reviewed journal; (3) reported stratified data for females 18 to 26 years of age; (4) referenced the HPV vaccine; (5)

conducted post-vaccine licensure; and (6) conducted in the United States. Studies were excluded if only a published abstract was available since not enough data would be available for abstraction.

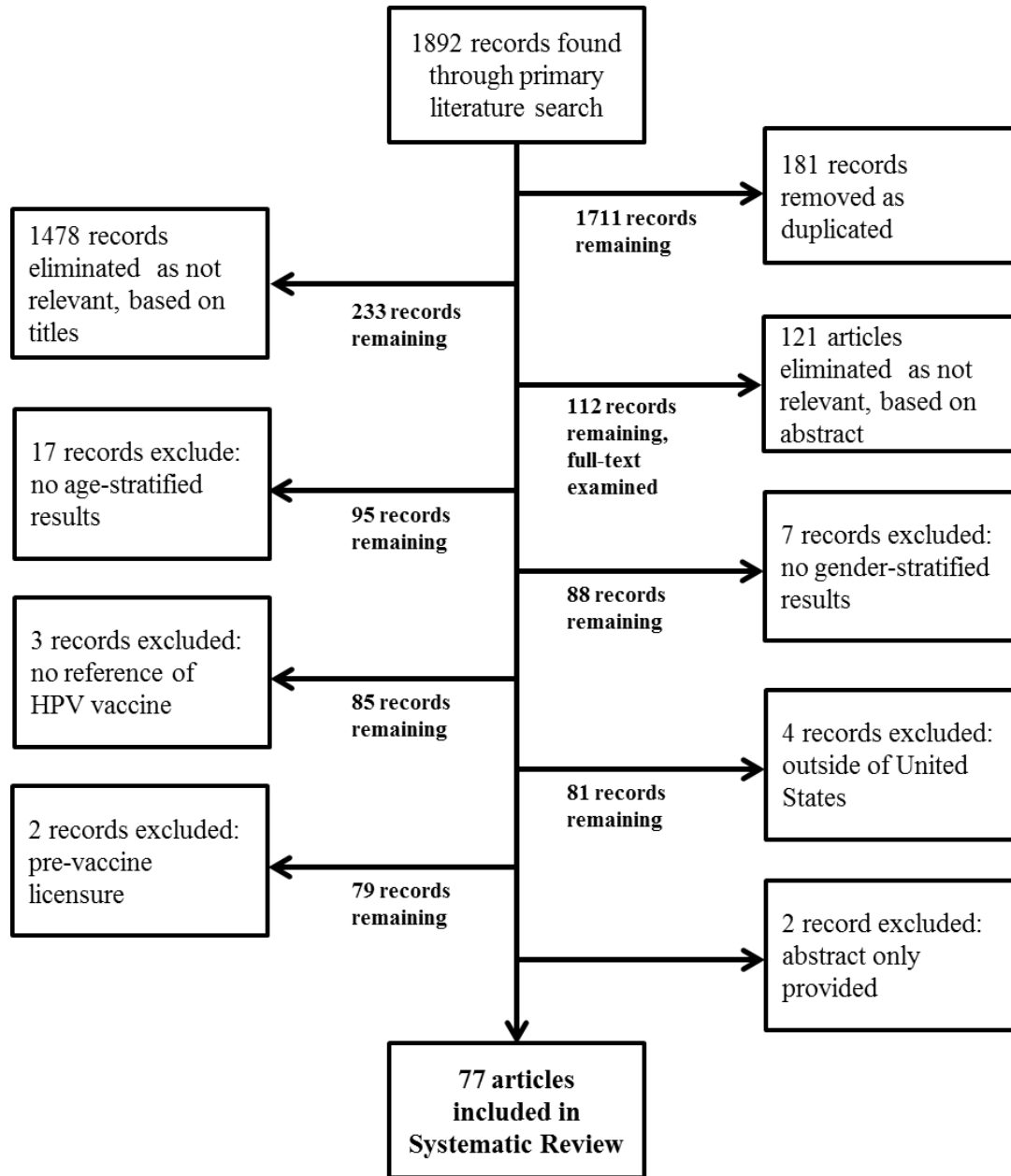


Figure 1: Search Results for Systematic Review

Figure 1 presents the search process for this systematic review. The primary search of the literature identified 1,892 records. After removing 181 duplicates, 1,711 articles remained. Articles were then screened based on titles and relevance to the research topic; this removed 1,478 articles. Next, articles were assessed based on the abstract to determine the relevance to the research topic; this resulted in 112 articles remaining. These remaining articles had the full-text examined to determine eligibility based on the inclusion and exclusion criteria. The following articles were removed: 17 for not providing age-stratified results, 7 for not providing gender-stratified results, 3 for not referencing the HPV vaccine, 4 for being outside of the United States, 2 for being before vaccine licensure, and 2 for only providing an abstract. As a result, 77 articles remained.

The included observational studies had the following types of samples: 29 *college* (Allen et al., 2009; Bednarczyk et al., 2011; Bendik et al., 2011; Bennett et al., 2012; Bynum et al., 2012; Bynum, Brandt, Friedman, Annang, & Tanner, 2011; Bynum, Brandt, Sharpe, et al., 2011; Cohen & Head, 2013; Daley, Vamos, et al., 2010; Dillard, 2011; Dillard & Spear, 2010; Gerend & Shepherd, 2011; Harper, Alexander, et al., 2014; Harper, Irons, et al., 2014; Hodge et al., 2011; Hopfer & Clippard, 2011; Krakow et al., 2015; Krieger, Kam, Katz, & Roberto, 2011; Licht et al., 2010; Lindley et al., 2013; Marchand et al., 2012; Marchand, Glenn, & Bastani, 2013; Patel et al., 2013; Patel et al., 2012; Ratanasiripong, 2014; Ratanasiripong et al., 2013; Roberts, Gerrard, Reimer, & Gibbons, 2010; Sandfort & Pleasant, 2009; Schaefer Ziemer & Hoffman, 2013), 17 *large national surveys* (Anhang Price et al., 2011; Caskey, Lindau, & Alexander, 2009; Ford, 2011; Gelman et al., 2013; Jain et al., 2009; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichter, et al., 2012; Pourat & Jones, 2012; Rahman, Islam, & Berenson, 2015; Rahman et al., 2013; Schmidt & Parsons, 2014; Tiro et al., 2012; Vanderpool,

Williams, Klawitter, & Eddens, 2014; Wei et al., 2013; Williams et al., 2015; Williams et al., 2013), 8 *insurance records or electronic health records* (Chao, Velicer, Slezak, & Jacobsen, 2009, 2010; Cowburn et al., 2014; Hirth, Tan, Wilkinson, & Berenson, 2012; Kharbanda, Parker, Nordin, Hedblom, & Rolnick, 2013; Rosenthal et al., 2011; Verdenius et al., 2013; Zimet et al., 2010), 5 *clinics* (Dempsey et al., 2011; Joseph et al., 2014; Kennedy, Osgood, Rosenbloom, Feinglass, & Simon, 2011; Klosky et al., 2015; Vanderpool, Casey, & Crosby, 2011), 3 *minority population* (e.g., American Indians) (Casey, Crosby, Vanderpool, Dignan, & Bates, 2013; Head & Cohen, 2012; Mills, Head, & Vanderpool, 2013), 2 *combination of samples* (e.g., clinic and community) (Crosby, Casey, Vanderpool, Collins, & Moore, 2011; Mills et al., 2011), 2 *community* (Manhart et al., 2011; Vanderpool, Dressler, Stradtman, & Crosby, 2015) and 1 *web-based* (Bernat et al., 2013). Of the 77 studies, 9 were interventions (Gerend & Shepherd, 2012; Gerend, Shepherd, & Lustria, 2013; Gerend, Shepherd, & Shepherd, 2013; Hopfer, 2012; Juraskova et al., 2012; Krieger & Sarge, 2013; Paiva, Lipschitz, Fernandez, Redding, & Prochaska, 2014; Patel et al., 2014; Vanderpool et al., 2013). Immunization rates, as well as, barriers and facilitators to HPV vaccination among females 18 to 26 years of age were abstracted from each article. These determinants were then stratified by levels of the Socioecological Model (i.e., intrapersonal, interpersonal, organizational, community, and policy) (McLeroy, Bibeau, Steckler, & Glanz, 1988). Pile sorting was used to assign a level and theme for each determinant identified in each paper (Bernard & Ryan, 2010c).

This review summarizes the *current state of HPV vaccination* and the *barriers and facilitators* of vaccination among women 18 to 26 years of age in the United States. It is evident from this review of the literature that the majority of the research available has focused on the intrapersonal level. Primarily, researchers have been interested in investigating the knowledge,

attitudes, and beliefs regarding HPV, HPV-related outcomes, and HPV vaccination among this age group.

Intrapersonal Barriers and Facilitators

Demographic characteristics. Given the recommendation for routine vaccination of females 11 to 12 years of age, it is not surprising that HPV vaccination initiation and completion is more likely among *younger women* (i.e., 18 to 21 year olds) in the 18 to 26 year old category (Bendik et al., 2011; Bynum, Brandt, Sharpe, et al., 2011; Chao et al., 2010; Dempsey et al., 2011; Hirth et al., 2012; Laz et al., 2013; Lindley et al., 2013; Rahman et al., 2015; Tiro et al., 2012; Wei et al., 2013; Williams et al., 2015). Additionally, this age category is unique, in that one barrier to vaccination is *pregnancy* or attempting to conceive (Verdenius et al., 2013; Zimet et al., 2010). To date, the HPV vaccine is not recommended for use during pregnancy (Markowitz et al., 2014).

Additionally, disparities exist with regard to sub-populations receiving the vaccine. *Racial and ethnic minorities* tend to have lower uptake rates (Lindley et al., 2013; Williams et al., 2015). African Americans are consistently less likely to initiate and complete the HPV vaccine series compared to whites (Bednarczyk et al., 2011; Chao et al., 2010; Dempsey et al., 2011; Ford, 2011; Kharbanda et al., 2013; Laz et al., 2013; Liddon, Leichliter, et al., 2012). Asians also have lower uptake rates (Kharbanda et al., 2013). According to NHIS 2010 data, Non-Hispanic whites were the most likely to be vaccinated (25.7%), followed by Non-Hispanic Asians (22.9%), Non-Hispanic blacks (21.5%), Other (19.0%) and Hispanics (16.7%) (Williams et al., 2013). In 2013, vaccination rates changed slightly for 19 to 26 year old women to whites (43.1%), followed by blacks (30.6%), Hispanics (30.3%), and Asians (19.8%) (Williams et al.,

2015). Yet, rates for HPV vaccine uptake have increased across all racial/ethnic groups, according to NHIS 2008 to 2012 data (Schmidt & Parsons, 2014).

Having a *low income* or being below the federal poverty level was consistently associated with non-vaccination (Chao et al., 2010; Jain et al., 2009; Laz et al., 2013; Rahman et al., 2013; Wei et al., 2013). This is most likely connected to other social determinants of health (Healthy People 2020, 2014), such as access to health care, which will be explored at the organizational level. Additionally, a *lower education level* or not being in school was associated with non-vaccination and lower awareness of the vaccine (Chao et al., 2010; Ford, 2011; Gerend & Shepherd, 2011; Manhart et al., 2011; Rahman et al., 2015; Rahman et al., 2013; Tiro et al., 2012).

Knowledge. In the majority of behavioral health theories, it is recognized that a person must have awareness or knowledge of the health behavior in order to successfully engage in it (Brewer & Rimer, 2008). As a result, the bulk of the literature on HPV vaccination in females 18 to 26 year olds has focused on *knowledge levels* related to HPV and the vaccine. Unfortunately, standard measures across studies do not exist; however, most studies conclude that limited knowledge is associated with lower vaccine uptake (Bynum, Brandt, Sharpe, et al., 2011; Daley, Vamos, et al., 2010; Hodge et al., 2011; Joseph et al., 2014). Many women cited needing more information about the vaccine as a primary barrier to vaccination (Joseph et al., 2014; Ratanasiripong et al., 2013; Zimet et al., 2010). Knowledge misperceptions include transmission of HPV (e.g., oral sex, genital skin to skin contact, genetics) and likelihood of cervical cancer (Cohen & Head, 2013; Sandfort & Pleasant, 2009). It must be noted that the majority of studies assessing knowledge do so among college samples of women, who may have higher levels of education. Therefore, this may overestimate HPV vaccine knowledge levels compared to the

general public. To support this notion, one study found that knowledge about the HPV vaccine was strongly associated with college educational attainment (Kennedy et al., 2011). Regardless, the NHIS indicates that awareness of the HPV vaccine has increased across years, and is less likely cited as a main reason for non-vaccination in 2010 compared to 2008 (Schmidt & Parsons, 2014).

Attitudes and beliefs. In addition to knowledge scales, many measures exist to assess women's attitudes toward the vaccine and beliefs about the vaccine. Given the novelty of the vaccine, many early studies reported *perceived barriers* such as concern that the vaccine is too new (Bednarczyk et al., 2011; Zimet et al., 2010), concern about side effects (Bednarczyk et al., 2011; Hodge et al., 2011; Joseph et al., 2014; Ratanasiripong et al., 2013; Zimet et al., 2010), and concern about efficacy (Cohen & Head, 2013). Moreover, women also reported an overall dislike or fear toward needles, which was a primary barrier to uptake of the vaccine (Joseph et al., 2014; Ratanasiripong et al., 2013). However, these barriers may be overcome with *perceived benefits* of the vaccine. Women were more likely to be vaccinated or intend to be vaccinated with higher perceived benefits (e.g., vaccination is preventing an HPV infection), higher perceived importance of the vaccine, and a more positive attitude toward the vaccine (Bendik et al., 2011; Bennett et al., 2012; Dillard, 2011; Ratanasiripong et al., 2013; Rosenthal et al., 2011; Schaefer Ziemer & Hoffman, 2013).

Additionally, given that HPV is a sexually transmitted infection, *stigma* surrounding this characteristic is apparent. Women have reported that the vaccine may endorse sexual behavior or that they have heard of stigmatizing messages related to HPV (e.g., “people who have STDs are careless and dirty,” “only sluts get HPV,” or “if you got HPV it means you weren't smart about who you were sleeping with”); and therefore are less inclined to be vaccinated (Hopfer &

Clippard, 2011, p. 269; Joseph et al., 2014). Interestingly, little research has focused on the concept that HPV is a sexually transmitted disease or associated with genital warts; rather the focus has been on framing the vaccine as a method of cancer prevention. In fact, women were more likely to be vaccinated when the vaccine was framed as cancer prevention (Hopfer & Clippard, 2011). This corroborates the finding that vaccine uptake is more likely if women have a higher perceived severity of cervical cancer, perceived likelihood of getting cervical cancer, or higher worry about cervical cancer (Bendik et al., 2011; Krakow et al., 2015). Yet, having fatalistic beliefs regarding cancer was associated with non-completion of the HPV vaccine series (Vanderpool et al., 2015).

Control. As in many health behavior theories, confidence in one's ability to perform the behavior is integral to overcoming barriers to perform that behavior (Champion & Skinner, 2008; Montano & Kasprzyk, 2008). As would be expected, women with higher *perceived behavioral control* and *self-efficacy* were more likely to be vaccinated or intend to be vaccinated (Dillard, 2011; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). These barriers that women overcome may not only be the barriers previously described at the intrapersonal level, but may exist at higher levels.

Risk perception and risk reality. One of the largest barriers to vaccination among females 18 to 26 years of age is a result of *poor risk perception*. Non-vaccinated women consistently report a low perceived HPV risk attributed to a number of reasons, including not being sexually active or using alternative HPV prevention methods (Anhang Price et al., 2011; Cohen & Head, 2013; Gelman et al., 2013; Hodge et al., 2011; Hopfer & Clippard, 2011; Joseph et al., 2014; Laz et al., 2013; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). However, national recommendations state that the HPV vaccine is the best prevention method

for HPV compared to condoms (e.g., inconsistent effectiveness) and monogamy or no current sexual activity (e.g., the possibility of future sexual partners) (Markowitz et al., 2014).

This concept of poor risk perception as a barrier is contrasted by the risk reality of many women who initiate the HPV vaccine. Interestingly, this is a health behavior that women who participate in *high-risk behaviors* are more likely to uptake. With regards to sexual activity, women who have a lower age of sexual debut, have more sexual partners, have vaginal sex, or engage in mutual masturbation are more likely to be vaccinated (Bednarczyk et al., 2011; Bendik et al., 2011; Bernat et al., 2013; Gerend & Shepherd, 2011; Lindley et al., 2013; Manhart et al., 2011; Mills et al., 2011; Ratanasiripong, 2014; Tiro et al., 2012). Additionally, women who have already been diagnosed with HPV, have had an abnormal Pap test, and have had no Pap test were also more likely to initiate the HPV vaccination series (Anhang Price et al., 2011; Laz et al., 2013; Ratanasiripong et al., 2013; Vanderpool et al., 2011). Finally, non-sexual risk behaviors are also associated with vaccine uptake; these include cigarette smoking, illegal drug use, and alcohol use (Manhart et al., 2011; Wei et al., 2013). As a result, it may be that these women who are engaging in high-risk behaviors have a more accurate perception of their risk profile, and are therefore more likely to be vaccinated. In contrast, other women may consider themselves “protected” from HPV given their sexual health profile; thus, these women have a lower perceived risk of HPV and are less likely to initiate the HPV vaccine series. This is especially important to recognize as this catch-up age category for HPV vaccination is the only age group where independent and autonomous decision-making can take place for the individual.

Interpersonal Barriers and Facilitators

Healthcare providers. *A healthcare provider recommendation* or offer for the HPV

vaccination consistently increased initiation (Daley, Vamos, et al., 2010; Klosky et al., 2015; Licht et al., 2010; Marchand et al., 2012; Rosenthal et al., 2011; Zimet et al., 2010). Women cited not being offered the vaccine from their providers as a reason for not being vaccinated (Anhang Price et al., 2011). Additionally, women reported a high level of trust in their providers, as well as using the providers' encouragement to overcome other barriers to vaccination (Dillard & Spear, 2010; Joseph et al., 2014). Rosenthal et al. (2011) identified physician recommendation as a moderating factor influencing HPV vaccination (OR=93.5, 95% CI 39.1-223.6), and as a result stratified the analysis to understand the effect more fully. Women who received a physician recommendation were more likely to be vaccinated the stronger the recommendation (OR=1.4, 95% CI 1.1-1.9) (Rosenthal et al., 2011). Characteristics of the healthcare provider also influenced HPV vaccination; women with male providers were less likely to be vaccinated (Chao et al., 2010). Similar to this is the specialization of the practitioner; women were more likely to be vaccinated when visiting a family medicine or internal medicine physician (Chao et al., 2009, 2010). It is therefore apparent that healthcare providers have an integral role as agents to HPV vaccination.

Subjective norms. Overall, when tested, *subjective norms* (i.e., perceived social pressure to perform a behavior) were a significant predictor to HPV vaccination and intention (Allen et al., 2009; Bennett et al., 2012; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). Subjective norms were strongest when considering "important people" as influential agents in decision-making (Bennett et al., 2012). Additionally, women reported higher uptake when encouraged by important others in their social network, such as sisters, sorority members, friends, mothers, and healthcare providers (Cohen & Head, 2013). Women who perceived higher social approval were also more likely to be vaccinated (Marchand et al., 2012). Thus, examining

the social network of women is necessary in order to elicit who are these “important people” that contribute to the decision-making process for the HPV vaccine. From the literature, three groups of people emerged: family members, peers, and partners.

Family members. Receiving supportive messages or hearing about the vaccine from *family members* increased the uptake of the vaccine (Hopfer & Clippard, 2011). Alternatively, women who reported that their parents advised them not to obtain the vaccine or were against the vaccine were less likely to be vaccinated (Ratanasiripong et al., 2013). Entangled in this issue is the reported barrier to vaccination of fear of parental disclosure, which may be emphasized among women who received negative messages about the vaccine from parents or family members (Hopfer & Clippard, 2011). This fear of disclosure may also be exacerbated among women who remain on family members’ insurance plans since evidence of HPV vaccination is provided on insurance billing forms.

Among family members, one key agent among young adult women was mothers. Mother-daughter communication and approval about the HPV vaccine positively impacted daughters’ vaccine behavior (Krieger et al., 2011; Roberts et al., 2010). One reason that mothers may appear to be influential agents compared to other family members is due to the design of studies to assess only *maternal* influence; however, one study did examine the role of fathers in HPV vaccination. In fact, among rural women, the perception that *fathers* wanted them to be vaccinated was a significant predictor of HPV vaccination (Casey et al., 2013).

Peers. Women reported that *peer descriptive norms* (e.g., friends being vaccinated), which reduced the stigma of HPV vaccination, were important to increasing the likelihood of vaccination (Hopfer & Clippard, 2011). Additionally, peer approval (i.e., injunctive norms) was reported as a facilitator for vaccine initiation (Manhart et al., 2011). Among a national survey of

college students, women who reported being vaccinated were more likely to be a member of a sorority, varsity athletics, or intramural/club sports (Lindley et al., 2013). Women in these groups may experience more support from their peer social networks when participating in these activities compared to women in non-formalized types of peer groups.

Partners. One of the most consistent findings in the literature was that *married women or women in a relationship* were less likely to be vaccinated or intend to be vaccinated (Anhang Price et al., 2011; Ford, 2011; Gelman et al., 2013; Jain et al., 2009; Joseph et al., 2014; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010). Furthermore, in a national survey among college students, women who were *not* in a relationship (OR=1.59, 95% CI 1.45-1.74) or in a relationship and *not* living with their partner (OR=1.31, 95% CI 1.20-1.43) were more likely to be vaccinated compared to women in a relationship and living with their partner (Lindley et al., 2013). Hopfer and Clippard (2011) reported that women may frame their perception of HPV susceptibility based upon their relationship status (Hopfer & Clippard, 2011). Thus, partnership status, or rather monogamy, may be a *key moderator* to uptake of the HPV vaccine among this age group of women. Additionally, women were more likely to have a preference for male partners who were vaccinated, regardless of the woman's vaccination status. This preference was stronger among women with a higher perceived vulnerability to HPV (Harper, Alexander, et al., 2014). Moreover, women were more likely to be vaccinated when they perceived the vaccine as being beneficial to their partner (Patel et al., 2013). Among all key change agents influencing HPV vaccination status, it appears that partners are consistently reported in the quantitative, survey-based research, yet little examination has occurred as to *how* these key agents are influential.

Organizational Barriers and Facilitators

In this context, the organizational level includes the healthcare system organization, specifically, access to healthcare, insurance coverage, and healthcare interactions.

Insurance coverage and cost. Women who are *uninsured* or *publically insured* were consistently less likely to be vaccinated compared to women with private insurance (Anhang Price et al., 2011; Dempsey et al., 2011; Ford, 2011; Hodge et al., 2011; Jain et al., 2009; Laz et al., 2013; Lindley et al., 2013; Rahman et al., 2015; Tiro et al., 2012; Wei et al., 2013; Zimet et al., 2010). Additionally, women with insurance were more aware of the availability of the HPV vaccine compared to women without insurance (Ford, 2011; Pourat & Jones, 2012). Yet one study found that insurance continuity (i.e., having insurance over a three year period) was not a significant predictor of vaccine initiation (Cowburn et al., 2014). The issue of insurance coverage may represent a more global barrier related to the *cost of the vaccination* series. Women without insurance would need to pay out of pocket for the vaccine, which may cost approximately \$140 to \$170 per dose (American Cancer Society, 2014b; Planned Parenthood, 2014). This is especially limiting since women (19 to 26 years) are no longer eligible for some programs that can circumvent the cost, such as Vaccines for Children (American Cancer Society, 2014b). Cost was repeatedly cited as a barrier to HPV vaccination among this target population (Head & Cohen, 2012; Joseph et al., 2014; Zimet et al., 2010). Moreover, among women who were not vaccinated and interested in obtaining the vaccine, one-third reported they would not receive the vaccine if they had to pay full cost (Williams et al., 2013). While insurance coverage and cost of the vaccine represent formidable barriers to vaccination, it must be recognized that these are not the only barriers that must be removed. Two studies offered the vaccine for free to women in rural areas of the United States. In these studies, despite the elimination of the main barrier, cost,

women still faced additional barriers to being vaccinated, such as distance to the clinic and fear of pain from the vaccine (Casey et al., 2013; Vanderpool et al., 2011).

Healthcare interaction. Women without a regular healthcare provider or without a visit to a healthcare provider in the last year were less likely to be vaccinated (Tiro et al., 2012; Wei et al., 2013; Williams et al., 2013). Given that women need to be seen by a medical provider in order to receive the vaccine, a *lack of interaction with a healthcare provider* is a key barrier. In order to assess this issue, many studies have used other types of health procedures or billing codes (e.g., Pap test in past three years⁶) as surrogate measures for healthcare interaction. Women who have not had a Pap test in the past three years or were not using hormonal birth control (which requires a prescription from a healthcare provider), were less likely to be vaccinated (Wei et al., 2013). Moreover, women who had sexually transmitted infection tests or Pap tests were more likely to be vaccinated compared to women who did not (Chao et al., 2010; Laz et al., 2013). Additionally, women who did not receive other types of vaccinations, such as influenza or Hepatitis B, were also less likely to be vaccinated (Anhang Price et al., 2011; Jain et al., 2009; Laz et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013). However, there are some types of visits that reduce the likelihood of vaccination. Women with an obstetric history (e.g., birth, pregnancy or abortion in medical record) or having one or more pregnancies were less likely to be vaccinated (Chao et al., 2009, 2010; Verdenius et al., 2013). Similarly, women with more emergency department visits were less likely to complete vaccination; this may be the result of more serious health conditions that take priority to HPV vaccination or a proxy measure of lack of insurance (Chao et al., 2009). In order to help facilitate

⁶ At the time of data collection (2010), Pap tests were recommended for women at the onset of sexual activity every three years.

HPV vaccination completion, utilization of immunization only appointments can increase rates of completion, especially for second and third doses (Dempsey et al., 2011).

Community Barriers and Facilitators

Region. Women residing in the *Northeast, West, or North Central/Midwest* were more likely to uptake the HPV vaccine compared to other United States' regions, while controlling for confounders, such as race and socioeconomic status (Lindley et al., 2013; Wei et al., 2013). Additionally, women in the South were the least likely to be vaccinated; however, these women reported the most interest in the vaccine (Rahman et al., 2013; Schmidt & Parsons, 2014). Thus, women in the South may face barriers to receiving the vaccine despite an interest in uptake.

Accessibility. Not only is region of the United States a factor impacting HPV vaccination among young adult females, but also level of urbanization. Women living in *rural areas* may face more difficulties physically accessing the HPV vaccine and thus have lower rates of uptake (Crosby et al., 2011; Hodge et al., 2011). Rural women reported wanting more accessible community locations where they could receive the vaccine (Mills et al., 2013). Additionally, accessibility may be impacted by a number of factors, including not knowing where to get the vaccine, transportation barriers, and other responsibilities (e.g., childcare, work, or school) (Mills et al., 2013). Confounding the issue of accessibility is the necessity for the *three-dose* vaccine, meaning three separate visits, which serve as additional barriers (Head & Cohen, 2012).

Policy Barriers and Facilitators

No studies reported policy-related barriers or facilitators to HPV vaccination among this specific age and gender group. However, this does not indicate there are none present.

Interventions

There is a dearth of interventions implemented among this population in order to increase HPV vaccination rates. Included in this review are nine studies that attempted to improve HPV vaccination intention, uptake, or completion. The majority of these interventions implemented educational techniques (e.g., tailored binder of information, education video, narrative message, fact sheet, online information, or DVD) (Gerend & Shepherd, 2012; Gerend, Shepherd, & Lustria, 2013; Hopfer, 2012; Juraskova et al., 2012; Krieger & Sarge, 2013; Paiva et al., 2014; Vanderpool et al., 2013).

Among these studies, a tailored educational binder to perceived barriers improved HPV vaccination intentions compared to a non-tailored message among unvaccinated college women. One of these barriers was “I’m in a monogamous/committed relationship.” While overall the intervention improved intention for vaccination, it is unknown the effect of each specific message (Gerend, Shepherd, & Lustria, 2013). Additionally, a DVD intervention improved completion of the HPV vaccination series compared to standard of care among a community sample of women (Vanderpool et al., 2013). One randomized control trial compared the effect of disease framing of HPV (either cervical cancer or genital warts) in a fact sheet among female university students; there was no significant effect (Juraskova et al., 2012). Similar results were found for a video that used loss-framing (i.e., emphasizing the costs of not getting vaccinated) or gain-framing (i.e., emphasizing the benefits of getting vaccinated) for vaccination among unvaccinated college women; there was no significant difference in vaccination between groups (Gerend & Shepherd, 2012). In comparison, another study assessed disease message framing and found framing HPV within the context of genital warts impacted intentions to talk to a healthcare provider about the HPV vaccine among college-age females (Krieger & Sarge, 2013). One other

study found a computer-based, tailored, education intervention to be feasible and acceptable among a sample of college women (Paiva et al., 2014). A potential bias of the majority of these educational interventions is that these were conducted among college/university students, who may have higher knowledge levels than community-based samples of 18 to 26 year old women (Kennedy et al., 2011), thus diminishing the effects of these interventions.

Patel et al. (2014) aimed to improve completion of the HPV vaccine series among women in a community reproductive health center. The intervention used cues to action, specifically automated reminder messages. These were delivered from the reproductive health center via patient's preferred method of communication. The reminder system did not successfully increase completion rates (Patel et al., 2014).

Only one study emphasized the role of healthcare providers and peers in vaccination at a university health center. In this randomized control trial, health messages included HPV susceptibility, self-efficacy and safety. These messages were delivered by four types of agents: peer only, medical expert only, combination or peer and medical expert, or neither. At the two month follow-up, the peer-expert combination had the strongest effect (OR=2.01, 95% CI 1.05-4.10), while the other modes of delivery did not significantly impact HPV vaccination (Hopfer, 2012).

Application of Theory in Interventions

The majority of these studies utilized a theoretical framework to develop or evaluate the intervention implemented. These theoretical frameworks included: the Health Belief Model using only the perceived barriers construct for the study (Gerend, Shepherd, & Lustria, 2013; Gerend, Shepherd, & Shepherd, 2013), the Culture-Centric Narrative Theory (Hopfer, 2012), the

Theory of Planned Behavior (Juraskova et al., 2012; Vanderpool et al., 2013), the Extended Parallel Process Model (Krieger & Sarge, 2013), the Transtheoretical Model (Paiva et al., 2014), and a combination of the Theory of Planned Behavior and the Health Belief Model (Gerend & Shepherd, 2012). Only one study did not use a theoretical framework in the intervention (Patel et al., 2014).

Limitations of Current Research

The review of the literature revealed as plethora of barriers and facilitators to HPV vaccination among young adult women. Despite the large amount of evidence describing these multi-level factors, there are a limited number of interventions among women 18 to 26 years of age. Among the nine interventions included in this review, only two included tailoring to specific sub-sets of women (e.g., tailored to perceived barriers or stage of change) (Gerend, Shepherd, & Lustria, 2013; Paiva et al., 2014). Yet, evidence supports the use of tailoring for health messages (Kreuter & Wray, 2003), more specifically with HPV vaccine messages (Allen et al., 2009; Gerend, Shepherd, & Lustria, 2013; Reiter, Brewer, Gottlieb, McRee, & Smith, 2009b). Therefore, it is necessary to identify the types of characteristics among the target population that require segmentation and tailored message framing in order to improve HPV vaccination.

Relationship Status and HPV Vaccination among Young Adult Women

According to the literature review, one of the most consistent predictors of HPV vaccination is relationship status among young adult women. Specifically, women in long-term or monogamous relationships are less likely to be vaccinated. The bulk of the available research has focused on epidemiological risk factor associations regarding relationship status and HPV vaccination using cross-sectional designs and large datasets or surveys. None of these studies

have investigated how relationship status operates as a risk factor and how to intervene to improve vaccination rates among young adult women.

Relationship Status is a Predictor of Vaccination – Quantitative Data

Among studies conducted within the 18 to 26 year old female target population, there are 14 studies supporting the association between relationship status and HPV vaccination (Anhang Price et al., 2011; Bernat et al., 2013; Ford, 2011; Joseph et al., 2014; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012; Lindley et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010). The majority of these studies utilized nationally-representative surveys, including the National Health Interview Survey (NHIS)⁷, the National Survey of Family Growth (NSFG)⁸, the Behavioral Risk Factor Surveillance System (BRFSS)⁹ and the National College Health Assessment (NCHA)¹⁰ (Table 7).

Using data from NHIS surveys between 2008 and 2010, adjusted odds ratios reporting the association between relationship status (reference group = married/in relationship) and HPV vaccination uptake ranged between 2.4 to 4.1, all statistically significant (Anhang Price et al., 2011; Laz et al., 2013; Wei et al., 2013; Williams et al., 2013). Similar findings were reported for NHIS data examining interest in the HPV vaccine (Schmidt & Parsons, 2014). Analyses using NSFG utilized different parameters for their populations and examined initiation of vaccination and intention for vaccination; all analyses found statistically significant associations between

⁷ NHIS is used to monitor the health status of the U.S. population on a range of health topics.

⁸ NSFG is used to describe pregnancy, fertility, and contraception rates among U.S. men and women.

⁹ BRFSS is used to monitor prevalence of major behavioral risk factors among the U.S. population.

¹⁰ NCHA is used to monitor the health status and risk factors for participating U.S. universities.

Table 7: Quantitative Studies Reporting Effect of Relationship Status on HPV Vaccine Uptake

Publication	Years	Dataset, Sample Age	OR, 95% CI	Comparison Group	Referent Group
Ford, 2011	2007-08	NSFG, 18-24	7.7, 1.8-33.3 [†]	Single	Married
Liddon, et al., 2012	2007-08	NSFG, 20-24	2.7, 1.4-5.4	Never Married	Other
Rahman, et al., 2013	2008-10	BRFSS, 18-26	1.4, 1.29-1.6 [†]	Never Married	Other + Married
Anhang, et al., 2011	2008	NHIS, 18-26	4.1, 1.9-8.6	Other	Married
Lindley, et al., 2013	2009	NCHA, 18-24	1.6, 1.5-1.7	Not in a relationship	In a relationship/ living together
Laz, et al., 2013	2010	NHIS, 18-26	3.1, 1.7-5.6	Single	Married
Wei, et al., 2013	2010	NHIS, 18-26	2.4, 1.4-4.2	Never Married	Married or living together
Williams, et al., 2013	2010	NHIS, 18-26	2.4, 1.4-4.2	Other	Married

[†]Inverse of the odds ratio calculated for consistency of referent group

these outcomes and relationship status (Ford, 2011; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012). One study used the BRFSS dataset for 2008 to 2010 and found that women who were married, divorced, widowed, or separated were less likely to be vaccinated than single, never married women (Rahman et al., 2013).

Overall, the survey-based, quantitative research supports the finding that young adult women in relationships are less likely to receive or have interest in the HPV vaccine compared to young adult women who are single. This consistent epidemiological support warrants further investigation to how this risk factor may be moderating HPV vaccination uptake among the 18 to 26 year old female population.

A Women's Health Issue

While males (18 to 21 years old, and 21 to 26 years old for high risk populations) may also make autonomous decisions regarding HPV vaccination in young adulthood, relationship status does not appear to be a significant risk factor among this group. In a systematic review examining HPV vaccine acceptability among males, relationship status was not a significant demographic factor identified in the 29 included studies (Newman et al., 2013). Moreover, in a web-based survey among young adult males and females, there were differences in factors associated with vaccine uptake; in particular marital status was a predictor among females and not a predictor among males (Bernat et al., 2013). This indicates the possibility of differences in risk profile among males and females in this age category for HPV vaccination.

Hypothesized Mechanism

While the epidemiological data support the connection between relationship status and HPV vaccination, these studies have not attempted to understand the mechanism for this association. However, other quantitative findings investigating perceived risk or susceptibility may connect this risk factor to HPV vaccination. Specifically, women who have lower HPV risk perceptions are less likely to be vaccinated (Anhang Price et al., 2011; Cohen & Head, 2013; Gelman et al., 2013; Hodge et al., 2011; Hopfer & Clippard, 2011; Joseph et al., 2014; Laz et al., 2013; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). Schaefer Ziemer and Hoffman (2013) examined how Health Belief Model constructs differed between vaccinated and unvaccinated women. Many unvaccinated women reported that they did not need the vaccine since they did not perceive themselves as at risk, especially with monogamous partners. Thus, these women were evaluating their proximal risk for HPV based on their current relationship or

sexual partnership rather than considering their future risk for HPV. A similar evaluation of risk occurs among women who report never having had sex and do not intend to be vaccinated; these women are also altering their risk perceptions for HPV based on proximal factors, but based on current sexual behavior (Liddon, Hood, et al., 2012). Schaefer Ziemer and Hoffman (2013) suggest that future behavioral HPV vaccination research and interventions should emphasize that future behavior and partner behavior affect HPV risk among women.

Similarly, Cohen and Head (2013) found that unvaccinated women reported an attitude of low perceived risk for HPV, which was supported by the beliefs that HPV can be prevented through monogamy and knowledge of their partners' sexual history. To date, only one qualitative study has investigated the narratives of HPV vaccinated and unvaccinated women as it relates to sexual behavior (i.e., sexually active, not sexually active). Hopfer and Clippard (2011) reported an emerging finding from this study that women framed their risk perceptions for HPV based on relationship status. Again, false beliefs regarding risk for HPV were prominent among these young adult women, including "I don't feel personally vulnerable [to HPV] because I am in a committed relationship where we are only seeing each other" (Hopfer & Clippard, 2011, p. 272).

Moreover, this discordance between risk perception and risk reality among women in this age category is evident among traditionally sexually high-risk groups (e.g., multiple sexual partners, previously diagnosed with HPV). In this case, many of the high-risk groups are getting vaccinated compared to the perceived low risk counterparts (Anhang Price et al., 2011; Bednarczyk et al., 2011; Bendik et al., 2011; Bernat et al., 2013; Gerend & Shepherd, 2011; Laz et al., 2013; Lindley et al., 2013; Manhart et al., 2011; Mills et al., 2011; Ratanasiripong et al., 2013; Tiro et al., 2012; Vanderpool et al., 2011). Overall, this concept is counterintuitive to

typical health-related research, which focuses on high-risk groups not accessing healthcare services.

Young adult women are not the only group with false beliefs regarding risk for HPV. Healthcare providers may also be contributing to the low HPV vaccine uptake among women in relationships. Zimet et al., (2011) reported physicians giving a lower priority to vaccinating female patients who were married or in a monogamous relationship compared to women who were single or dating. In contrast, these physicians surveyed did not alter priority perceptions based on women's sexual history (e.g., HPV infection, abnormal Pap test) (Zimet et al., 2011). Thus, healthcare providers may suffer from the same risk perception bias as young adult women regarding relationship status and HPV vaccination. This finding is concerning since recommendation for vaccination from a healthcare provider was significantly associated with HPV vaccine uptake among this population. Rosenthal et al. (2011) found that the strength of physician recommendation was the strongest predictor of HPV vaccine uptake, and in fact marital status was no longer a significant predictor. The authors suggested that despite married women being less inclined to be vaccinated, a strong physician recommendation may increase that likelihood (Rosenthal et al., 2011).

But isn't, "Monogamous Sex, Safe Sex"?

While monogamy is considered a protective factor for many sexual and reproductive health outcomes, it is not necessarily a guarantee to be protected from HPV throughout the lifespan. In the United States, monogamy is often conflated with serial monogamy. Most people are not lifetime monogamists with only one sexual partner (Conley, Ziegler, Moors, Matsick, & Valentine, 2013). The average number of lifetime partners among women in the U.S. is 3.6,

according to the National Survey of Family Growth 2006-2008 (Chandra et al., 2011). Evidence supports that serial monogamy is considered a risk factor for acquiring HPV. Even if a woman's current sexual partner is monogamous, that does not circumvent the issue of that partner's previous sexual network, which is critical for HPV transmission (Burchell et al., 2006). Additionally, recent research has evaluated the prevalence of HPV in recently formed partnerships. The study found that heterosexual dyads in their "first relationship" with vaginal sex had a prevalence of HPV that was approximately 17% (Burchell et al., 2014).

Moreover, if a woman has one sexual partner at the time for her vaccination decision, that does not preclude her from exposure to HPV at the time of vaccination or in the future. The prevalence of HPV is highest among females age 20 to 24 (59.8%, 95% CI 54.0-65.3%) (Markowitz et al., 2013). Furthermore, it is estimated that the average lifetime probability of acquiring HPV among women with at least one male partner is approximately 85% (Chesson, Dunne, et al., 2014). In a study examining the incidence of HPV among heterosexual couples, women in a heterosexual relationship had a 28% (95% CI 14%-40%) cumulative incidence of any HPV type and 17% (95% CI 8%-26%) cumulative incidence of oncogenic HPV over a 12 month period. The 24 month prevalence of HPV among women in a heterosexual couple was 67.7% for any type of HPV and 46.5% for oncogenic HPV types (Nyitray et al., 2013). This demonstrates that the risk for HPV among women in relationships or with lower sexual risk profiles is not as low as perceived.

Despite this evidence supporting the risk for HPV with serial monogamy, heuristic beliefs regarding the safety of monogamy overshadow the actual risk. Monogamy is perceived as being "safe sex" and protecting individuals from STIs. However, serial monogamy without additional protective behaviors (e.g., STI testing, waiting an amount of time for sexual behavior)

does not necessarily protect against STIs. In fact, serial monogamy may produce added risk for an individual who proceeds with sexual interaction with a partner without added precautions, such as condom use (Conley et al., 2013).

Impact of Relationship Status on Other Health Behaviors

Other sexual and reproductive health behaviors are influenced by relationship status, specifically condom use. A similar discrepancy occurs where persons in regular, long-term relationships have less condom use compared to more transient or new relationships (Macaluso, Demand, Artz, & Hook, 2000; Santelli et al., 1996). However, the differences between how condom use and HPV vaccination relates to relationship status may be attributed to the proximity of the behavior and outcome. Condom (non-)use and its associated outcomes, such as pregnancy and STIs, is a proximal connection between behavior and outcome. In contrast, HPV vaccination and its associated outcomes, such as future HPV infection or HPV-associated cancers, is a more distal association between behavior and outcome. Thus, the connection of relationship status to perceived risk of an outcome may be operating similarly among condom use and HPV vaccination; however, it may differ based on the proximity of the outcome (e.g., short term STI vs. long-term cervical cancer).

Theoretical Framework

The theoretical framework utilized for this study was the Information, Motivation, and Behavioral Skills (IMB) Model to understand and promote HPV vaccination among young adult women (Fisher & Fisher, 2002; Fisher, 2012). This study was supplemented with two constructs from the Health Belief Model, perceived severity and perceived susceptibility, which were

included within the Risk Perception sub-construct of the Motivation construct of IMB (Champion & Skinner, 2008).

IMB Model Overview

The IMB Model was developed as a way to understand HIV risk and prevention in the context of social-psychological conceptualizations (Fisher & Fisher, 2002). Not only does the IMB Model provide a theoretical framework that can be applied to a range of preventive behaviors, including condom use (Misovich, Fisher, & Fisher, 1997), but it also has a methodological approach for designing theory-based interventions. Specifically, the approach involves three steps: elicitation, intervention design and implementation, and evaluation of the intervention (Fisher & Fisher, 1992). The IMB Model includes three overall determinants to behavior: information, motivation, and behavioral skills (see Table 8 for the description of each construct and an example application to HPV vaccination). There are sub-categories within the motivation and behavioral skills constructs, which further delineate the determinants for behavior. In addition to these constructs, the IMB Model also recognizes macro-level factors that may work directly or indirectly to influence a behavior (Fisher, 2012).

IMB Model Application to Condom Use and Relationship Status

As previously stated, the IMB Model was initially developed as a behavioral framework for preventing HIV. As such, one of the health behaviors of interest was condom use. Interestingly, previous research has been conducted to evaluate the impact of relationship status on condom use utilizing the IMB Model, and the finding may have some application to this current research (Misovich et al., 1997).

Table 8: IMB Model Constructs and Application to HPV Vaccination Examples

Construct	Definition	Application
Information	Information regarding preventive behavior	Information about risk for HPV and potential protection from HPV vaccination
Motivation Personal Social Perceived vulnerability	Attitudes toward practicing preventive acts Perceptions of social support for performing acts Perceived vulnerability to the disease/outcome	Distrust of vaccines Physician recommendation Perceived vulnerability to HPV
Behavioral Skills Objective ability Perceived self-efficacy	Ability to perform behavior Confidence in ability to perform behavior	Schedule appointment Confidence to discuss vaccine with partner
Macro Factors	Factors that directly or indirectly impact behavior	Insurance coverage and vaccine cost

Within this model, Misovich, Fisher & Fisher (1997) posit that distinctive Information, Motivation, and Behavioral Skills exist among persons in a relationship and the use of condoms. Regarding *Information*, people in relationships are more likely to rely on heuristic beliefs that “monogamous sex is safe sex” and “known-partners-are-safe-partners.” These beliefs may impede the individual from appropriately evaluating the risk of unprotected sex and the risk for HIV. Moreover, there appear to be beliefs that limit the individual from evaluating their partner’s risk for HIV, further elevating risk. For *Motivation*, personal motivation for condom use is largely associated with trust in the relationship and of the partner. Especially if the individual does not receive social support for condom use from their partner, they are less likely to engage in the behavior. The most important motivating factor, which aligns with the issues described in the information construct, is the low perceived vulnerability for HIV for themselves and partners. These are largely formed by the false heuristic beliefs that inform the risk evaluation. Finally, the

Behavioral Skills described are unique to the self-efficacy and ability to perform behaviors related to condom use, specifically negotiating use with a partner and maintaining proper use (Misovich et al., 1997).

The authors of this review emphasized the unique composition of the IMB Model constructs for persons in relationships as it relates to condom use. The deficits in each of these constructs should be targeted for prevention interventions in order to improve condom use (Misovich et al., 1997). Moreover, the findings from this review have implications for this research. Specifically, the *Information* and *Motivation* constructs report heuristic beliefs, partner-specific influences, and perceived risk that translate for HPV vaccination among women in relationships. Thus, these findings were applied in the in-depth interview guide instrument development to recognize the potential issues that women may face for HPV vaccination decisions in the context of the IMB Model.

IMB Model Application to Current Study

The IMB Model was used as the theoretical framework for guiding the study of informational needs, motivations, and behavioral skills framed by relationship status impacting HPV vaccination among young adult females (Figure 2). The study involved an assessment of the four constructs (i.e., information, motivation, behavioral skills, and macro-level factors), which may influence HPV vaccination behavior among four groups of women: (1) married or living with a partner; (2) single, but in a long-term monogamous relationship; (3) single and dating; and (4) single, but not in a relationship or dating (Zimet et al., 2011). These constructs were also assessed across two groups of women based on vaccination status: (1) recently HPV vaccinated; and (2) HPV unvaccinated.

The first construct considered is *Information*. Traditionally, the IMB Model has described this construct as cognitive processes that influence a behavior. However, given that women are receiving information from a range of health information sources (e.g., Internet, peers, family, partners, healthcare providers) (Daley, Vamos, et al., 2010; Sandfort & Pleasant, 2009), it is necessary to include a measure of trustworthiness or value regarding these information sources. The more valued the information source, the more likely the woman may be to prioritize that information (Redmond, Baer, Clark, Lipsitz, & Hicks, 2010; Worsley, 1989). Additionally, information about HPV and the HPV vaccine can influence motivation, behavioral skills, and

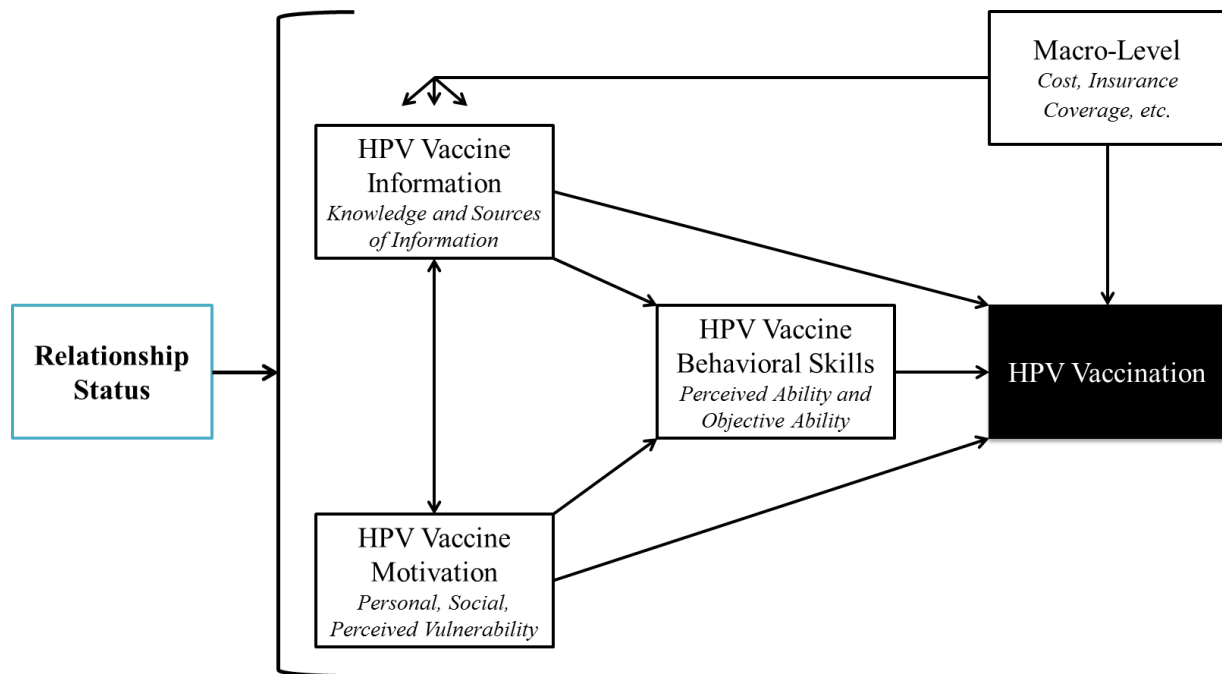


Figure 2: Application of IMB Model to HPV Vaccination in Young Women

vaccination. Many women cited needing more knowledge about the vaccine as a primary barrier to vaccination, indicating how lack of information may impact motivations or behavioral skills to vaccination (Joseph et al., 2014; Ratanasiripong et al., 2013; Zimet et al., 2010). Moreover, from

the literature, there appear to be heuristic beliefs that monogamous sex is safe sex or that condoms alone can prevent the transmission of HPV (Anhang Price et al., 2011; Cohen & Head, 2013; Gelman et al., 2013; Hodge et al., 2011; Hopfer & Clippard, 2011; Joseph et al., 2014; Laz et al., 2013; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). These informational beliefs may inform how women align their current sexual health behaviors and relationships with the need for the HPV vaccine. Therefore, Phase II of the study included a measure of women's basic knowledge of HPV and the HPV vaccine, as well as assess the information's source trustworthiness, which may impact how likely that person is to act on that information. Additionally, in Phase I of the study, some of the NHIS reasons for non-vaccination align with these false beliefs reported in the literature (e.g., don't know enough about the vaccine; not sexually active). How these differ based on relationship status is reported.

The second construct is HPV vaccine *motivation*. Fisher & Fisher have conceptualized this construct to include three primary components: personal motivation, social motivation, and perceptions of personal vulnerability to the disease (Fisher & Fisher, 2002). In this study, personal motivation encompassed factors such as attitudes about vaccination and perceived benefits and barriers to vaccination. Additionally, social motivation included perceived support and social norms from significant others. From the review of the literature, important others include: healthcare providers, partners, parents/family, and peers. Therefore, this study elicited the injunctive norms of approval/disapproval from important others for HPV vaccination. Perceptions of personal vulnerability to HPV will also be evaluated to determine if risk perceptions regarding acquiring HPV differ based on relationship status and motivate the need for HPV vaccination. The concept of personal vulnerability to HPV was operationalized utilizing the Health Belief Model constructs of perceived susceptibility and perceived severity, which

together operate as perceived threat. Perceived susceptibility is one's belief regarding the chance of getting a condition, in this case HPV and HPV-related outcomes. Perceived severity is one's belief of the seriousness of the health condition (Champion & Skinner, 2008). The combination of the Health Belief Model perceived threat construct with the IMB Model has been used and evaluated previously (DeBate et al., 2013).

Behavioral skills is the third construct of the IMB Model. This concept is typically ignored in other health behavior theories, which only emphasize perceived ability or control, rather than actual skill or competence to perform the behavior. The skills considered integral to HPV vaccination include: communication with important others (e.g., healthcare provider, partner), funding the vaccine, accessing the vaccine, and complying with the three dose series (Fisher, 2012). To help understand the skills required for vaccination, participants were asked to describe how they would go about obtaining the HPV vaccine (unvaccinated) or how they went about getting the vaccine (vaccinated) in order to elicit the procedural knowledge to obtain the vaccine.

The final construct included the *macro-level factors*, which are higher-level determinants that may directly or indirectly impact behavior. From the review of the literature, it was clear that HPV vaccination is not only situated at an intrapersonal level; rather, higher levels of influence impact this behavior. The review of the literature revealed barriers that extend beyond a woman's control, including cost of the vaccine, insurance coverage, and healthcare interaction (Anhang Price et al., 2011; Dempsey et al., 2011; Ford, 2011; Head & Cohen, 2012; Hodge et al., 2011; Jain et al., 2009; Joseph et al., 2014; Laz et al., 2013; Lindley et al., 2013; Tiro et al., 2012; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010). It was important to take into

consideration these potentially significant macro-level barriers that can impact a woman's HPV vaccination behavior.

This study has the potential to move the IMB Model field forward by demonstrating application of the model to the HPV vaccination topic among young adult females. Fisher (2012) emphasized the need for research using the IMB Model for this specific behavior, HPV vaccination. Empirical evidence to support the framework in the elicitation phase will support the justification that this robust theory has the ability to explain vaccination behavior in this population. Moreover, the research findings from this study can inform the development of validated instruments for using the IMB Model for HPV vaccination in quantitative research studies. This can eventually assist in the development and evaluation of theory-based interventions using the IMB Model.

In summary, the IMB Model is the most appropriate theoretical framework for guiding the research to understand *why* and *how* informational needs, motivations, and behavioral skills may be framed by relationship status for HPV vaccination among young adult females. This robust framework comprises information, motivation, behavioral skills, and macro-level factors constructs that can be applied to this focused area of research.

CHAPTER 3: METHODS

Overview

The long-term goal of this research is to increase HPV vaccination rates among young adult women 18 to 26 years of age, ultimately decreasing HPV-related disease (i.e., HPV-associated cancers, genital warts). The purpose of this study was to understand how young adult women's relationship status influences informational needs, motivations, and behavioral skills related to HPV vaccination. This objective was achieved through the following specific aims and mixed-methods study design:

1. Assess how relationship status affects primary reasons for non-vaccination among 18 to 26 years old women.

A secondary data analysis using the 2010 National Health Interview Survey was conducted to determine if women in relationships were less likely to be *interested* in vaccination and identify the *primary reasons* (e.g., misinformation, motivations, behavioral skills) for non-vaccination among different relationship status groups.

2. Understand how relationship status frames HPV vaccine informational needs, motivations, and behavioral skills among 18 to 26 year old women.

In-depth interviews were completed with a sample (N=50) of 18 to 26 year old women at the University of South Florida, stratified by relationship status and HPV vaccine status. A comparative thematic analysis was conducted to determine if there were differences in informational needs, motivations, behavioral skills, and HPV decision-making.

Timeline

Table 9: Timeline for Dissertation Research Study

Activity	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct
Dissertation proposal	X								
Phase I									
IRB approval		X							
Data cleaning		X							
Data analysis		X	X						
Report findings			X	X	X	X	X	X	X
Phase II									
Develop instruments	X								
Pilot interview guide and recruiting materials	X								
Finalize instruments		X							
IRB approval		X							
Recruitment		X	X						
Data collection		X	X						
Data analysis			X	X	X				
Report findings						X	X	X	X
Dissertation defense									X

Population

HPV vaccination is approved for use among adolescent females 11 to 12 years of age, but also as catch-up vaccination until the age of 26 (Centers for Disease Control and Prevention, 2010a; Markowitz et al., 2007). The target population for this research study was women in the 18 to 26 year old age range. Two separate samples were used in this concurrent mixed-methods study that included this target population. The first sample for Phase I was derived from a nationally-representative cross-sectional survey and restricted to 18 to 26 year old females who were HPV unvaccinated. The second sample for Phase II was recruited from the University of South Florida and included 18 to 26 year old females based on relationship status and HPV vaccination status.

Approach

This mixed-methods study design included two separate phases that both aligned with the study objective to understand how young adult women's relationship status influences informational needs, motivations, and behavioral skills related to HPV vaccination. Phase I was a quantitative analysis of a nationally-representative health survey and Phase II was a qualitative analysis of in-depth interviews from a smaller sample of women.

Phase I: Quantitative, Secondary Data Analysis

Overview

The purpose of this research phase was to assess how relationship status affects the primary reasons for non-vaccination among women 18 to 26 years old. To achieve this goal, a

secondary data analysis was conducted using the National Health Interview Survey (NHIS) 2010 with supplemental cancer questions related to HPV vaccination. Previous studies using this dataset have reported marital status as a significant factor for HPV vaccine uptake among this population and reported the overall primary reasons for non-vaccination; however, there has not been a specific investigation regarding the different categories of marital status (e.g., single, married, divorced, separated, widowed) and vaccination interest, combined with reasons for non-vaccination among young adult women (Laz et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013).

Subjects and Setting

The purpose of the NHIS is to monitor the health status of the United States' population among civilian noninstitutionalized persons. The survey has been conducted since 1957 and the content of the survey is continuously updated. The NHIS is a cross-sectional household interview survey with a multistage area probability design sampling plan that is representative of households in the United States. The sampling plan is updated following each decennial census. Moreover, the sampling procedure oversamples for Black, Asian and Hispanic persons. For the 2010 survey, within each household sampled, one civilian adult was randomly selected to complete the Sample Adult questionnaire. Survey participation was completely voluntary. Details regarding the complex sampling design for the NHIS can be found in Parsons et al. (2014). The 2010 survey data were collected through a household interview by trained interviewers from the U.S. Bureau of the Census. The questionnaire was completed using a computer assisted personal interviewing device, where interviewers can directly impute the participants' responses.

The 2010 survey included a final sample size of 27,157 for persons 18 years of age or older that completed the Sample Adult component of the interview. The conditional response rate for this component among eligible sample adults was 77.3%. However, the final response rate for the Sample Adult was 60.8% considering the refusal household response rate (Division of Health Interview Statistics & National Center for Health Statistics, 2011a)

Phase I: Research Question I

Research question. Among unvaccinated 18 to 26 year old women, were married women less likely to be interested in HPV vaccination compared to non-married women? It was hypothesized that women who were married (in a relationship) were less likely to be interested in the HPV vaccine compared to non-married women.

Sample. The sample was restricted to NHIS Sample Adults (N=27,157) who were female and between the ages of 18 to 26 years (N=2,011). The sample was further restricted to women who responded to the HPV vaccine questions (N=1,892) and were not vaccinated with the HPV vaccine (N=1,461) as these participants responded to the *interest in the HPV vaccine* questions. Finally, cases were removed that had missing data for the primary analysis variables, including HPV interest (N=1) and unknown marital status (N=3). This resulted in a final sample size of 1,457 women for Analysis 1 (Figure 3).

Data collection procedures. The datasets, formats, and codebooks were downloaded from the NHIS website. These included information from the Person, Sample Adult, Cancer Supplement, and Income Imputation datasets. The datasets were sorted by household and persons ID numbers (HHX and FPX) and merged together in SAS 9.4. Only variables required for this analysis were kept in the final dataset.

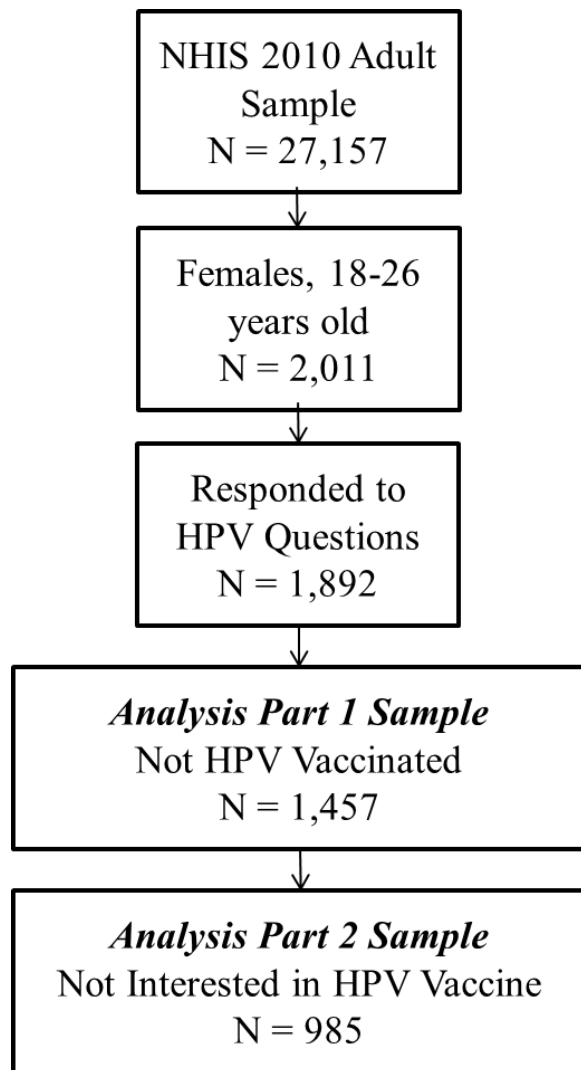


Figure 3: NHIS Sampling Strategy

Instrumentation. The variables considered for this analysis were based on previous HPV vaccine research among young adult women (Laz et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013). Univariate analysis procedures, such as Proc Survey Freq and Proc Survey Means, were used to examine the distribution of each variable. Additionally, NHIS codebooks were consulted to identify any skip patterns in the dataset. Based on this review, the variables for consideration in the final model were re-coded (Table 10).

Table 10: Recoding of Variables for Phase 1 Research Question 1 Analysis

Description	Variable	Question	Response Categories
Primary Variables			
Interest in Vaccine	HPVINT	Would you be interested in getting the HPV vaccine?	1 Yes 2 No or Don't Know
Relationship Status	R_MARITL	Are you now married, widowed, divorced, separated, never married, or living with a partner?	0 Married 1 Widowed, Divorced, or Separated 2 Living with Partner 3 Never married
Health-Related Variables			
Had HPV	HPVHAD	Have you ever been told by a doctor or other healthcare professional that you had HPV?	0 Yes 1 No or Don't Know
Heard HPV Vaccine	SHHPVHRD	Two vaccines, or shots, to prevent HPV infection are available in the United States. Both vaccines prevent cervical cancer and one also prevent genital warts. The two HPV vaccines are sometimes called CERVARIX ® or GARDASIL ®. Before this survey, have you ever heard of HPV vaccines or shots?	0 Yes 1 No
Abnormal Pap Test	PAPABN3	Have you had a Pap test in the LAST 3 years where the results were NOT normal?	0 Yes 1 No (includes women who did not have a Pap in the last 3 years)
Regular Healthcare Provider	AMDLONG	About how long has it been since you saw or talked to a doctor or other healthcare professional about your own health?	0 In the last year 1 More than a year
OB/GYN	AHCSYR7	During the past 12 months, have you seen or talk to any of the following healthcare providers about your own health? A doctor who specializes in women's health?	0 In the last year 1 More than a year

Table 10 (Continued)

General Physician	AHSCY8_9	During the past 12 months, have you seen or talk to any of the following healthcare providers about your own health? A doctor who treats a variety of illnesses (a doctor in general practice, family medicine, or internal medicine)?	0 In the last year 1 More than a year
Flu Shot	SHTFLUYR	During the past 12 months, have you had a seasonal flu shot?	0 Yes 1 No
Hepatitis B Shot	SHTHEPB	Have you EVER received the hepatitis B vaccine?	0 Yes 1 No
Demographic Variables			
Region	REGION	NHIS – Recode	0 Northeast 1 Midwest 2 South 3 West
Hispanic	ORIGIN_I	Does person consider self Hispanic/Latino?	0 Yes 1 No
Race	RACERPI2	NHIS – Recode	0 White only 1 Black/African American only 2 Other (AIAN, Asian, Other, Multiple Race)
Age	AGE	NHIS – Recode	0 18-21 years 1 22-26 years
Education	EDUC	What is the HIGHEST level of education you completed or the highest degree you have received?	0 Less than High School Diploma 1 GED or High School Diploma 2 More than High School
Health Insurance	NOTCOV	NHIS – Recode	0 Not covered or Don't know 1 Covered
Family Income	POVRATI3	NHIS – Recode and Multiple Imputation Ratio of family income to the federal poverty level	0 200% + 1 100% < 200% 2 < 100%

The initial research plan intended to utilize personal reported income in the last year as a measure of income for this analysis. However, upon examining the frequencies for this variable, 440 participants had missing data (due to skip pattern of being an unemployed adult), 106 did not know, and 43 refused to answer. Due to the amount of missing data for the income variables in the NHIS dataset, multiple imputation was utilized as an analysis tool to account for the missing data. Five separate datasets were developed by the NHIS with the imputed values for family income. These imputations were based upon a variety of demographic and health-related variables. The imputed family income variable was transformed using the U.S. Census Bureau's poverty threshold to calculate the poverty ratio value (Division of Health Interview Statistics & National Center for Health Statistics, 2011b).

For this analysis, the Income Imputation file was downloaded from the NHIS website and the SAS code for multiple imputation was used to generate the 5 separate imputed datasets. Each of these datasets was merged with the primary study dataset including the variables listed above. Family poverty ratio was the only variable in this analysis that included imputed values. This continuous variable was then transformed into a 3-level categorical variable (<100%, 100% < 200%, and 200% + of the federal poverty level).

Data analysis. All analysis procedures utilized survey-weighted SAS 9.4 procedures, unless otherwise specified. These survey-weight procedures were weighted using primary sampling units, strata and clustering variables (STRAT_P, PSU_P, and WFTA, respectively). Univariate descriptive statistics were computed for each variable after re-categorization using frequencies. Due to limitations in multiple imputation analysis using Proc Survey Freq, only the first multiple imputation dataset was used to report poverty level frequencies. Bivariate frequencies and Rao-Scott chi-square tests were then calculated to compare each independent

variable to the outcome variable, *interest in HPV vaccine*. The Rao-Scott chi-squared test was used since it is the default chi-square test for survey-weighted data. It uses a simple correction to the Pearson chi-square test, which accounts for the complex sampling design of the survey that limits the assumption of independent and identically distributed observations. This correction considers the generalized design effect of the data (Rao & Scott, 1981).

Model building. Survey logistic regression was used to estimate the crude odds ratios and 95% confidence intervals between the outcome variable and each independent variable. This provided the unadjusted effect for each variable on interest in the HPV vaccine. Interaction was then assessed prior to evaluating potential confounding (Kleinbaum, Kupper, Nizam, & Rosenberg, 2014). Since the primary purpose of this analysis was to describe the impact of relationship status on HPV vaccine interest, the approach for assessing effect modification examined only the primary predictor variable of interest (i.e., relationship status) with all other independent variables. These models were hierarchically well-formulated, meaning it included the interaction term (relationship status and the independent variable tested) and the two main effects for these variables. None of the interaction models produced a significant interaction term ($p > 0.10$); therefore, it was determined that effect modification of the relationship status and HPV vaccine interest association was not present.

Next, models were fitted to estimate the odds of interest in the HPV vaccine with relationship status and each remaining predictor variable. The purpose of this exercise was to screen for confounders to include in the final analysis model. Confounders were screened for inclusion in the model if addition of that variable resulted in a change of the adjusted odds ratios of more than 10% (Greenland & Rothman, 2008). However, no variables produced a 10% change. Therefore, in order to develop the final model for analysis, crude odds ratios were

examined for significance with the outcome variable and the literature was consulted for the most salient confounding variables. This selection process produced the final model for consideration to include the following variables: relationship status, Hispanic, race, region, age, insurance coverage, poverty ratio, abnormal Pap test, heard of the HPV vaccine, flu shot in last 12 months and receipt of the hepatitis B vaccine.

Model diagnostics. Model assumptions for logistic regression were assessed; these include: detecting outlying or influential points (Pearson residuals and DFBETAs), a test of linearity for continuous predictors (not applicable), and model fit assessment (Hosmer-Lemeshow Goodness of Fit Test) (Vittinghoff, Glidden, Shiboski, & McCulloch, 2005). Note that the diagnostic procedures for the model did not utilize survey weights as SAS 9.4 does not support these procedure options in survey-weighted models. The plots for the Pearson residuals and DFBETAS did not identify any observations that would be considered outliers or influential. The Hosmer-Lemeshow Goodness of Fit Test produced a chi-square value of 3.1330 and a p-value of 0.9257. This non-significant value indicated no gross lack of fit with the model. Additionally, the c-statistic for the model was 0.668.

The model was also assessed for multicollinearity. While the logistic regression function in SAS 9.4 does not support the ability to assess multicollinearity, linear regression functions can be used since these assessments do not rely on the outcome variable (IBM, 2014). A linear regression model was fitted with the binary outcome variable and predictors. All categorical predictors were re-coded as dummy variables for this analysis. This model produced the tolerance and variance inflation factors used to assess multicollinearity. None of the predictor variables had a tolerance level less than 0.2 or a variance inflation factor greater than 5, indicating multicollinearity was not present in the model (Logan, 2011).

This study was adequately powered to investigate the research question in Analysis 1, which used logistic regression. According to a preliminary sample size analysis using G*Power, the sample size of 1,457 was more than the minimum 849 required for 95% power (Faul, Erdfelder, Lang, & Buchner, 2007). This power analysis was based on the following criteria: two tailed test, odds ratio of 1.30, proportion of women interested in the vaccine who are in a relationship 35%, alpha level 5%, and power level 95%. The parameter for the prevalence in the unexposed is based on previous research: 35% proportion of women interested in the vaccine who are in a relationship (Schmidt & Parsons, 2014). The hypothesized odds ratio represents a small effect size (Chen, Cohen, & Chen, 2010).

Final model. Survey weighted logistic regression was used to produce crude and adjusted odds ratios and 95% confidence intervals for the odds of interest in the HPV vaccine with the following independent variables: relationship status, Hispanic, race, region, age, insurance coverage, poverty ratio, abnormal Pap test, heard of the HPV vaccine, flu shot in last 12 months and receipt of the hepatitis B vaccine. This model included the domain function to account for the 5 imputed datasets for the poverty ratio variable. SAS multiple imputation analysis procedures (PROC MIANALYZE) was used to estimate the model effects of the log odds ratios and log odds 95% confidence interval for each variable. These were then exponentiated to produce odds ratios and 95% confidence intervals, while accounting for the imputed data.

Prevalence ratios. The odds ratios and 95% confidence intervals produced by the logistic regression models (crude and adjusted) were converted to prevalence ratios due to the high prevalence of the outcome in this analysis (Zhang & Yu, 1998). The equation for conversion is: $RR = OR / (1 - P_o) + (P_o \times OR)$. The prevalence of the outcome in each reference category was

used to estimate the prevalence ratio. The prevalence ratios and 95% confidence interval were reported.

Sensitivity analysis. Due to the small frequency of the Widowed, Separated, and Divorced relationship status category (<5%), a sensitivity analysis was conducted to determine if removing this group from the final model affected the measures of effect significantly. The same procedures for multiple imputation, logistic regression, and prevalence ratio conversions were used on a subset of the data excluding women in the “Widowed, Separated, and Divorced” category (N=1,392). A threshold of 10% was used for each measure of effect to determine if significant change had occurred between the final model and the sensitivity analysis model.

Phase I: Research Question II

Research question. Among unvaccinated 18 to 26 year old women, who are not interested in the vaccine, is there an association between relationship status and the primary reasons for non-vaccination? It was hypothesized that there were differences in primary reasons for non-vaccination among relationship status group categories.

Sample. The sample was restricted to NHIS Sample Adults (N=27,157) who were female and between the ages of 18 to 26 years (N=2,011). The sample was further restricted to women who responded to the HPV vaccine questions (N=1,892), were not vaccinated with the HPV vaccine or refused this question (N=1,479), and reported being not being interested in the HPV vaccine or don't know if interested in the HPV vaccine (N=988) as these participants responded to the *reasons for not interested in the HPV vaccine* questions. Finally, cases were removed that had missing data for the primary analysis variables, including unknown marital status (N=3) and

refusing the primary reason for non-vaccination question (N=1). This resulted in a final sample size of 984 women for Analysis 2.

Data collection procedures. The datasets, formats, and codebooks were downloaded from the NHIS website. These included information from the Person, and Sample Adult, Cancer Supplement datasets. The datasets were sorted by household and persons ID numbers (HHX and FPX) and merged together in SAS 9.4. Only variables required for this analysis and descriptive sample variables were kept in the final dataset.

Instrumentation. Two variables were of interest for this research question, specifically primary reason for non-vaccination and relationship status. Univariate frequency analysis procedures were used to examine the distribution of each variable. Based on this review, the relationship status variable was re-coded (Table 11).

Table 11: Recoding of Variables for Phase 1 Research Question 2 Analysis

Description	Variable	Question	Response Categories
Primary Variables			
Relationship Status	R_MARITL	Are you now married, widowed, divorced, separated, never married, or living with a partner?	0 Married 1 Widowed, Divorced, or Separated 2 Living with Partner 3 Never married
Primary Reason	HPVNOT	What is the MAIN reason you would NOT want to get the vaccine?	01 Does not need vaccine 02 Not sexually active 03 Too expensive 04 Too old for vaccine 05 Doctor didn't recommend it 06 Worried about safety of vaccine 07 Don't know where to get vaccine 08 My spouse/family member is against it 09 Don't know enough about vaccine 10 Already have HPV 11 Other 99 Don't know

Data analysis. Univariate survey-weighted frequencies were computed for the reasons for non-vaccination variable and the relationship status variable. Next, a bivariate cross-tabulation was calculated for these two variables, which revealed multiple cells with less than 5 observations. Due to the survey-weighting of these data and lack of exact tests available for these survey procedures in SAS (SAS Institute Inc., 2015), data were transformed for the survey-weighted chi square test to determine if there was an association between relationship status and reasons for non-vaccination. The cross-tabulations indicated the majority of the missing data was in the Widowed, Separated, and Divorced relationship status category, therefore this was removed from the final analysis (N=940). Additionally, the top four reasons for non-vaccination were identified and the remaining reasons were combined into an “other” category to allow for the chi-square test to be operational with the survey-weighted procedures. The top four reasons were selected because remaining survey responses had cells with small numbers, which SAS survey procedures are not equipped to handle (i.e., Fishers Exact test is not available with survey procedures in SAS) (SAS Institute Inc., 2015).

Phase II: Qualitative Interviews, Young Adult Women

Overview

The purpose of Phase II was to understand how relationship status frames HPV vaccine informational needs, motivations, and behavioral skills among 18 to 26 year old women. *In-depth interviews* with college women were conducted. Qualitative methods were preferred in this instance since the research question aimed to understand and explain people’s views and behaviors, ultimately using an interpretivist approach (Hennink, Hutter, & Bailey, 2011b).

Additionally, this methodology was consistent with the IMB Model approach to study design (Fisher & Fisher, 2002). The first step is the elicitation process to identify the existing information, motivation, and behavioral skills for the health promotion behavior (Fisher & Fisher, 2002).

Subjects and Setting

Phase II recruitment and data collection was conducted between March 2015 and April 2015. The target population for this research question was women between the ages 18 to 26 years at the University of South Florida. Women were recruited for participation through multiple modalities in order to increase participation, which included: (1) course announcements in multiple disciplines across campus (e.g., public health, anthropology, nursing), (2) on-campus flyers at different locations (e.g., Education Building, Interdisciplinary Sciences Building, College of Medicine, Morsani Center, Library, and Gym), (3) various USF department/organization listserv announcements (e.g., Department of Civil and Environmental Engineering, Department of Anthropology, USF Sororities), (4) handouts distributed through Student Health Services healthcare providers at USF, and (5) a mass-informational email to all USF-Tampa female students between the ages of 18 and 26 years. The combination of these recruitment methods resulted in 1,113 people taking the recruitment eligibility survey (Appendix A). Women who completed the survey and in-depth interview were provided an electronic \$10 gift card to either Amazon or Starbucks.

Moreover, the study used quota sampling strategy (Bernard & Ryan, 2010e). There were eight stratified sub-groups for which adequate sample sizes were aimed to reach. Participants were stratified by relationship status (married or living with a partner; single but in a long-term

monogamous relationship; single and dating; single but not in a relationship or dating) and HPV vaccination status (vaccinated in the last six months or non-vaccinated). The categorization for relationship status was based on previous research conducted by Zimet et al. (2011) regarding healthcare providers' preferences for HPV vaccination based on relationship status and sexual history. This provided built in variability to the data to assess the impact of relationship status on information, motivation, and behavioral skills related to the vaccine. According to Guest et al. (2006) major themes and saturation can be achieved at a minimum of six interviews (Guest, Bunce, & Johnson, 2006). The minimum number of women that were recruited for each stratum was six with the option of adding additional participants to reach data saturation. This resulted in a total of 50 participants; six per stratum, except for the long term monogamous relationship status categories, which each had 7 participants in attempt to reach data saturation (Table 12).

Table 12: Phase II Sampling Strategy

	Unvaccinated	Vaccinated
Married or living with a partner	N=6	N=6
Single, but in a long-term monogamous relationship	N=7	N=7
Single and dating	N=6	N=6
Single, but not in a relationship or dating	N=6	N=6

Women were eligible for the study if they met the following criteria: (1) student at the University of South Florida, (2) between 18 and 26 years of age, (3) has not received any doses of the HPV vaccine **OR** has received the first dose of the HPV vaccination series in the last 6 months; (4) speaks English, and (5) provides informed consent. Women were screened to determine which stratified category for sampling they qualify. The only exclusion criterion was if sampling was completed for a category.

Recruitment Challenges

The recruitment process for seven out of the eight strata was achieved in a two week period in March and April 2015. However, only two women started the eligibility survey and fell in the married/living with a partner and recently vaccinated category; one was interviewed and one did not provide contact information. To help assist in the recruitment process for this group of women, the recruitment handouts and announcements were revised to specify these specific relationship status and vaccination criteria. These were then distributed through USF's organizations listserv. Through this second round of recruitment, an additional five women were recruited and participated in the study.

Data Collection Procedures

The recruitment and sampling plan included multiple steps (Figure 4). Recruitment announcements were distributed through the modalities previous described. Within these recruitment materials was a link and/or QR code to a web-based survey to screen for eligibility through Qualtrics (Qualtrics, 2013). Persons who were eligible to participate then completed an

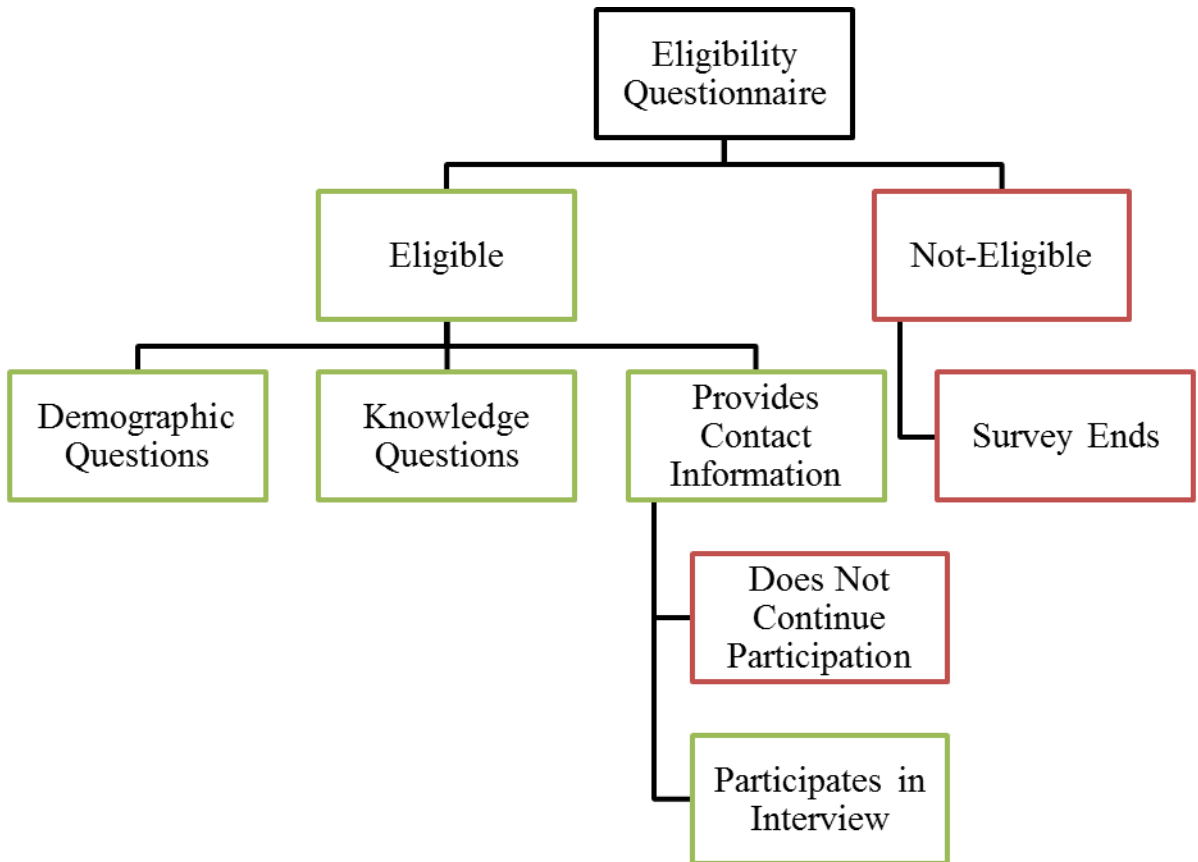


Figure 4: Phase II Procedures

informed consent document, demographic questions, knowledge questions and provided contact information to schedule the in-depth interview (i.e., name, email, phone number). Among persons who completed the baseline eligibility survey, selected participants scheduled a 20 to 25 minute in-depth interview via telephone or Skype (based on participant’s preference). Due to the high volume of women responding to the eligibility survey and providing contact information in some of the quota sampling strata, eligible participants were contacted on a first-come first-serve basis, as well as with consideration for scheduling preferences. The eligibility survey was initiated by 1,331 persons; 60% received the HPV vaccine, 31% never received the HPV vaccine. Among the sample initiating the survey, 7% received the HPV vaccine in the last 6

months. Among those persons, 388 were eligible, 375 consented, and 352 completed the entire survey with contact information. Therefore the response rate among those considered eligible for the study was 90.7%. The women selected for an in-depth interview were contacted via email with multiple dates and times to schedule an interview based on the participant's preferences.

All interviews were conducted over the telephone, which was the preference of all participants rather than using video conferencing. During the interview administration, field notes were written to allow the interviewer to reflect on important details of the interview, which may not have been captured by reading transcripts in data analyses. All interviews were audio-recorded with two devices (one for back-up). Audio-recordings were then be transcribed verbatim (11 were transcribed by the researcher and 39 were transcribed using professional services – Verbalink). Transcriptions did not include participants' names or any other type of identifying information. Once transcriptions were completed, the audio files were destroyed to protect participants' confidentiality. A unique participant identifying number was used to link the survey content to the interview transcript/audio file. Data from the surveys were downloaded from USF Qualtrics (Qualtrics, 2013). The names and contact information from the participants were only used for scheduling the interview. Once the interview was completed the names and contact information were destroyed.

Instrumentation

Four sets of instruments were developed for Phase II data collection: (1) eligibility questionnaire; (2) demographic questions; (3) knowledge questions; and (4) semi-structured interview guide (Appendix B). These instruments were pre-tested with three individuals who were similar to the target population of this study and who were not included in the final sample.

This assisted in the quality of the instruments prior to implementation for data collection. The primary purpose of the pilot tests was to assess content validity, feasibility, and acceptability of the interview guide. The norm for qualitative interviews is to pilot test with a few interviews among people with similar characteristics to the target population (Hennink, Hutter, & Bailey, 2011a).

Eligibility questionnaire. The eligibility questionnaire asked participants screening questions based on inclusion criteria. These included sex (female), age (18 to 26), HPV vaccination status (not-vaccinated or vaccinated within the last 6 months), and relationship status. Persons who met the criteria continued with the demographic and knowledge questions. Those persons who did not meet the criteria ended the survey.

Demographic questions. The participant demographic questions described the respondent's socio-demographics (e.g., race/ethnicity, insurance status, sexual orientation).

Knowledge questions. The knowledge questions were a true/false format and content related to HPV transmission and the HPV vaccine. The knowledge test was the validated HPV vaccine knowledge scale, previously administered to college females (Daley, Vamos, et al., 2010). These close-ended questions objectively assessed the HPV and HPV vaccine knowledge level among participants. Additionally, the respondents were asked to report information sources for the HPV vaccine.

Interview guide. The interview was conducted using a semi-structured interview guide. The interview guide was developed using the constructs from the IMB Model (i.e., Information, Motivation, Behavioral Skills, and Macro Factors) and preliminary research related to condom use and relationship status using the IMB Model (Fisher & Fisher, 2002; Fisher, 2012; Misovich et al., 1997). Questions regarding perceived vulnerability/threat to HPV were developed based

on constructs of perceived severity and perceived susceptibility in the Health Belief Model (Champion & Skinner, 2008). All questions were open-ended with probing questions to allow for more detail (Bernard & Ryan, 2010a). Moreover, the content validity of the interview guide was examined by the IMB Model co-creator, William A. Fisher PhD, Distinguished Professor in the Department of Psychology and the Department of Obstetrics and Gynecology at the University of Western Ontario.

During the data collection process, an additional question was added to the information section of the interview guide. Women reported on who they have heard about the HPV vaccine from and who they trusted the most. However, to add detail on where they wished to receive more information from, a question on information source preferences for the future was asked. These modifications were added after pilot testing of the interview guide.

Pilot Testing

Pilot testing was conducted on March 12, 2015 with three subjects. Two were unvaccinated, but one was “living with a partner” and the other was “single, but not dating.” One was vaccinated and “living with a partner.” The length of the interviews was between 15 to 25 minutes. The pilot test entailed completing the online survey and the telephone interview. After the survey and interview was completed, the pilot participants were asked their feedback on the instruments and the process.

The primary area that required revisions was the beginning portion of the interview – the information section and transition to the remaining part of the interview. Prior to conducting the interview, the scores from the knowledge survey for each participant were reviewed to identify three to four questions that the participants were unsure about or were incorrect. These were used

to fill the stem, “People mention _____. What do you think about this statement? Why?” Participants had a difficult time describing how they felt about the statement. Their responses were either, “I don’t know” or “I don’t know a lot about HPV.” This important feedback informed revisions of the interview instrument. Moreover, the revisions assisted in standardizing this section of the interview guide. First, any similarities between the three pilot participants on questions that were frequently missed on the knowledge scale were examined. Next, the survey results from Daley et al. (2010), which was conducted among female college students, was evaluated to determine the most frequently missed questions. These two processes elucidated general categories of information that were frequently missed to HPV and the HPV vaccine. The information questions were revised as follows:

1. What are some of the things you know about HPV?
 - a. Probe: Transmission
 - b. Probe: Outcomes – cancer, genital warts, herpes, HIV
 - c. Probe: Curability and length of infection
2. What are some of the things you know about the HPV vaccine?
 - a. Probe: Who can get it?
 - b. Probe: When should you get it?
 - c. Probe: Any negative effects associated with it?

The next area identified that required modifications was transitions. First, after the participant was asked if the conversation can be audio-recorded, they were then ask, “So to start, what do you think about the HPV vaccine?” This overlapped with some of the information elicited in the information section. Therefore, this question was removed. Second, the interview guide contained a script describing the HPV vaccine so that all participants move forward in the

interview with basic knowledge about the vaccine. One of the pilot participants mentioned that because she had low knowledge about the vaccine, she thought this was only being read to her due to her low knowledge. She was reassured that this was not the case, and she recommended including a statement prior to reading this script that this is read to *all* participants and is part of the standard procedures for the interview. As a result, prior to reading the HPV vaccine description, the interview guide included:

“I am going to read you a quick description of the HPV vaccine. I read this to all participants in the interview that way we are all on the same page moving forward with our conversation. Is that okay?”

Finally, I reflected as the interviewer on how the three pilot interviews went. I needed to be cognizant of my affirmations and include a larger variety other than “okay.” I realized that I used this throughout the interviews due to the fact that it is being conducted on the telephone. I want the interviewee to know that I am paying attention to what they are saying by verbally acknowledging it, since they cannot see my body cues. Additionally, I needed to be comfortable with the interview guide in order to be flexible with the order of questions. Overall, the pilot testing was a needed exercise to revise the instruments and practice the interviewing process.

Data Analysis

Qualitative data analysis is a cyclical and iterative process. First, a codebook was developed with the *a priori* deductive codes based on the IMB Model. Each code contained a code name, description, and examples. Open coding was conducted to apply these initial deductive codes to the data. Additionally, during this process, emergent codes were identified and added to the codebook (Bernard & Ryan, 2010d; Vamos, n.d.). These emergent codes

included *anti-vaccine movement* and *personal decision*. The constant comparative method was used to assist in categorizing codes (Bernard & Ryan, 2010c). Once all the codes were applied to the transcripts, themes and relationships among codes were identified through axial coding. Summaries of major themes were written, and representative quotes were selected. A final read through of the data was conducted using selective coding to validate the relationships between categories (Bernard & Ryan, 2010d; Vamos, n.d.). Throughout the coding process, memos were written to document emerging ideas, insights, or thoughts related to the data analysis. Data analysis was conducted using Atlas.ti 7 data management software (Atlas.ti Scientific Software Development, 2012).

Because stratified groups of women were sampled for this study, a comparative thematic analysis was used to compare and contrast information, motivation, behavioral skills, and macro factors among the groups (Bernard & Ryan, 2010c; Guest, MacQueen, & Namey, 2012). Specifically, matrices were developed to quantitatively and qualitatively compare the content of the codes across interviews within stratified groups. Four group comparisons occurred during data analysis (Figure 5). These included: (1) comparing the IMB themes across the four different relationship status categories among unvaccinated women; (2) comparing the IMB themes across the four different relationship status categories among vaccinated women; (3) comparing the IMB themes across vaccination status among women single *and* single and dating; and (4) comparing the IMB themes across vaccination status among women in married or living with a partner *and* single, but in a long-term monogamous relationship.

Within each of these groups, data saturation was assessed. Saturation is reached once information is no longer being added with each additional interview (Glaser & Strauss, 2009). The study design of including at least six participants per group was based on empirical evidence

that data saturation can be reached at this level (Guest et al., 2006). While composing summary statements for each group among major themes for this analysis, saturation was assessed by

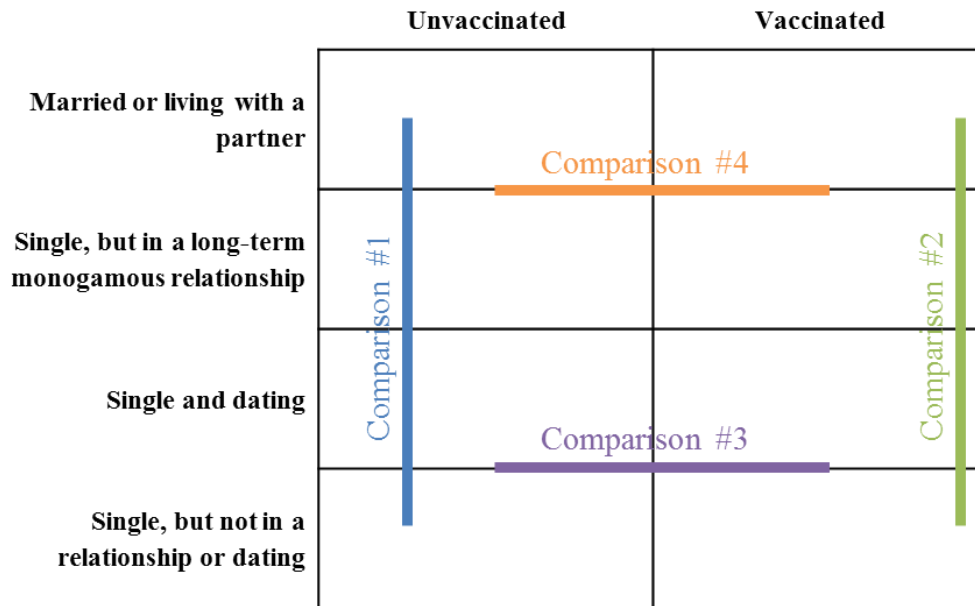


Figure 5: Phase II Analysis Strategy

reviewing the homogeneity of the participant responses. The two groups for long-term monogamous relationship status required additional interviews to reach data saturation due to outlier cases in the sample. As a result, one interview was added to each of these two groups.

One method to improve the objectivity of results was to assess the reliability of the data analysis process. Inter-rater reliability is a methodology used to compare the coding process between one or more individuals (Bernard & Ryan, 2010b). The purpose was to confirm that the coding process was systematic and reproducible. To determine the reliability of the coding process and codebook, an additional researcher coded 10% of the transcripts to produce an inter-rater reliability measure. Once the primary researcher (Thompson) coded all of the transcripts (N=50), a second researcher then coded 10% sample of the transcripts (N=5) independently using the developed codebook. Any discrepancies in the codes were discussed between coders

and a final decision on the appropriate approach to proceed was determined. A threshold of a Cohen's kappa of 80% was used to indicate "almost perfect agreement" among coders (Bernard & Ryan, 2010b; Landis & Koch, 1977). The inter-rater reliability coding process for this study produced a Cohen's kappa of 88% indicating almost perfect agreement.

Triangulation

The findings from Phases I and II meaningfully informed the interpretation of the overall results. Phase I quantitatively reported the differences in the primary reason for non-vaccination by relationship status among young adult women using a nationally representative sample. Phase II elicited the knowledge and perceptions of young adult women to explain why these reasons may exist. Together this provided an overall picture of the disparities for HPV vaccination as it relates to relationship status among young adult women with generalizability and depth.

Protection of Human Subjects

This project aimed to protect the human subjects involved. The project received two separate Institutional Review Board (IRB) approvals prior to commencement of each phase of the research study. This project was non-invasive and presented minimal risk to human subjects. Subjects were women between the ages of 18 and 26 years old. There were two aims, each of which had different human subjects, risks and benefits, and data monitoring plans.

Phase I

To achieve the specific aim of Phase I, a secondary data analysis of NHIS 2010 was conducted. This is a publically available dataset distributed by the National Center for Health

Statistics. The data are de-identified, thus protecting the anonymity and confidentiality of participants. Therefore, this phase was categorized as Exempt Review of Human Subjects Research, Category Four according to the University of South Florida IRB. Data were downloaded from the CDC website and stored on a personal hard drive. All results were reported in aggregate numbers and cells less than five were not reported.

Phase II

Human subjects. To achieve the specific aim of Phase II, in-depth interviews were conducted with young adult 18 to 26 year old women attending the University of South Florida. Women were recruited through announcement, handouts, and flyers at the University of South Florida. Fifty were recruited and invited to participate in a scheduled interview. Women were eligible for the study if they meet the following criteria: (1) student at the University of South Florida, (2) between 18 and 26 years of age, (3) has not received any doses of the HPV vaccine **OR** received the first HPV vaccine within the last 6 months; (4) speaks English, and (5) provides informed consent. Women were provided an informed consent form electronically during the eligibility screening questionnaire, which required a check box to consent prior to proceeding with the survey. Women who consented were asked to provide contact information to schedule an in-depth interview that would last approximately 30 to 45 minutes. The interview was conducted via telephone. An in-depth interview guide was used to lead the interview and was based on the IMB Model constructs. The interview was audio-recorded and transcribed. All identifiers were removed and the data de-identified. Additionally, participants completed the eligibility questionnaire, as well as a knowledge survey scale. These were collected using Qualtrics. All data were de-identified and only linked to using a unique participant code. The

unique participant code was only linked to a participant's name and contact information (phone and email) to schedule and contact for the follow-up interview. Once a contact and interview was conducted, the identifying information was destroyed. No identifiers were included in any report or dissemination product following this research. All electronic files were stored on a password protected computer.

This study followed all guidelines designated by the USF IRB, including informed consent and voluntary participation/withdrawal from the study.

Risks and benefits. The following risks were reasonable in relation to the benefits of this study. This research was considered to be minimal risk. There were no known additional risks for participating in this study. While name and contact information data were collected, these were not linked to any participant data from the surveys or interviews. No personally identifying information was used in any dissemination products.

There were limited benefits to participating in this study. All participants contributed to formative research for future HPV vaccination interventions that will benefit the larger public. Moreover, participants were offered \$10 for their time and participation.

CHAPTER 4: RESULTS

Overview

The goal of this study was to understand the information, motivation, and behavioral skills related to HPV vaccination among young adult women. The results of this dissertation are presented in two sections. First, the quantitative analysis of the National Health Interview Survey 2010 is presented, which examined the association between relationship status and interest in HPV vaccination among unvaccinated women. Second, the results of the qualitative analysis of information, motivation, and behavioral skill decision-making factors for HPV vaccination among a sample of college women interviewed are presented.

Phase I: Quantitative Analysis

The quantitative analysis for Phase I comprised two separate research questions used to examine the National Health Interview Survey 2010.

Phase I Research Question I – Interest in HPV Vaccination

Description of sample. The final analytic sample from the NHIS 2010 dataset comprised 1,457 women (Table 13). The majority of women had no interest in receiving the HPV vaccine (69%). With regard to relationship status, over half were never married (59%), and the remaining were married (22%), living with a partner (14%), or widowed, divorced, or separated (4%). Demographic characteristics revealed the majority of the sample was non-Hispanic, White, from

the South, between the ages of 22 and 26, had insurance coverage, and 200% above the poverty ratio. Nearly 70% of women had heard of the HPV vaccine in the past. Within the sample, only 11% had a previous abnormal Pap test and 11% had a flu shot in the past 12 months. Over half of participants received the Hepatitis B vaccine previously.

Bivariate analyses. Each predictor variable was examined with the outcome variable, interest in the HPV vaccine. Significant associations were found for all variables, except for race, age, and insurance coverage (Table 13). Crude prevalence ratios estimated the effect size for the association between the predictor variable and outcome variable. Women who were living with a partner (PR=1.50, 95%CI 1.13-1.92) or never married (PR=1.41, 95%CI 1.14-1.71) were significantly more likely to be interested in the HPV vaccine compared to married women. There were no significant differences between women who were married and women who were widowed, divorced, or separated. Additionally, women who were Hispanic, <100% below the poverty ratio, had a history of an abnormal Pap test, heard of the HPV vaccine, had a flu shot in the last 12 months, and received the Hepatitis B vaccine were more likely to be interested in the HPV vaccine. Women living in the Midwest were less likely to be interested than women living in the South.

Final model. The final regression model examining the effect of relationship status on interest in HPV vaccination adjusted for Hispanic ethnicity, race, region, age, insurance coverage, family poverty ratio, abnormal Pap history, heard of the HPV vaccine, flu shot in the last 12 months, and ever received the Hepatitis B vaccine (Table 14). Compared to crude effects, the adjusted model had attenuated effects for living with a partner (PR=1.50; aPR=1.44), region (Midwest: PR=0.73, aPR=0.71), abnormal Pap (PR=1.79, aPR=1.75), and Hepatitis B vaccine (PR=1.37, aPR=1.30), while having an augmented effect for Hispanic (PR=1.25, aPR=1.39),

<100% of the poverty level (PR=1.24, aPR=1.27), heard of the HPV vaccine (PR=1.53, aPR=1.58), and had a flu shot (PR=1.41, aPR=1.49).

Women who were living with a partner (PR=1.44, 95% CI 1.07-1.87) or never married (PR=1.41, 95% CI 1.12-1.73) were more likely than married women to be interested in the HPV vaccine. There were no significant differences between women who were married or widowed, divorced, or separated. Hispanic women were more likely to be interested in the vaccine compared to non-Hispanic women (PR=1.39, 95% CI 1.15-1.64). Other significant demographic factors include women living in the Midwest being less likely to be interested in the vaccine compared to women living in the South. Additionally, women below 100% of the poverty level compared to women 200% or more above the poverty level were more likely to be interested. Other health indicators also significantly increased likelihood of interest in the HPV vaccine, including having an abnormal Pap test, having a flu shot, and having the Hepatitis B vaccine. Finally, women who have heard of the HPV vaccine were 58% more likely to be interested in the vaccine compared to women who had not heard of the vaccine.

Sensitivity analysis. Among the sample of 1,457 women for this analysis, 0.3% were widowed, 1.8% were divorced, and 2.3% were separated. Due to the low frequencies of these groups, and as a combined group, a sensitivity analysis was conducted, which examined the full model while excluding these records (N=1,392). Comparing the adjusted prevalence ratios of the full model with the adjusted prevalence ratios of the sensitivity analysis did not identify any changes greater than 10% in the measures of effect (Table 15). Therefore, this group did not significantly alter the prior analysis.

Table 13. Frequencies of Demographic and Health Characteristics by Interest in the HPV Vaccine among the NHIS 2010 Sample of Women 18-26 Years (N=1,457)

Variable	N Total	% Total	N Yes	% Yes	P-value
HPV Interest					
Yes	483	31.5%			
No	974	68.5%			
Relationship Status					<0.01
Married	313	22.1%	85	23.7%	
Widowed, Div, Sep	65	4.3%	21	30.9%	
Living with Partner	211	14.2%	77	35.6%	
Never Married	868	59.4%	300	33.4%	
Hispanic					<0.01
Yes	366	14.6%	138	38.0%	
No	1091	85.4%	345	30.4%	
Race					0.28
White	998	74.4%	320	30.6%	
Black	296	17.0%	107	35.4%	
Other	163	8.6%	56	31.6%	
Region					<0.01
South	563	39.3%	209	34.6%	
Northeast	188	14.2%	56	28.7%	
Midwest	325	25.7%	84	25.1%	
West	381	20.8%	134	35.5%	
Age					0.85
18-21 years	463	31.6%	150	31.1%	
22-26 years	994	68.4%	333	31.6%	
Insurance Coverage					0.90
Yes	1043	73.3%	342	31.6%	
No	414	26.7%	141	31.2%	
Poverty Ratio					0.03
200% +	566	41.9%	172	27.9%	
100 < 200%	363	24.2%	120	32.8%	
< 100%	528	33.9%	191	35.0%	
Abnormal Pap Test					
Yes	161	11.1%	84	51.8%	<0.01
No	1296	88.9%	399	28.9%	
Heard of the Vaccine					<0.01
Yes	954	70.4%	358	35.1%	
No	503	29.6%	125	22.9%	
Flu Shot last 12 mo					<0.01
Yes	159	11.3%	68	42.3%	
No	1298	88.7%	415	30.0%	
Hepatitis B Vaccine					<0.01
Yes	805	57.4%	315	35.5%	
No	652	42.6%	168	26.0%	

Table 14. Crude and Adjusted Converted Prevalence Ratios for Interest in the HPV Vaccine among the NHIS 2010 Sample of Women 18-26 Years (N=1,457)

Variable	%Interest	Crude OR [†] (95% CI) ^{††}	Crude PR ^{†††} (95% CI)	Adjusted OR (95% CI)	Adjusted PR (95% CI)
Relationship Status					
Married	23.7%	Referent	Referent	Referent	Referent
Widowed, Div, Sep	30.9%	1.44(0.78, 2.66)	1.30(0.82, 1.91)	1.36(0.73, 2.54)	1.26(0.78, 1.86)
Living with Partner	35.6%	1.78(1.18, 2.69)	1.50(1.13, 1.92)	1.67(1.09, 2.56)	1.44(1.07, 1.87)
Never Married	33.4%	1.62(1.19, 2.19)	1.41(1.14, 1.71)	1.62(1.17, 2.24)	1.41(1.12, 1.73)
Hispanic					
Yes	38.0%	1.41(1.09, 1.82)	1.25(1.06, 1.46)	1.68(1.24, 2.27)	1.39(1.15, 1.64)
No	30.4%	Referent	Referent	Referent	Referent
Race					
White	30.6%	Referent	Referent	Referent	Referent
Black	35.4%	1.24(0.95, 1.63)	1.16(0.96, 1.37)	1.23(0.90, 1.69)	1.15(0.93, 1.40)
Other	31.6%	1.05(0.73, 1.51)	1.03(0.79, 1.31)	1.19(0.81, 1.74)	1.12(0.86, 1.42)
Region					
South	34.6%	Referent	Referent	Referent	Referent
Northeast	28.7%	0.76(0.57, 1.02)	0.83(0.67, 1.01)	0.75(0.53, 1.05)	0.82(0.64, 1.03)
Midwest	25.1%	0.63(0.48, 0.84)	0.73(0.58, 0.89)	0.61(0.45, 0.82)	0.71(0.56, 0.88)
West	35.5%	1.04(0.79, 1.37)	1.03(0.85, 1.21)	1.05(0.78, 1.42)	1.03(0.84, 1.24)
Age					
18-21 years	31.1%	Referent	Referent	Referent	Referent
22-26 years	31.6%	1.02(0.80, 1.31)	1.02(0.85, 1.20)	1.02(0.78, 1.35)	1.02(0.84, 1.22)
Insurance Coverage					
Yes	31.6%	Referent	Referent	Referent	Referent
No	31.2%	0.99(0.76, 1.27)	0.99(0.83, 1.17)	0.97(0.74, 1.27)	0.98(0.81, 1.17)
Poverty Ratio					
200% +	27.9%	Referent	Referent	Referent	Referent
100 < 200%	32.8%	1.27(0.96, 1.68)	1.18(0.97, 1.41)	1.26(0.91, 1.73)	1.17(0.94, 1.44)
< 100%	35.0%	1.37(1.07, 1.77)	1.24(1.05, 1.46)	1.42(1.06, 1.89)	1.27(1.04, 1.52)
Abnormal Pap Test					
Yes	51.8%	2.65(1.91, 3.67)	1.79(1.51, 2.07)	2.53(1.79, 3.57)	1.75(1.46, 2.05)
No	28.9%	Referent	Referent	Referent	Referent
Heard of the Vaccine					
Yes	35.1%	1.81(1.44, 2.28)	1.53(1.31, 1.76)	1.91(1.48, 2.46)	1.58(1.34, 1.84)
No	22.9%	Referent	Referent	Referent	Referent
Flu Shot last 12 mo					
Yes	42.3%	1.70(1.21, 2.40)	1.41(1.14, 1.69)	1.88(1.28, 2.75)	1.49(1.18, 1.8)
No	30.0%	Referent	Referent	Referent	Referent
Hepatitis B Vaccine					
Yes	35.5%	1.57(1.27, 1.94)	1.37(1.18, 1.56)	1.44(1.15, 1.81)	1.30(1.11, 1.49)
No	26.0%	Referent	Referent	Referent	Referent

†OR = odds ratio

†† 95%CI = 95% confidence interval

†††PR = prevalence ratio

Table 15. Sensitivity Analysis for Adjusted Converted Prevalence Ratios for Interest in the HPV Vaccine among the NHIS 2010 Sample of Women 18-26 Years (N=1,392)

Variable	%Interest	Adjusted PR (95% CI)[†]	% Change
Relationship Status			
Married	23.5%	Referent	
Living with Partner		1.44(1.07, 1.87)	0%
Never Married		1.40(1.11, 1.71)	0%
Hispanic			
Yes		1.40(1.16, 1.65)	1%
No	30.4%	Referent	
Race			
White	30.3%	Referent	
Black		1.20(0.97, 1.45)	4%
Other		1.17(0.90, 1.46)	4%
Region			
South	34.2%	Referent	
Northeast		0.84(0.65, 1.07)	2%
Midwest		0.73(0.59, 0.90)	3%
West		1.05(0.85, 1.28)	2%
Age			
18-21 years	31.3%	Referent	
22-26 years		1.01(0.83, 1.21)	1%
Insurance Coverage			
Yes	31.6%	Referent	
No		0.99(0.80, 1.19)	1%
Poverty Ratio			
200% +	27.6%	Referent	
100 < 200%		1.21(0.97, 1.46)	3%
< 100%		1.29(1.07, 1.53)	2%
Abnormal Pap Test			
Yes		1.74(1.44, 2.05)	1%
No	28.9%	Referent	
Heard of the Vaccine			
Yes		1.65(1.38, 1.93)	4%
No	22.5%	Referent	
Flu Shot last 12 mo			
Yes		1.36(1.13, 1.58)	9%
No	41.4%	Referent	
Hepatitis B Vaccine			
Yes		1.27(1.08, 1.47)	2%
No	26.3%	Referent	

[†]Prevalence ratio and 95% confidence interval

Phase I Research Question II – Reason for Non-Interest in HPV Vaccine

Description of sample. The second sample from the NHIS 2010 dataset comprised 984 women who provided a reason for non-interest in the HPV vaccine (Table 16). Due to skip patterns in the dataset, this sample contained a different subset of women compared to the analytic sample one in Table 13. The majority of women were never married (58%), followed by married (25%), living with a partner (13%) and widowed, divorced or separated (4%). Most women were non-Hispanic, White, from the South, between the ages 22 and 26 years, and had insurance coverage. Additionally, most women had not had an abnormal Pap test and had heard of the HPV vaccine. Approximately half of participants received the Hepatitis B vaccine and less than 10% received the flu shot in the last 12 months.

Primary reasons for non-vaccination. The percentage of each primary reason among each relationship status category is reported since the percentages are adjusted for survey weighting (Tables 17 and Figure 6). Within each relationship status category, the most common reason for non-vaccination and non-interest was reported as “does not need vaccine” (40% overall). The second most common reason for women who were married (14%); widowed, divorced, or separated (18%); and never married (13%) was “doesn’t know enough about vaccine,” while women who were living with a partner had “worried about safety of the vaccine” (15%). Overall, more than 70% of responses among all relationship status categories were “does not need vaccine,” “doesn’t know enough about vaccine,” “worried about vaccine safety,” and “doctor didn’t recommend.” Very few participants reported the remaining available factors as reasons for non-vaccination. The only exception being that women who were never married were more likely to list “not sexually active” compared to other relationship status categories (11%).

Table 16. Description of NHIS 2010 Sample of Women 18 to 26 Years who were Not Interested in the HPV Vaccine (N=984)

Variable	N Total	% Total
Relationship Status		
Married	231	24.7%
Widowed, Div, Sep	44	4.3%
Living with Partner	135	13.2%
Never Married	574	57.8%
Hispanic		
Yes	231	13.2%
No	753	86.8%
Race		
White	683	75.3%
Black	192	16.1%
Other	109	8.6%
Region		
South	357	37.5%
Northeast	132	14.7%
Midwest	244	28.1%
West	251	19.8%
Age		
18-21 years	317	31.8%
22-26 years	667	68.2%
Insurance Coverage		
Yes	707	73.1%
No	277	26.9%
Abnormal Pap Test		
Yes	79	8.0%
No	905	92.0%
Heard of the Vaccine		
Yes	601	66.4%
No	381	33.3%
Flu Shot last 12 mo		
Yes	92	9.6%
No	892	90.4%
Hepatitis B Vaccine		
Yes	498	54.2%
No	483	45.8%

Table 17. Primary Reason for Non-Interest and Non-Vaccination by Relationship Status among NHIS 2010 Women 18 to 26 Years (N=984)

	Married	Widowed, Divorced, Separated	Living with Partner	Never Married	Total
Does Not Need Vaccine	47.6%	51.8%	40.9%	34.7%	39.5%
Doesn't Know Enough About Vaccine	14.4%	18.4%	8.3%	12.7%	12.8%
Worried About Safety of the Vaccine	3.9%	10.0%	15.2%	14.9%	12.0%
Doctor Didn't Recommend	10.4%	<2%	7.8%	6.3%	7.3%
Not Sexually Active	<2%	<2%	<2%	11.1%	6.8%
Too Expensive	2.2%	3.8%	2.1%	2.8%	2.6%
Too Old for Vaccine	2.1%	2.2%	4.8%	3.1%	3.1%
Don't Know Where to Get Vaccine	<2%	0	<2%	<2%	<2%
My Spouse/Family Member is Against It	<2%	0	0	<2%	<2%
Already Have HPV	3.3%	3.6%	5.4%	2.2%	2.9%
Other	13.0%	5.1%	13.2%	9.4%	10.6%
Don't Know	<2%	3.3%	<2%	2.0%	<2%

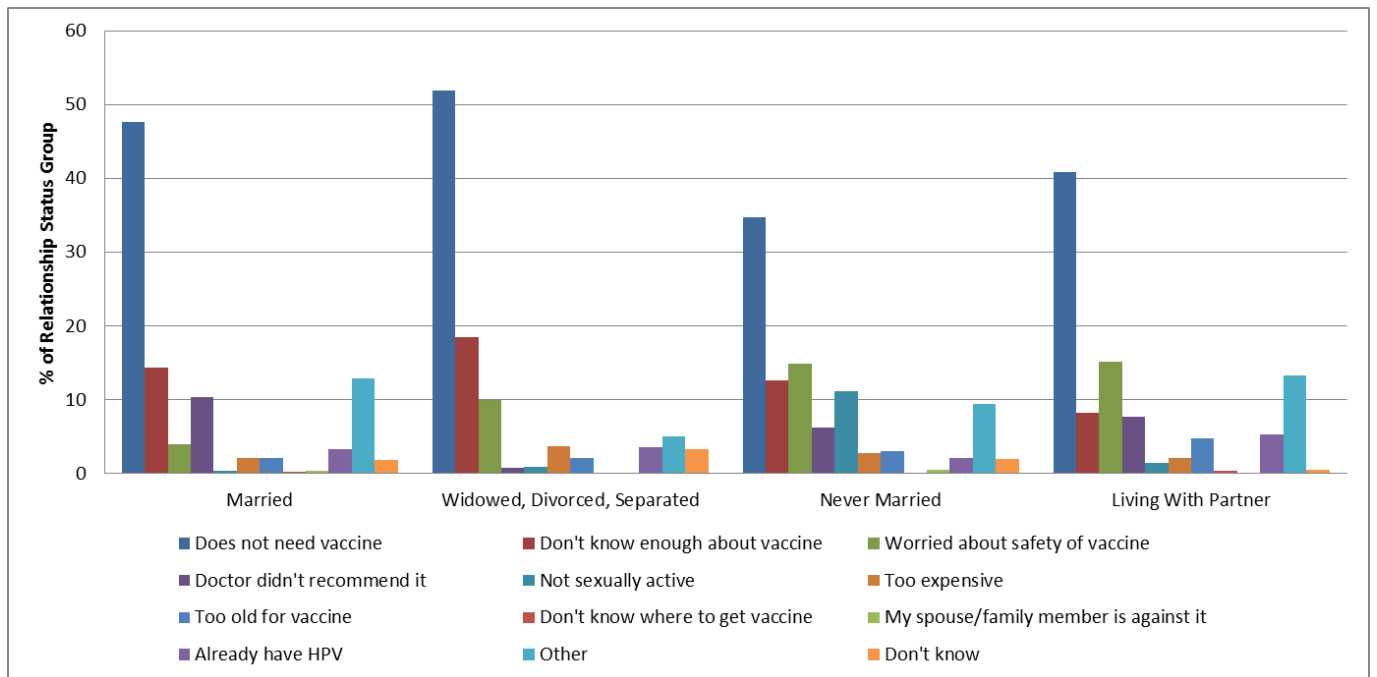


Figure 6. Percentages of Main Reason for Non-Vaccination by Relationship Status

Due to the limited number of responses in many categories, these were combined to reflect an “other” reason for non-vaccination and non-interest. Additionally, the widowed, divorced, and separated group was removed from the analysis due to low frequencies (N=44). The resulting 940 participants’ primary reason for non-vaccination is provided in Table 18. Using a Wald chi-square test, an association between relationship status and primary reason for non-vaccination was present ($\chi^2 = 63.77, p\text{-value} < 0.0001$). Women who were married were more likely than other relationship status categories to believe that they did not need the vaccine, while women living with a partner were more concerned about the safety of the vaccine. In contrast, never married women were the most likely to report an “other” reason for non-vaccination, which may be attributed to the large percentage indicating not being sexually active.

Table 18. Primary Reason (*condensed*) Non-Interest and Non-Vaccination by Relationship Status among NHIS 2010 Women 18 to 26 Years (N=940)

	Married	Living with Partner	Never Married	Total
Does Not Need Vaccine	47.6%	40.9%	34.7%	38.9%
Doesn’t Know Enough About Vaccine	14.4%	8.3%	12.7%	12.5%
Worried About Safety of the Vaccine	3.9%	15.2%	14.9%	12.1%
Doctor Didn’t Recommend	10.4%	7.8%	6.3%	7.6%
Other	23.6%	27.9%	31.6%	28.9%

This research study involved two phases, a quantitative and qualitative phase. To assist in the comparison of the quantitative results in this phase to the interview results in Phase II, the two relationship status categories Married and Living with a Partner were combined in order to compare these to the Never Married group (Table 19). Similar sampling stratifications were used in Phase II. Using a Wald chi-square test, an association between relationship status and primary reason for non-vaccination was present ($\chi^2 = 25.57, p\text{-value} < 0.0001$). More women in the

relationship groups believed they did not need the vaccine compared to the never married group. In contrast, more women in the relationship status group did not receive a doctor recommendation for the vaccine compared to the never married group. More women in the never married group cited safety concerns as a reason for non-interest in the HPV vaccine.

Table 19. Primary Reason (*condensed*) Non-Interest and Non-Vaccination by *Combined* Relationship Status among NHIS 2010 Women 18 to 26 Years (N=940)

	Married or Living with Partner	Never Married	Total
Does Not Need Vaccine	45.3%	34.7%	38.9%
Doesn't Know Enough About Vaccine	12.3%	12.7%	12.5%
Worried About Safety of the Vaccine	7.9%	14.9%	12.1%
Doctor Didn't Recommend	9.5%	6.3%	7.6%
Other	25.1%	31.6%	28.9%

Phase II: Qualitative Analysis

Descriptive characteristics of the eligible sample and interviewed sample are reviewed. Additionally, key themes from the in-depth interviews by IMB construct are described.

Descriptive Characteristics of Sample

Description of eligible sample. A total of 352 women completed the eligibility questionnaire, informed consent, and provided contact information for the in-depth interviews. The majority of women who were eligible for the study did not receive the HPV vaccine (85%) (Table 20). Approximately a third of the sample were either single or in a long term monogamous relationship, respectively. The smallest category was women who were married or

living with a partner (13%). The average age of respondents was 21 years (range 18-26). Regarding race and ethnicity, 19% were Hispanic, 9% were international students, and 52% were White. The majority of women self-identified as heterosexual (87%). The primary mode of insurance was through private insurance (63%), while 9% reported being uninsured. Most women had heard of the HPV vaccine from a healthcare provider (68%) and the average knowledge scale score was 15.3 out of a possible 23 (higher score indicating higher knowledge).

Description of interview sample. The final interview sample comprised 50 women from the eligible 352. The relationship status and vaccination status frequencies reflect the quota sampling technique employed for conducting interviews. All groups had 6 participants, with the exception of women in the long term monogamous relationship categories, each of which had 7 participants. Descriptive characteristics were relatively similar when comparing the eligible sample to the interview sample (Table 20).

Moreover, characteristics were similar across the eight quota categories (Table 21). The knowledge scale score was the highest for women who were vaccinated and married or living with a partner, and lowest for women who were unvaccinated and single and dating (this is attributed to one participant listing unsure for every knowledge item resulting in a zero score).

This study's sampling design was stratified by relationship status: married/living with a partner; long-term monogamous relationship; single and dating; and single. Women were asked to self-identify their relationship status on the eligibility questionnaire and then described their relationship status in more detail during the interview. Women who were unvaccinated described their relationship at the present time and women who were vaccinated were asked to recall their relationship at the time of vaccination. Descriptions of these relationship status groups are presented in Table 22.

Table 20. Descriptive Demographic Characteristics of Eligible Sample and Interviewed Sample

	Eligible Sample (N=352)	Interview Sample (N=50)
HPV Vaccination		
Never	299 (84.9%)	25 (50.0%)
Last 6 months	53 (15.1%)	25 (50.0%)
Relationship Status		
Married or Living with Partner	46 (13.1%)	12 (24.0%)
Long Term Monogamous	116 (33.0%)	14 (28.0%)
Single and Dating	79 (22.4%)	12 (24.0%)
Single	111 (31.5%)	12 (24.0%)
Age	21.1 (2.0) years	21.3 (2.1) years
Hispanic	68 (19.3%)	12 (24.0%)
International Student	32 (9.1%)	2 (4.0%)
Race		
American Indian/Alaskan Native	3 (0.9%)	1 (2.0%)
Asian	50 (14.2%)	8 (16.0%)
Native Hawaiian/Pacific Islander	1 (0.3%)	0 (0%)
Black	67 (19.0%)	8 (16.0%)
White	188 (53.4%)	24 (48.0%)
Other	23 (6.5%)	4 (8.0%)
Multiracial	20 (5.7%)	5 (10.0%)
Sexual Orientation		
Bisexual	23 (6.5%)	4 (8.0%)
Homosexual	12 (3.4%)	0 (0%)
Heterosexual	305 (86.7%)	45 (90.0%)
Unsure	7 (2.0%)	1 (2.0%)
Other	5 (1.4%)	0 (0%)
Insurance Status		
Private	220 (62.5%)	29 (58.0%)
School	23 (6.5%)	4 (8.0%)
Medicaid	24 (6.8%)	8 (16.0%)
Other	44 (12.5%)	3 (6.0%)
Uninsured	32 (9.1%)	6 (12.0%)
Not Sure	9 (2.6%)	0 (0%)
Knowledge Scale Score	15.3 (4.1)	15.3 (3.9)
Heard of HPV From....		
Healthcare Provider	238 (67.6%)	38 (76.0%)
Family	112 (31.8%)	17 (34.0%)
Partner	9 (2.6%)	2 (4.0%)
Friends	128 (36.4%)	21 (42.0%)
Radio	25 (7.1%)	5 (10.0%)
TV	147 (41.8%)	17 (34.0%)
Internet	109 (31.0%)	18 (36.0%)
Other	34 (9.7%)	3 (6.0%)
Never	29 (8.2%)	0 (0%)

Table 21. Descriptive Demographic Characteristics of Interviewed Sample by Stratifications

(N=50)

Vaccination Status	Unvaccinated				Vaccinated			
Relationship Status	M/LP	LTM	SD	S	M/LP	LTM	SD	S
N	6	7	6	6	6	7	6	6
Age	22.8 (1.5)	21.9 (2.7)	21.3 (2.4)	21.5 (1.9)	22.0 (1.1)	20.1 (2.0)	19.5 (1.6)	21.5 (1.9)
Hispanic	1	2	2	1	1	3	1	1
International Student	0	0	0	1	1	0	0	0
Race								
American Indian/Alask. Native	0	0	0	0	1	0	0	0
Asian	0	2	1	2	1	0	0	2
Native Hawaiian/Pacific Island.	0	0	0	0	0	0	0	0
Black	0	0	1	2	0	3	1	1
White	5	3	3	1	4	3	3	2
Other	0	2	1	1	0	0	0	0
Multiracial	1	0	0	0	0	1	2	1
Sexual Orientation								
Bisexual	1	1	0	0	0	1	1	0
Homosexual	0	0	0	0	0	0	0	0
Heterosexual	5	6	6	6	6	5	5	6
Unsure	0	0	0	0	0	1	0	0
Other	0	0	0	0	0	0	0	0
Insurance Status								
Private	3	5	4	2	5	3	2	5
School	1	1	1	0	1	0	0	0
Medicaid	0	0	0	3	0	3	1	1
Other	0	1	0	0	0	0	2	0
Uninsured	2	0	1	1	0	1	1	0
Not Sure	0	0	0	0	0	0	0	0
Knowledge Scale Score	15.0 (3.8)	15.3 (3.9)	13.5 (7.0)	14.0 (3.2)	18.2 (2.8)	15.6 (3.4)	16.0 (2.5)	14.5 (4.0)
Heard of HPV From....								
Healthcare Provider	3	5	6	3	6	6	3	6
Family	2	3	3	1	2	3	1	2
Partner	0	0	0	0	2	0	0	0
Friends	1	5	4	2	1	3	3	2
Radio	1	1	1	1	0	0	0	1
TV	5	3	2	2	0	2	2	1
Internet	2	3	3	2	1	1	3	3
Other	1	0	0	0	0	1	1	0

Table 22. Description of Relationship Status by Sampling Group

Vaccination	Relationship	Description
Unvaccinated	Married/Living with Partner	All women mutually monogamous with current partner. All women stated they saw a future with this partner. One married, the rest living with a partner. Length of relationship range 1 year – 7 years
	Long-Term Monogamous	Five women mutually monogamous with current partner and two women not sexually active with current partner. All women stated they saw a future with this partner. Length of relationship range 1 year – 6 years
	Single and Dating	Four women mutually monogamous with current partner; length of relationship range 2 months – less than a year. Two women dating; one was not sexually active at the time and the other was sexually active with her partner.
	Single	All women were not sexually active or in any type of partnership at the time of interview.
Vaccinated	Married/Living with Partner	All women mutually monogamous with partner at the time of vaccination. All women stated they saw a future with this partner. One married, the rest living with a partner at the time of vaccination. One woman was no longer living with her partner, but they were still in a relationship at the time of interview. Length of relationship range 2 years – 4 years.
	Long-Term Monogamous	Six women were mutually monogamous with partner at the time of vaccination; one woman was not sexually active at the time. All women stated they saw a future with this partner at the time; one of the women is no longer in that relationship. Length of relationship range 5 months – 3 years.
	Single and Dating	All but one woman had been sexually active at the time of the vaccination or prior to vaccination. Two women described their relationships as “on-and-off again.” Two women said they were currently sexually active and monogamous in the partnership.
	Single	Only one woman was never sexually active. The remaining five women were currently single, but had sexual partners in the past or currently (not monogamous).

IMB Model Factors Influencing HPV Vaccination

Information – HPV and HPV vaccine. Women's knowledge about HPV and the HPV vaccine were assessed through two modalities, the closed-ended survey and the open-ended interview. The percent correct for each knowledge survey question was compared to findings from the qualitative interviews (Table 23).

Overall, there were no major differences in knowledge about HPV or the vaccine by vaccination status or relationship status. When asked generally about HPV in the interviews, some women stated that it is the human papillomavirus and described differences in HPV presentation/transmission between sexes. However, the majority of women needed to be probed on the topic. In the survey, the majority of women correctly knew that there were many types of HPV (78%), men and women would get HPV (96% and 78%), and you can have HPV without knowing it for you and your partner (96%). Less than half of the sample knew that HPV was not a bacterial infection, while over 90% reported that HPV is a virus.

With regard to the curability of HPV, most women in the interview reported that people have HPV for life and that it cannot go away (N=20). However, the majority of these statements included the context of uncertainty by qualifying the statement with "I don't know" or "I'm unsure." This limited knowledge on the curability of HPV in the interviews agrees with the lower frequencies of similar questions correct on the knowledge scale. This was especially true for only 12% getting the statement correct for "Most HPV infections clear up within a short time."

The survey only focused on two prevention methods for HPV: condoms (78%) and the vaccine (98%). The majority of participants answered these questions correctly. Similar answers were reported in the interviews; however, additional prevention methods were cited, including abstinence and sex with known partners.

Table 23. Comparison of Quantitative and Qualitative Assessment of Knowledge about HPV

	Quantitative Knowledge Survey (% correct)	Themes from Qualitative Knowledge Interview
General Info	<p>There are many types of HPV (78%) Only men can get HPV (96%)* You can have HPV without knowing it (96%) You can always tell when someone else has HPV (96%) HPV is a virus (92%) Only women can get HPV (78%)* HPV is a bacterial infection (44%)*</p>	<p>HPV stands for human papillomavirus Awareness that females and males could get HPV, but uncertainty regarding if males are affected or just carriers Limited knowledge regarding types of HPV</p>
Cure	<p>Antibiotics can cure HPV (58%)* HPV can be cured (40%)* Most HPV infections clear up within a short time (12%)</p>	<p>Most women stated you have HPV for life or that it does not go away (N=20); others were uncertain Uncertainty regarding curability of HPV</p>
Prevent	<p>Using a condom decreases the chance of HPV transmission (78%) There is a vaccine for women that prevents certain types of HPV (98%)</p>	<p>Women reported varies prevention modalities: vaccine (N=21), condoms or barrier methods (N=18), abstinence (N=8), sex with known partners (N=2)</p>
Transmission	<p>HPV is spread on toilet seats (56%)* Transmission of HPV can occur through sexual contact with another person (88%) HPV is a sexually transmitted infection (68%) HPV can be passed to a newborn at birth (52%) Even if you do not see a wart, you can transmit HPV (76%)</p>	<p>Most women knew that HPV was sexually transmitted (N=38); however there was uncertainty regarding exact routes of transmission (e.g., skin to skin, oral, vaginal-penile, bodily fluids, kissing)</p>
Outcomes	<p>Some types of HPV cause cervical cancer (94%) HPV can cause HIV/AIDS (56%)* HPV can cause abnormal Pap smears in women (74%) HPV can cause herpes (30%)* HPV can cause genital warts (60%) HPV can affect a woman's ability to get pregnant (6%)*</p>	<p>The most frequently reported outcome associated with HPV was cervical cancer (N=24) Other outcomes included: genital warts (N=13), cancer unspecified (N=5), reproductive cancers (N=2), vaginal cancer (N=1), uterine cancer (N=1), ovarian cancer (N=4), penile cancer (N=1), rectal cancer (N=1), anal cancer (N=2), orolaryngeal cancer (N=1), infertility (N=2)</p>

*False statement; % reflects the proportion of participants who were correct

Most women in the interview knew that HPV was transmitted sexually (N=38); however, some were uncertain when stating this. Similarly 68% and 88%, respectively, of the interviewed sample correctly reported on the knowledge scale that “HPV is a sexually transmitted infection” and that “transmission of HPV can occur through sexual contact with another person.” Moreover, while women knew the sexually transmitted nature of the virus, they were unsure of specific routes, such as penile-vaginal sex, oral sex, or skin to skin contact.

Women were more likely to know that HPV causes cervical cancer in both the survey and interview. Fewer women were aware that HPV could cause genital warts, abnormal pap smears, and other types of cancers (e.g., anal, vaginal, oral). Additionally, women often conflated genital warts with herpes in their description of the outcomes related to HPV. Of particular concern is that approximately half of the participants believed that HPV causes HIV/AIDS and the majority of women believe HPV affects fertility.

During the interview, women were asked to share everything that they knew about the HPV vaccine. There was confusion as to whether males could also receive the HPV vaccine. Yet more than half of the women were aware that both sexes could receive the HPV vaccine (N=28). Moreover, there were a variety of age ranges reported for when people should receive the HPV vaccine. For the most part, the ranges were between teens and twenties; however, some women reported that people should get the vaccine *after* becoming sexually active (N=7). Some of the participants mentioned that there are side effects associated with the HPV vaccine; however, this was usually a nebulous statement. Only four women, who had received the HPV vaccine, were able to accurately describe what these side effects entailed (e.g., pain, fainting).

Information – Trusted and preferred sources. The majority of women in the interview sample reported they had heard of HPV from a healthcare provider (76%). During the interview,

the interviewer listed the information sources each woman had marked on the survey and then asked her to describe which source she trusted the most. The majority of women said that they trusted a healthcare provider the most as the source for HPV information (N=31 out of 38 who listed it). This was attributed to them knowing the individual's medical history, having training in the field, and having their best interests in mind.

"I feel like I trusted them a lot. They reassured me about the vaccine, told me not a lot about it. But I mean enough that I felt safe enough to take it. And they gave me a packet explaining what it was. I didn't actually read a lot of it. In all of my honesty, but yeah." (P9, Vaccinated, Long-term Monogamous).

"Because they are medical professionals and you know they take the oath so I assume that they have my best interests at heart." (P10, Unvaccinated, Married/Living with Partner)

"Because, um, they're like, my doctor, and I feel like they would be like – I guess, more objective view, versus like, your friends and stuff. Um, I don't know, 'cause they're a doctor, I guess. They're paid to know what they're talking about." (P36, Vaccinated, Single)

"Normally they [doctors] are very informative and they had more experience dealing with certain fields than I have so I would trust them to give me the right advice when it comes to certain things like vaccines, what you should have done,

um the types of care that would be best for you, stuff like that. I know this isn't always going to be the case but you just you kind of have to have faith in your doctor and hope that they will.” (P45, Vaccinated, Married/Living with Partner)

Other trusted sources of information included: parents, friends, or Internet. Women were asked where they would prefer to receive additional information about the HPV vaccine during the interview. The two primary modes of information were a healthcare provider or the Internet. When the Internet was mentioned, women said they would prefer reputable sources, such as WebMD or scientific reports.

Motivation – Attitudes about vaccines in general. Similar to the information theme, there were no major group differences in attitudes about vaccines generally. Most women had favorable opinions about vaccines (N=44) stating that they were valuable for personal and population health since these could prevent diseases.

“I think – well, because they protect a lot of people from, you know, it’s kind of like a tier one preventative measure that can be taken so that like widespread, you know, diseases and stuff or to prevent the disease from becoming really widespread.” (P8, Unvaccinated, Single and Dating)

A few women even mentioned the benefit of herd immunity, and the importance of getting vaccinated since certain groups cannot get vaccinated (N=4).

And, I think vaccines are important because you're not just protecting, like, yourself; you're protecting others who may not necessarily be able to get the vaccine, or people who have like, weaker immune systems and are more susceptible to it.” (P36, Vaccinated, Single)

“I think there's more benefits than risk and I'm a strong advocate of herd immunity as well for those who can't get vaccinated. And a lot of people think that because certain diseases aren't prevalent in America anymore they are still prevalent in other countries and because of all the international travel there is it's important that everyone remains - continues to get vaccinated.” (P50, Vaccinated, Married/Living with Partner)

However, there were women across all subgroups who were more weary of vaccines (N=10). Reasons for concern included: too many vaccines, needing different dosing schedules, favored natural medicine, unsure of efficacy, distrust in the FDA and clinical trials, wanting to be aware of what is in the body, wanting to be more informed, fear of bad reactions, and that their attitude depends on the vaccine.

“I'm not a proponent. Um, I never get a flu shot. I don't really believe in vaccines. I think it just puts a lot of unnecessary stuff in your body and, you know, with the flu shot they only – like they pick the seven most common strains they're predicting for that year and give it to you, so you could still end up with the flu. I think it's not a guaranteed thing. So I wouldn't say that I'm pro-vaccine.

Um, I mean I think – I mean I'm not one of those people that believes that like vaccines cause autism. I think we should all get vaccinated for chicken pox and measles and what-have-you, but I don't really believe in taking anything additionally.” (P15, Vaccinated, Married/Living with Partner)

One emergent theme during the discussion of vaccines was the polarization of this topic. A few women reported being “pro-vaccine” when asked how they feel about vaccines in general (N=3). Women then elaborated on the anti-vaccine movement resulting in people not vaccinating their children, which has invaded the culture in the United States. General attitudes about the anti-vaccine movement were that it was not evidence-based, it was causing more harm than good, and influenced by celebrity figures.

Motivation – Attitudes about HPV vaccine. Women were then asked to describe their attitudes specifically about the HPV vaccine. There were significant group differences, with the unvaccinated groups having more mixed feelings about the HPV vaccine and the vaccinated group having more favorable attitudes about the HPV vaccine.

Most unvaccinated women had favorable opinions about the HPV vaccine (N=13), which was attributed to disease prevention. A couple even questioned why they had not received the vaccine yet given the positive attributes (N=2). However, negative attitudes about the HPV vaccine were apparent, including: negative side effects (N=3), unsure of the intended audience (e.g., sexually active only) (N=2), newness (N=2), is for people more at risk of HPV (e.g., more sexual partners) (N=2), and promotes sexual activity (N=1). Others were generally unaware about the HPV vaccine (N=6). In contrast, vaccinated women had more favorable opinions (N=23), similar to the unvaccinated women citing that it was important due to its potential for disease

prevention. A few women even stated that they believed everyone should get the HPV vaccine (N=3).

Overall there was a sentiment that the HPV vaccine was a different type of vaccine compared to required (e.g., MMR) or optional vaccines (e.g., flu) currently available. As one participant summarized,

Interviewer: "Do you see the HPV vaccine as being an important vaccine?"

Interviewee: "Um, yeah. I would see that as more important than, like, a flu shot."

Interviewer: "Okay, but maybe how about compared to the vaccines that are required?"

Interviewee: "Hmm. Um, probably not as important." (P13, Unvaccinated, Long-term Monogamous)

In contrast, some participants echoed this concept of the HPV vaccine being in its own class of vaccines. Women had a difficult time placing it as either a required or optional vaccine for the public.

Interviewer: "In terms of comparing it to other vaccines, do you think it should be a required vaccine, or is it something that's more optional?"

Interviewee: "I think it's definitely more optional. Um, I'm not sure if it should be required 'cause I feel like everybody should have that type of choice. But I know the HPV vaccine when they were like trying to give it to younger girls, there was

like an issue about like basically, 'Is that promoting younger girls to have sex?' which it's not. It's just preventing if I ever do decide to have sex, you know, that they'll have that protection. Um, but, yeah, I think it should be optional, and I think, you know, people should decide like the steps or the choices you should make on that." (P25, Vaccinated, Long-term Monogamous)

Despite the differences in attitudes about the HPV vaccine between vaccinated and unvaccinated women, there were generally four key messages about the *good* things about the HPV vaccine across all groups. These themes included: (1) prevents diseases (e.g., HPV, genital warts, cervical cancer, cancer) (N=43); (2) keeps you safe and protected (N=8); (3) reduces spread of HPV and/or protects partners (N=8); and (4) not having to worry about HPV or some of its outcomes (N=7).

"Good things, um, well one thing, even if you are not sure about your partner you know that even if that person he or she has something, if you got HPV vaccinated, you will be safe. You will not have to worry about it. And most importantly it can lead to cervical cancer and I think you are protected against that." (P5, Unvaccinated, Single)

"It will make me safer in the future 'cause I won't, you know, spread – if I don't already have it, HPV, which I don't, then if I, you know, I have intercourse with more people then I won't spread it to them if I am protected against it." (P35, Unvaccinated, Single and Dating)

Similarly there were no major differences in *bad* attributes of the HPV vaccine. These included (1) side effects (N=20); (2) the fact that it was a shot or a vaccine (N=8); and (3) the cost (N=5). There were a quarter of participants who could not list any negative attributes about the vaccine—seven vaccinated and six unvaccinated. Cost was mentioned in the context of it is an expensive vaccine for women who do not have insurance, but not necessarily a personal barrier.

“...maybe cost? For some people. I'm not sure. Uh, I mean I don't know if HPV [vaccine] is covered under all people's insurance or sometimes if the vaccine is not required, it's not necessarily covered for people.” (P1, Unvaccinated, Married/Living with Partner)

Additionally, women had fear of shots or needles, which translated in the vaccine being less favorable due to the administration method.

“For me, I just don't like shots, so for me it'd be like having to go get a shot that would probably the worst to me.” (P21, Unvaccinated, Single and Dating)

Side effects were again cited as a *bad* feature of the vaccine; however, participants continued to have difficulties describing these side effects. Six vaccinated women and three unvaccinated were able to describe the side effects, which were primarily pain, nausea, and rash. One woman described weighing the costs and benefits, essentially her risk for HPV against the potential side effects.

“So I think the bad thing would be if there was any side effects, whatever that would come along with. You know, if it goes cause like some sort of – maybe like some discomfort, like uncomfortable sex or something like that. And if I’m not sexually active or if my partner later on is not – doesn’t have HPV, then why would I get the vaccine if I know I’m not gonna get it?” (P6, Unvaccinated, Single)

Motivation – Social influences. Women were asked who in their life influenced their decision for vaccination or non-vaccination. For unvaccinated women, these influential agents impacted their decision not to get the vaccine or would be influential if they decided to get the vaccine. All were probed for key groups identified in the literature, which include healthcare providers, parents, peers, and partners. Again, there were no major differences observed by sampling group. More than half of participants reported that their healthcare provider’s recommendation influenced or would influence (for unvaccinated women) their decision to get the HPV vaccine (N=33). This was attributed to providers being familiar with their health history, being able to explain their risk for HPV, and reassuring the participant that it was a good vaccine to get.

“Like my doctor probably. But only 'cause she's pretty like trustworthy. I feel like, um, if she is really, um – uh, what's the word I'm looking for – like sympathetic. Like I don't feel like she's like the kind of – like not try to get this over, and over and get in, get out, "Tell me what your complaints are." So if she recommended something, I would feel like it was because she's trying to do

something good rather than just like trying to make money.” (P23, Unvaccinated, Long-term Monogamous)

“It made me worry a little less, so I, like I said, I trust my doctor. He’s been my doctor since – you know, my pediatrician since birth. So, he wouldn’t do anything – he wouldn’t make me do anything stupid.” (P27, Vaccinated, Single and Dating)

The second key agent to HPV vaccine decision-making was a parental figure, specifically the mother (N=23). Some mothers’ negative opinions about the HPV vaccine or medicine in general influenced women’s decisions about the vaccine. However, mothers were seen as important because they ensured health and healthcare throughout childhood.

“Um, well, 'cause she's always been very like adamant about like making sure that my health needs are provided for, and making sure that, um, I have the proper vaccinations...” (P23, Unvaccinated, Long-term Monogamous)

Additionally, some women reported that mothers’ personal experiences with HPV or cervical cancer were also influential (N=2). Other family members were mentioned as being important figures, but not as frequently as mothers. These were fathers, sisters, and grandparents.

Less influential figures were peers and partners. Friends were seen as important figures in the HPV vaccine decision-making process when they could share their experience with the

vaccine (N=18). These narratives of getting the vaccine reassured women that the vaccine was safe and a good option for them.

“Um, I guess friends, too, like a couple other friends have had it, like I haven't, like, gone into detailed conversations with them about it, but just seeing, like, like the majority of my friends, like, have it or get it done, I guess that would persuade me more to get it, like I feel like, "Okay," like, "This is safe. If this person did it, then I'll be fine.”” (P11, Unvaccinated, Single and Dating)

Across all relationship status groups, partners were rarely mentioned as influential for getting the HPV vaccine (N=11). Women reported they discussed the vaccine with their partner and that it was dismissed or the partner had no opinion. This was illustrated by this participant's description of her boyfriend,

“Him [boyfriend] personally, he didn't really have an opinion on it [HPV vaccine] which was weird because I wanted to talk to him, I wanted to get his opinion. He's not really opinionated on stuff like that so, he didn't really give me it.” (P48, Vaccinated, Married/Living with Partner)

Others mentioned they thought their partner should look into the vaccine too. However, only a few of these comments reported that the partner had a major influence on the individual's decision-making.

One emergent theme during this interview process was the idea that HPV vaccine decision-making was a personal decision, rather than dependent upon others. Approximately a quarter of the women reported that getting the HPV vaccine was a personal decision (N=12). However, most of these women also mentioned influential others described above. Therefore, for this group of women while others in the social environment may influence HPV vaccine decision-making, the ultimate decision rested with the individual to decide if the vaccine is right for her.

Motivation – Reasons for (non-)vaccination. To gain context to the HPV vaccine decision-making process, participants were asked the primary reason they did not receive the HPV vaccine when they were an adolescent. Three primary reasons emerged across all sampling groups. The first was that the vaccine was never brought up by a healthcare provider or any other agent (N=21). In other words, the participant never heard of the HPV vaccine during adolescence. The second reason for non-vaccination was a maternal figure deciding that the adolescent female did not need the HPV vaccine (N=14). This is similar to the comment from the social motivation that mothers were the primary caretakers for health-related needs during childhood and adolescence. Mothers did not want the female adolescent to get the vaccine out of fear of increased sexual activity, the newness of the vaccine, the side effects, or not seeing their daughter at risk.

“My mom said it wasn't important, and this was in high school, because my doctor offered it to me, and I was 16 – I think I was 16 or 17, and my mom was just like, “Oh, you don't need that,” and especially since, I mean, I don't know why she said that. Probably because I wasn't having sex then, but that's really why I

never got the vaccine, and I wasn't offered it again, you know, like out of sight, out of mind.” (P12, Unvaccinated, Long-term Monogamous)

Finally, many women mentioned that they did not receive the HPV vaccine as an adolescent because they were not sexually active at the time (N=11). This corroborates the misperception that the HPV vaccine is only for persons who have initiated sexual activity and at higher risk of HPV. As one participant stated, *“I wasn't having sex so I didn't see a need for it.” (P49, Vaccinated, Long-term Monogamous)*. It was not only the individual participant who believed that they did not need the vaccine due to sexual inactivity, but it was also perceived that parents and healthcare providers agreed with this belief.

While there was consistency across groups regarding the reasoning for not getting a vaccine at a younger age, there was more variability for HPV vaccine decisions in young adulthood. Unvaccinated women in relationships (long-term monogamous or married/living with a partner) described four primary reasons: (1) monogamy or perceived low risk (N=5); (2) not offered or recommended by a healthcare provider (N=4); (3) time and/or money (N=2); and (4) use of other preventive measures (e.g., Pap test) or belief in natural medicine (N=2).

Unvaccinated women who were single and dating were more unsure of the reasons why they have not received the HPV vaccine as a young adult (N=3). Women who were unvaccinated and single only also stated two primary reasons for non-vaccination. The first was a lack of awareness about the vaccine (N=2), and the second was they perceived themselves not at risk for HPV due to sexual inactivity (N=3). Cost was also a reason for two participants in the single and dating, and single groups. Overall in the unvaccinated groups, it was clear that lack of awareness

of the HPV vaccine served as a primary obstacle to vaccination, as well as perceptions of low risk of HPV.

In contrast, there were many more factors that contributed to the decision-making process among women in the vaccinated groups. Women who were vaccinated and in relationships had a variety of cues that influenced their decision to get the vaccine. These included a family history of cancer (N=3), a history of HPV or an abnormal Pap (N=2), becoming sexually activity (N=2), needed follow-up shots (N=2), getting insurance (N=1), vaccine was free until age 19 (N=1), living with a partner (N=1), became aware of the vaccine recently (N=1), belief that the vaccine was required for college (N=1) and parents recommending (N=1). Women who were vaccinated and single and dating or single only stated that they received the vaccine now because a doctor/friend/mother recommended the vaccine (N=7), they just became aware of the vaccine and wanted the added protection (N=2), belief it was required for school (N=2) or it was convenient (N=1). While doctor recommendation was a factor for women *not* in relationships, it was not listed as a reason for women in relationships.

Motivation – Relationship status and HPV vaccine decision-making. Participants were asked how they thought their relationship status impacted their decision to get the HPV vaccine. The summaries are presented by relationship status category in Table 24. Note that women in married/living with a partner and long-term monogamous categories were consolidated into one group due to similar findings. It was the original intention to consolidate single and dating and single only into one category as well; however, these groups had distinct responses that are presented individually.

There was variability observed for how relationship status impacted HPV vaccine decision-making. Unvaccinated women who were either in a relationship or single only stated

that their current relationship status was reasoning for not getting the vaccine now, this was attributed to monogamy or number of partners and sexual inactivity. Women in both of these groups said they would be more likely to get the vaccine if their relationship were to change. In contrast, women who were single and dating reported that their relationship status did not impact their decision not to get the HPV vaccine. If their relationship changed to a long-term relationship, they reported they would be less inclined to get vaccinated. Across all groups of vaccinated women, relationship status was less influential on their decision to get the vaccine; rather the women reported wanting the security of protection.

Motivation – Risk perceptions – Perceived susceptibility. Participants' perceived susceptibility to HPV was evaluated by asking what they thought their risk of HPV was with and without the vaccine. The summaries are presented by relationship status category in Table 25.

Risk perceptions for HPV differed primarily across relationship statuses, rather than vaccination status. This is likely attributed to the questioning of the perceptions of risk qualified by with or without the vaccine. Women in relationships stated that their perceived risk of HPV was low, which was attributed to monogamy and number of sexual partners. These women said their risk would minimally decline with the vaccine. The perception of risk was more variable for single and dating women, who attributed their risk to similar factors, but also unprotected sex, annual exams, distance to partner, and sexual activity. All women in these groups said their risk would decrease with the vaccine. Finally, women who were single said that their risk for HPV was low and that their risk would decline or remain the same with the vaccine. A larger proportion of unvaccinated women who were single were sexually inactive compared to women who were vaccinated.

Table 24. Comparison of Relationship Status’ Impact on HPV Vaccine Decision-Making by Sampling Group

	Unvaccinated	Vaccinated
<p>In a Relationship</p> <p><i>(Includes Married/Living with Partner and Long-term Monogamous)</i></p>	<p>Because they were in monogamous relationship and/or had few partners they did not need the HPV vaccine.</p> <p><i>“Because, I know that it is a sexually transmitted infection and I believe that if I’m in a monogamous relationship that the likelihood that I get it is less than. I know that people aren’t perfect, things happen. But I genuinely believe that we are going to be mutually exclusive, long-term.” (P10)</i></p> <p>If relationship status changed, they would consider getting the vaccine because they need protection from the uncertain risk.</p> <p><i>“So if he had had more sexual partners or if I was interested in having more sexual partners, I would definitely go out and get the vaccine just because I don’t know where like his partners would have been coming from, or wouldn’t have known where my future partners are coming from.” (P23)</i></p>	<p>Some women (N=5) said they wanted the vaccine for the protection in their relationship at that time.</p> <p><i>“Yes, it’s – it’s really wanting protection as well, just not myself but also him, I didn’t want him to accidentally get it from me if I somehow got it.” (P41)</i></p> <p>The majority of women (N=8) said that it was a personal decision only to get the vaccine and their relationship had no influence.</p> <p><i>“...it was more for my own personal health.” (P9)</i></p> <p>If relationship status changed to single, it would be even more important to get the vaccine.</p> <p><i>“So I feel like if I wasn’t in a monogamous relationship I probably would’ve been more concerned, ‘cause I would’ve felt like there’s more chance of contracting it.” (P15)</i></p>
<p>Single & Dating</p>	<p>Relationship did not have a major influence on decision, but there was a concern of needing it for future partners.</p> <p><i>“Right now, since I’m not sleeping with anyone, I’m like, ugh, I don’t need to get it yet, but then at the same time I’m like, well, I might sometime soon so I probably should be protected and that’s where I’m at with that.” (P35)</i></p>	<p>Half women said they wanted to get the vaccine because of the uncertainty of their current/future sexual partners’ history.</p> <p><i>“Yes, only because like we were sexually active, and I was like any kind of like extra protection I was game for. He – he had been with other people before, and I’m like you can’t really tell when somebody has HPV; he might not even know.” (P19)</i></p>

Table 24 (Continued)

<p>Single & Dating</p>	<p>Women said they would be less inclined to get the vaccine if they became monogamous or entered a long-term relationship.</p> <p><i>“I feel like if I, like, was with this person, like long-term and that's it, like I probably wouldn't be as inclined to do it.” (P11)</i></p>	<p>Half women said it was a personal decision only to get the vaccine and their relationship had no influence.</p> <p><i>“I don't remember thinking about the relationship when I got the vaccine. I thought more, um, I guess in the future. I thought about, like, um, more up, like, later on in life, you know, as you would want to be, you know, protected against that....Like, I didn't want to eventually be married and have that, you know, worry in my mind about HPV.” (P27)</i></p>
<p>Single Only</p>	<p>Women said they did not need the vaccine due to lack of sexual activity.</p> <p><i>“Yeah, in – in a sense it does ‘cause as I mentioned before, I – my lifestyle is to be abstinent ‘til marriage so the fact that I’m not married just means that I’m not going to – I’m not going to need the vaccine. So in a sense, like if I got marriage and my partner ended up being – ended up having HPV or something, then I would get the vaccine.” (P6)</i></p> <p>If relationship status changed to a serious relationship or if they were to get married, they would consider getting vaccinated.</p> <p><i>“Interviewer: Let's say hypothetically if your relationship status changed in the future, maybe you found a partner, would this change your decision about the vaccine? Interviewee: Yes it would. I would go and get the vaccine.” (P5)</i></p>	<p>Women in this group said that their relationship status did not impact their decision to get the HPV vaccine.</p> <p><i>“I don't think it [relationship status – single] really impacted it. Like, I think even if I hadn't been seeing anyone I probably would've gotten it anyway because my doctor recommended it. So, I don't think it really had a major impact on my decision.” (P36)</i></p>

Table 25. Comparison of Perceived Risk of HPV *With* and *Without* the Vaccine by Sampling

Group

	Unvaccinated	Vaccinated
<p>In a Relationship</p> <p><i>(Includes Married/Living with Partner and Long-term Monogamous)</i></p>	<p>Without Vaccine: Low risk for HPV attributed to monogamy and number of sexual partners.</p> <p><i>“I have this thing – like this – this, uh, association, “Oh, we’ve been together. We don’t have it. We’re fine,” though I know that’s not always the case that, you know.” (P16)</i></p> <p>With Vaccine: Risk would decline slightly or stay the same because it is already low.</p> <p><i>“I feel like if I were in – I don’t know like single or perhaps in like a non-exclusive relationship, it’s something that I would think about a little bit more. But as – yeah, I’m just like – it – it hasn’t really felt as relevant for me, but I definitely think that there’s like a lot of benefits to it.” (P7)</i></p>	<p>Without Vaccine: Low risk for HPV attributed to monogamy and number of sexual partners; however, some (N=5) women stated it was high because of uncertainty or “you never know.”</p> <p><i>“I’d probably say it is low... Um, just that I’m only with one person at one time. So it’s like I don’t have multiple partners.” (P49)</i></p> <p><i>“I feel like it’s high, but I’m also the same person that, like, you know, when you hear like 1 in 4 people have an STD, I find that to be extremely high. In my mind it feels high.” (P15)</i></p> <p>With Vaccine: Risk would decrease minimally because already low.</p> <p><i>“Um, of course, now it’s [risk for HPV] definitely much, much lower. There’s still a risk because the vaccine doesn’t work 100 percent.” (P46)</i></p>
<p>Single & Dating</p>	<p>Without Vaccine: Varied risk among women, ranging from low, medium, high, and unsure. Risk for HPV was attributed to monogamy, unprotected sex, and annual checkups.</p> <p><i>“I don’t know. I don’t think it’s – I don’t think it’s very high. But you don’t know. I mean I – ‘cause it’s not my choice. Like I don’t – you know, I don’t have a lot of sexual partners and I haven’t in the past and I only have one ever. So like - but still, it only takes one person to get it so I don’t know. I don’t think in the high risk group, but maybe I am.” (P35)</i></p>	<p>Without Vaccine: Varied risk among women, ranging from low, medium, to high. Risk was attributed to current sexual activity (e.g., distance partner, not sexually active, on-and-off again partner).</p> <p><i>“Um, honestly, I know that the, like, amount of people that have this [HPV] is high. So, um, I honestly don’t date a lot. I haven’t had, like, a lot of boyfriends and stuff that are sexual relationships with people, so my chances are fairly low, but I know there are a lot of people out there. So I would say, you know, still the risk is, is high.” (P27)</i></p>

Table 25 (Continued)

<p>Single & Dating</p>	<p>With Vaccine: All women said risk would decline with the vaccine.</p> <p><i>“Yeah, whatever risk I may have had, yes, it will definitely decline with the vaccine.” (P37)</i></p>	<p>With Vaccine: All women said risk would decline with the vaccine.</p> <p><i>“Yes, I think that – I mean I’m not a 100 percent protected from it but a lot less prone to the infection or the virus I mean.” (P40)</i></p>
<p>Single Only</p>	<p>Without Vaccine: Zero risk because not sexually active.</p> <p><i>“Personally, I think it’s probably like a .01 percent. Again, because of the abstinence policy that I abide by and again, if I had a marriage – when – when I get married I – it’s – it’s sort of like a trust thing, you know? You should know if your –if your partner has HPV.” (P6)</i></p> <p>With Vaccine: Half of women said there would be no change in risk because they are not at risk to begin with, while the other half said the risk could decrease.</p> <p><i>“No, my risk wouldn’t change ‘cause although like I would understand getting the vaccine would change my mindset, it still wouldn’t change my lifestyle, like just because – just because I wear a seatbelt in the car doesn’t mean that I’m gonna drive faster.” (P6)</i></p>	<p>Without Vaccine: Four said low risk attributed to sexual history and two said high because of either their partner’s sexual history or because HPV is common.</p> <p><i>“If you’re sexually active, then probably a high risk. If you’re not sexually active, then I guess you’re kind of okay. I think I’m a low risk. I’m not sexually active.” (P30)</i></p> <p>With Vaccine: All but one said the risk would decline; the one who said no change stated her risk was already low to begin with.</p> <p><i>“I think it’s lower than it was before I got the vaccine.” (P36)</i></p> <p><i>“Yeah, I mean, I still think I’m at low risk because I have the vaccine. It’s an extra safety net for me.” (P3)</i></p>

Motivation – Risk perceptions – Perceived severity. Perceived severity of outcomes associated with HPV was assessed by questioning participants about how they perceived the consequences of HPV. There were no salient group differences among sampling groups, rather

three primary consequences emerged. The first outcome focused on by participants was cervical cancer, or more generally cancer (N=45). This was seen as the most severe outcome associated with HPV attributed to the fact that it is life-threatening, serious, has significant treatment costs, and fatal.

“I would say, well if it was, if it was as bad as cervical cancer, I would say the consequences would be awful. Um, potentially life threatening, would be the best way I could put that.” (P48, Vaccinated, Married/Living with Partner)

Some women even drew on experiences of knowing others who suffered through cancer to emphasize the severity of this disease. Others mentioned that cervical cancer would ultimately affect their fertility and potential to have children in the future.

The second outcome described was genital warts; however, sometimes this was referred to as just warts or conflated it with herpes (N=40). The general sentiment was, “...*genital warts, I've seen pictures and it does not look very pleasant.*” (P17, Unvaccinated, Married/Living with Partner) In comparison to cancer, women reported that it was not as serious as cervical cancer, but still serious due to it being uncomfortable, cosmetically displeasing, and painful. “*Well, I mean to me the scariest one is cervical cancer, and plus I don't know anyone that wants warts.*” (P15, Vaccinated, Married/Living with Partner) Others mentioned that they would not have to want to disclose having genital warts to a partner and that it would affect their sex life.

“I mean I guess especially it's not appealing if you're trying to engage in any type of sexual activity with anybody. But if you would be self-conscious and you would

feel not clean with yourself, you know. It's not a good thing to feel like you have. It's not something that you would wanna advertise or anything like that.” (P25, Vaccinated, Long-term Monogamous)

Finally, some participants described the emotional responses of having HPV (N=9). Psychosocial reactions included loss of trust in partners, the stigma of having a sexually transmitted infection, and being self-conscious. These emotional responses were primarily a reflection of how others, specifically future or current sexual partners, would perceive them with an HPV diagnosis.

“...you know, diagnosed some psychological or emotional I guess turmoil of sorts; and so have to deal with, "Oh, I have an STD," and not seeing it's pretty, uh, negative in our culture.” (P23, Unvaccinated, Long-term Monogamous)

A comment made by one participant put into context how some women may perceive HPV in the realm of sexually transmitted infections. She stated,

“I feel like it's, it's – in a way, I just feel like it's HIV's little sister. Like it's just, it's just you can get – you can get it so many times until you actually get the HIV. So it's definitely – it's like a chance. You can a chance to like get yourself together; and it's just a red flag. Like, "Hey, you have to protect yourself. You have HPV, now you have to protect yourself, you know, right before you, you know, things can get out of hand.” (P26, Vaccinated, Single and Dating)

This indicates that HPV may be a surrogate for sexual behavior that may place a woman at more risk for other, perceived more serious, sexually transmitted infections.

Behavioral skills – Procedural knowledge. In order to elicit the behavioral skills needed to get the HPV vaccine series, participants were asked to describe the steps for getting it. For unvaccinated women, this was a hypothetical situation of what they thought would be involved. For vaccinated women, they recalled the process. Overall the groups were similar in displaying procedural knowledge for getting the HPV vaccine. For the vaccinated women, approximately half of participants said they went to a regularly scheduled annual exam or other healthcare appointment where the HPV vaccine was discussed. It was at these visits that the women decided to get the vaccine then based on conversations with healthcare providers or other staff. In contrast, the other half made specific appointments to get the HPV vaccine; however, this was usually the result of another cue to action for getting the vaccine. Most women described speaking to their healthcare provider about the vaccine prior to initiating the series.

“I went to my healthcare provider because, in order to go to college, I had to get a couple more vaccines. And he said that there was another vaccine that was available for me to have in case I became sexually active or already was. And, he told me a little bit about it. He told me about what it prevents, such as, you know, cancers, genital warts. I told him to give me the need-to-know information and all the cons, and I remember he said auto-immune disease was a con. And, I decided it's better safe than sorry, and because I do believe in vaccines, I decided to go ahead with it.” (P3, Vaccinated, Single)

The majority stated they used insurance coverage to pay for the vaccine; only three said they received the vaccine for free and another said her mother covered the payment.

Women who were vaccinated were in different stages of getting the follow-up shots. Of the women who reported completing the vaccine series (N=16), these women made follow-up appointments in advance and typically had an immunization-only appointment. Unvaccinated women mentioned that in order to successfully complete the vaccine series, they would need to schedule follow-up appointment in advance.

In comparison, women who were unvaccinated reflected on the steps they would need to take if they hypothetically decided to get the HPV vaccine. Women said they would go to a scheduled annual exam or schedule a specific visit for the vaccine, then ask for more information from their healthcare provider to clarify that the vaccine was right for them.

“So I would go to the gynecologist and then I would be talking with them at my appointment and then one of us would say, ‘Hey, do you want to get – you can get a HPV vaccine?’ Or if they didn’t ask me this time I would bring it up because I’ve been thinking about it a lot and then I would say, ‘Should I get the vaccine?’ Or actually I’d say something I want ‘cause it sounds like I probably do really want it and so I’d say, ‘I want to get the vaccine. Should I now – is it good for me?’ And then I would ask them like how we would go about doing this, like when will I get the first shot or what – and then I’d ask what maybe the complications are, like people’s side effects they’ve had from the vaccine. And that would be – that would be it. I either get it or I wouldn’t.” (P35, Unvaccinated, Single and Dating)

Most women said their insurance would cover the vaccine, but there were seven women who said they would need to figure out their finances to cover the expense. Finally, they stated they would need to schedule follow-up visits for the additional shots. These steps were essentially the same as the vaccinated group indicating that the unvaccinated have the procedural knowledge to get the HPV vaccine.

Behavioral skills – Facilitators. Women were asked to describe factors that would make the vaccination process easier for them, considering the steps needed to get the vaccine (Figure 7). For vaccinated women, this involved reflection on events that had occurred, while unvaccinated women described what they believe would facilitate the process. Interestingly, women in the unvaccinated group were able to describe more facilitators compared to the vaccinated group, 39 and 30, respectively. This may be due to women in the unvaccinated group describing hypothetical scenarios for themselves and women generally, whereas the vaccinated women reflected on their individual experiences.

All groups of women described logistics and convenience as the primary facilitator for HPV vaccination (N=19). This included items such as time off of work, distance to the provider's office, easy scheduling, vaccine only appointments, and efficiency of the office. Additionally low cost of the vaccine or insurance coverage was also a facilitator (N=23). Women in the unvaccinated group were more interested in the cost aspect compared to vaccinated women.

All groups of women emphasized that a trusting relationship or reassurance from a healthcare provider would help/helped the decision-making process (N=13). These women described an evaluation process to determine if the vaccine was right for them and a reliance on a healthcare provider's judgement. As one participant stated, "*Just the reassurance from talking to*

the doctor” (P4, Vaccinated, Long-term Monogamous) made the process easier. Additionally, women also described having a regularly seen healthcare provider or a provider they could trust as a facilitator. Support from influential others agreeing with the decision for the vaccine was also reported (N=4); these influential others included parents and partners.

Since unvaccinated women were still undecided or decided against getting the HPV vaccine, when describing facilitators for vaccination, some women mentioned the desire to have more information or awareness about the vaccine (N=5). This is another opportunity for a healthcare provider to have a role in the decision-making process.

There were a few facilitators that were described that were unrealistic. Women stated they would rather the shot be in a pill format or that there were fewer shots (N=5). This is similar to the negative attributes described about the HPV vaccine.

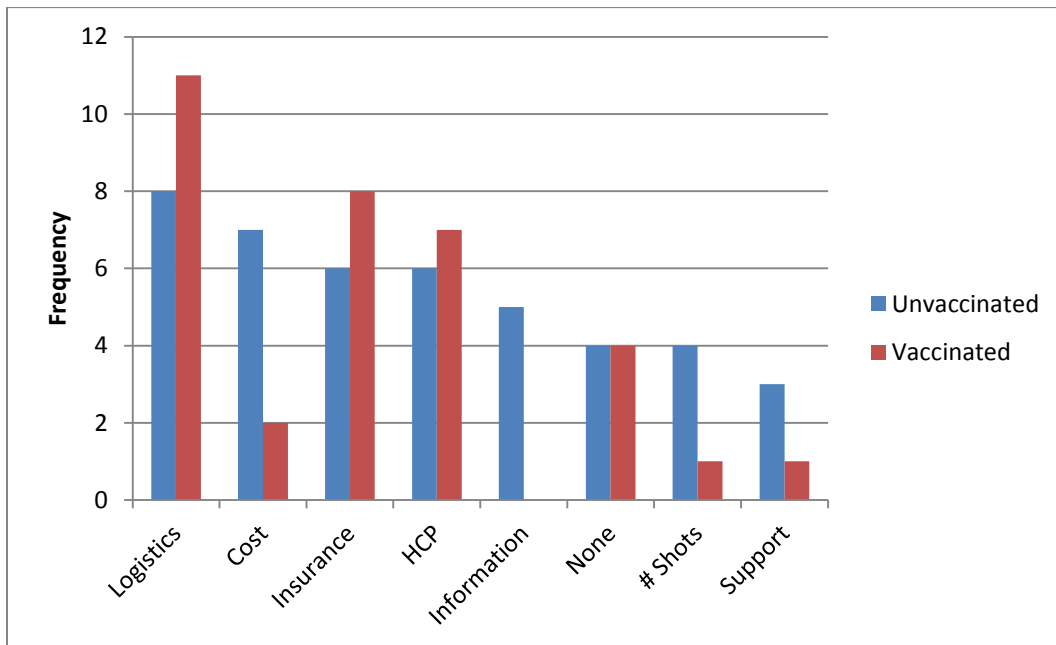


Figure 7. Frequency of Facilitators for HPV Vaccination by Vaccination Status

Behavioral skills – Barriers. Similar to the facilitators for the HPV vaccination process, women were asked to also describe perceived barriers (hypothetical or actual). Unvaccinated women had 33 accounts of describing barriers compared to vaccinated women at 19 (Figure 8). This is largely attributed to 40% of the vaccinated women stating that there were no barriers to vaccination, which may be due to the recall of the process.

Logistics continued to be of prime importance to the young adult women across vaccination status (N=15). Again, this included factors such as time, convenience, and accessibility. However, in this scenario 15 unvaccinated women described insurance or cost as a potential barrier, while only one vaccinated woman described the insurance process. Again, this is likely due to the fact that vaccinated women were able to overcome this obstacle and no longer see it as a barrier, while unvaccinated women were describing what they perceive to be future obstacles.

Lack of healthcare provider support or recommendation was not seen as a significant barrier (N=3); rather healthcare provider input appears to be more of a positive factor. Lack of support from influential others was also seen as a barrier (N=4); these important others included parents and partners. Only one vaccinated woman described wanting to receive more information prior to getting the vaccine as a factor that made the process difficult. Finally, many of the barriers described were opposite of the facilitators listed; however, there were a few new items, including fear of needles (N=6) and fear of side effects (N=5).

Macro factors – Healthcare interaction. Women were asked how many times they visited a healthcare provider in the last year. Almost all women (N=41) reported seeing at least one physician in the past year, typically a gynecologist or general practitioner for an annual appointment. Women who did not see a doctor in the last year mentioned that they only see a

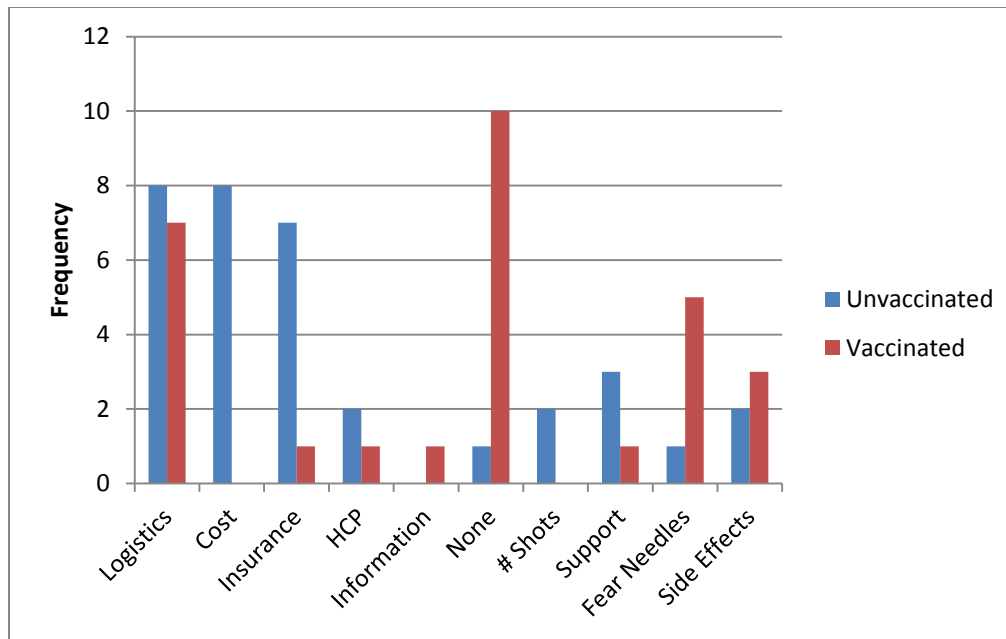


Figure 8. Frequency of Barriers for HPV Vaccination by Vaccination Status

doctor when they are sick. Among this group of women with low healthcare interaction (N=9), a third was women who were unvaccinated and single only. These women reported not being currently sexually active, which may contribute to their low utilization of healthcare services from a gynecologist.

Macro factors – Health insurance. According to the survey administered prior to the interview, a total of six participants did not have insurance at the time of the interview. There were two vaccinated participants without health insurance, and four unvaccinated participants without health insurance. The majority of participants, 58%, had some form of private insurance (N=29). The remaining had Medicaid (N=8), school-sponsored (N=4), and other (N=3).

Macro factors – Social and cultural factors. Finally, participants were asked to share any social or cultural factors that influenced their decision or opinion about the HPV vaccine. This concept was difficult for women to articulate, and as result they were probed about

government involvement, vaccine discussions in our culture, and media messages. There were no group differences in these factors; in fact, the items listed by women were very individualized. Only eight women could not list any social or cultural factors that influenced their opinion about the HPV vaccine (N=3 unvaccinated and N=5 vaccinated).

Societal norms regarding views on medicine and vaccines in the United States were discussed. Women reported having a distrust in the American medical system and/or a focus on natural and holistic medicine (N=8). Many of the women's preferences for holistic and natural remedy stemmed from their culture or upbringing. Similarly, a couple of women reported the skepticism they had for new medicine and lack of information on long-term outcomes (N=2).

“Just that I come from a family that’s more into like holistic remedies and cures for things. We don’t really go to the doctor or take a whole lot of medicine, um, things like that, so I’m always leery of vaccines and vaccinations.” (P15, Vaccinated, Married/Living with Partner)

Yet despite these preferences for natural medicine, women still recognized the importance of the HPV vaccine for prevention of disease.

“I think, I think definitely I’ve, I’ve carried it on [traditional medicine] in the sense like I don’t, I don’t take over-the-counter stuff when I’m sick or, you know, things like that. But definitely things that are more out of my control like, you know, getting an STI, or like if, if I can prevent something like that, then I’ll definitely try to because it’s like, it’s like my life being in somebody else’s hands,

it's not really my life in my own hands.” (P25, Vaccinated, Long-term Monogamous)

Additionally, there were HPV vaccine specific societal attitudes that impacted the participants’ opinions about the HPV vaccine. These HPV vaccine factors included (1) connection of the vaccine to sex, abstinence, and stigma (N=4); (2) lack of awareness in society of this vaccine (N=2); (3) non-required vaccine indicating its lack of importance (N=2); and (4) negative reputation of the vaccine (N=1).

The most prominent theme discussed by women was the anti-vaccination movement (N=11). These women reported not agreeing with the movement, but recognized that it contributes to negative views of the HPV vaccine. As one woman stated, there are polarizing opinions on vaccination in our society,

“Society’s view of vaccinations, like I just think it’s like half and half, like half of them say it’s very good, half of them say it’s super bad.” (P11, Unvaccinated, Single and Dating).

Finally, women described media messages they had viewed about the HPV vaccine and vaccines generally. Among these messages, there were negative (N=6), positive (N=4), and mixed or incomplete messages (N=2). Two specific media campaigns/advertisements were described, these included “One Less” and “Tell Someone.” One participant also mentioned an episode of the HBO television show, *Girls*, mentioning HPV and its relation to sexual activity. Most women reported a level of skepticism of the mass media messages that were presented.

“I haven’t seen many – like a lot of media promoting HPV except here in like the - and with pamphlets and like the - student health services that’s advocating for it. But I’ve seen a lot of like stuff against it saying that it causes autism in kids and stuff like that since that has been disproven.” (P41, Vaccinated, Long-term Monogamous)

Summary of IMB Factors for HPV Vaccine Decision-Making

The research questions for this phase aimed to compare informational needs, motivations, and behavioral skills for HPV vaccination across vaccination status (i.e., vaccinated and unvaccinated) and relationship statuses (i.e., married/living with partner, long-term monogamous, single and dating, and single). During these comparisons, it was clear that there were no significant differences across these groups for the following constructs: *Information: Knowledge, Preferences, and Trust; Motivation: Attitudes about Vaccines, Social Motivation, Reasons for Non-Vaccination at a Younger Age, and Perceived Severity; Behavioral Skills: Procedural Knowledge; and Macro Factors: Healthcare Interaction, Insurance, and Social/Cultural Factors* (Figure 9).

When comparing across vaccination status, there were differences between vaccinated and unvaccinated women for *Motivation: Attitudes about HPV Vaccine, Motivation: Reason for (Non-)Vaccination Now, and Behavioral Skills: Facilitators and Barriers*. Finally, differences were observed across relationship status categories (i.e., In a relationship; Single and Dating; and Single Only) for *Motivation: Perceived Risk of HPV and Motivation: Reason for (Non-) Vaccination Now*.

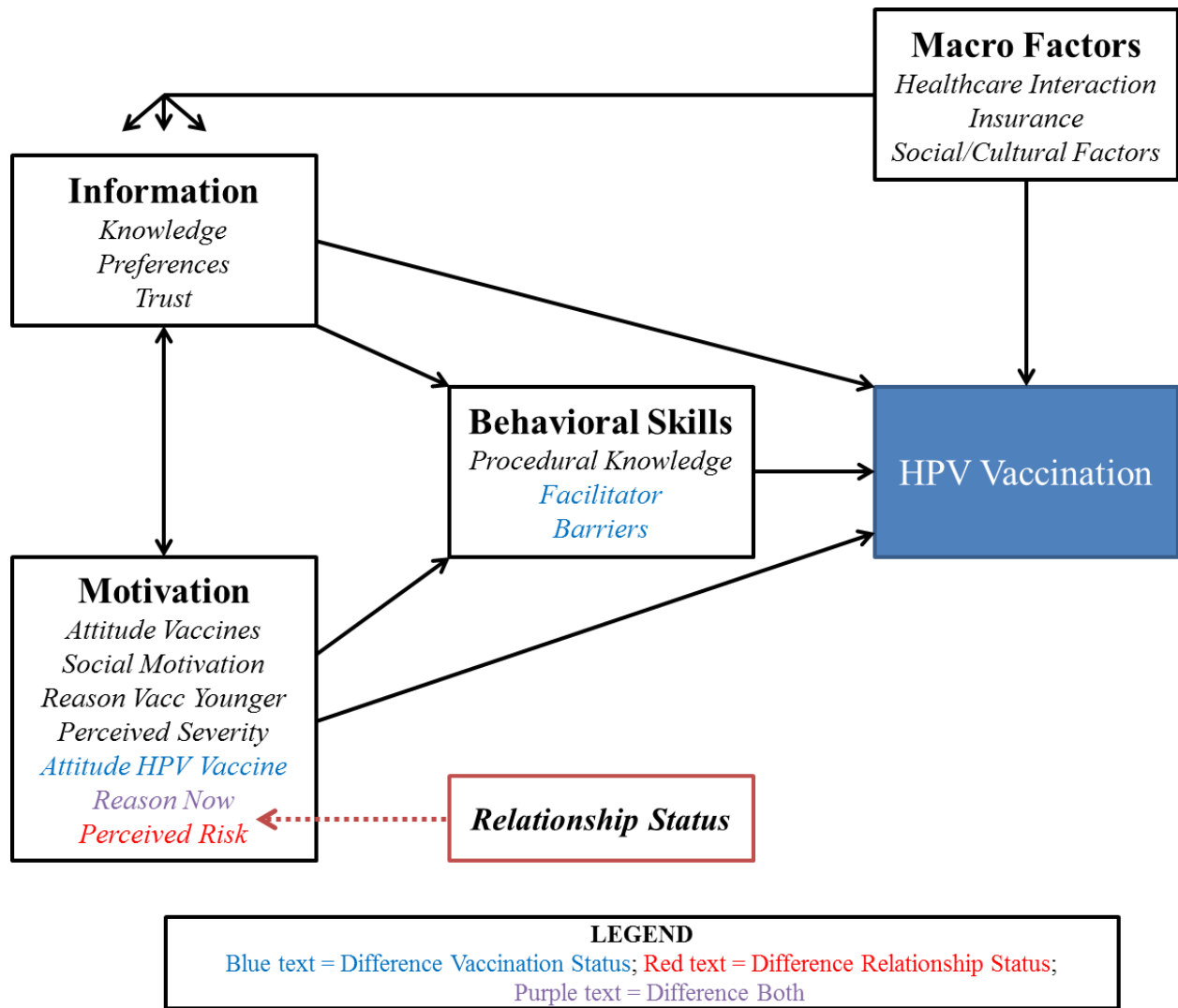


Figure 9: IMB Model for HPV Vaccination among Young Women

Chapter 5: Discussion

Overview

HPV vaccination has been available for the prevention of HPV-related disease among females since 2006 (Markowitz et al., 2007). While targeted toward young adolescents aged 11 and 12 years, the rate of uptake among this group continues to be below optimal (Healthy People 2020, 2015c; Stokley et al., 2014). As a result, unvaccinated young adult women continue to fall in the catch-up age range of 18 to 26 years for HPV vaccination. Unfortunately, approximately only a third of 18 to 26 year old women have received the HPV vaccine resulting in a large proportion of women who cannot benefit from this type of prevention for HPV-related disease (Schmidt & Parsons, 2014).

In order to improve HPV vaccine rates among this catch-up range of women, it is necessary to examine groups who continue to have low rates. Repeatedly in the literature, married women or women in relationships are identified as having lower HPV vaccine uptake rates compared to women who are single (Anhang Price et al., 2011; Bernat et al., 2013; Ford, 2011; Joseph et al., 2014; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012; Lindley et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010). However, until now, it was unknown the particular reasons for this disparity.

This study aimed to understand the information, motivation, and behavioral skills influenced by relationship status for HPV vaccine decision-making among young adult women.

This was achieved through a two phase, mixed methods research study. Phase I comprised a quantitative analysis of a nationally representative dataset to examine how interest in HPV vaccination and primary reasons for no interest in HPV vaccination differed by relationship status among young adult women. Phase II expanded upon this premise, by conducting in-depth interviews with young adult women to understand their HPV vaccine decision-making process, specifically their informational needs, motivations, behavioral skills and the influential macro factors. Women were stratified by relationship status and vaccination status to allow for qualitative comparisons between groups.

Relationship Status and HPV Vaccination

Phase I – Reasons for Non-Interest in HPV Vaccination

Using data from the National Health Interview Survey, this study found that married women were approximately 40% less likely to be interested in HPV vaccination compared to never married women and women living with a partner. This confirmed the hypothesis that women who were married would be less likely to be interested in HPV vaccination compared to other relationship status groups. These findings are similar to other studies examining marital status and HPV vaccination interest using epidemiological data (Anhang Price et al., 2011; Bernat et al., 2013; Ford, 2011; Joseph et al., 2014; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012; Lindley et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010); however, this study utilized more specific categorizations of relationship status, specifically dividing non-married to never married and living with a partner. No significant differences were observed when comparing

married and widowed, divorced, or separated relationship status groups. This may be due to the latter group once being in a marital relationship.

Moreover, while previous research examined how relationship status (i.e., married, not married) was associated with interest in the HPV vaccine, it did not evaluate the reasons for non-interest in vaccination (Schmidt & Parsons, 2014). Using the NHIS dataset, differences in primary reasons for non-vaccination were observed by relationship status category, confirming the study's hypothesis. Belief that they did not need the HPV vaccine was the primary reason for non-vaccination among all relationship status groups, yet it was highest among the married women (48%). This may be attributed belief that they are perceived not at risk for HPV in this relationship status, and therefore do not need the HPV vaccine (Schmidt & Parsons, 2014).

Additionally, married women were more likely to cite lack of doctor recommendation as a primary reason for non-vaccination compared to other relationship status groups. Previous research has indicated that healthcare providers may have a bias that reduces their recommendation for HPV vaccination to young adult female patients in relationships (Zimet et al., 2011). While lack of doctor recommendation and perceived lack of need of the HPV vaccine were key factors for married women, other relationship status groups were more likely to list worried about the safety of the vaccine; 15.2% and 14.9%, respectively compared to 3.9%.

Phase II –Relationship Status, Risk Perception, and HPV Vaccine Decision-Making

The primary purpose of conducting Phase II was to elucidate the connection between relationship status and HPV vaccination decision-making. Women in long-term relationships reported that their current relationship status impacted their decisions not to receive the HPV vaccine. Women attributed their decision not to receive the vaccine to current monogamy and

few sexual partners. Moreover, these women described their perceived risk for HPV as low and indicated that their risk for HPV would not significantly change with the vaccine due to it already being quite low. This connects to what is seen in the quantitative literature that women in relationships are less likely to receive the HPV vaccine, and how previous researchers hypothesized this was attributed to risk perceptions (Anhang Price et al., 2011; Laz et al., 2013; Lindley et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013).

Similarly, women in this sample who were in relationships and vaccinated stated that their risk for HPV was low for comparable reasons. However, these women were less likely to state that their relationship status impacted their decision for vaccination, rather reasons for vaccination varied widely for this group. One of the primary themes among these cues to action for HPV vaccination was a realization of high risk for HPV or HPV-related outcomes, which was in the form of being diagnosed for HPV or an abnormal Pap, having a family history of cancer, or changing relationship or sexual status (e.g., becoming sexually active or moving in with partner). This indicates that while relationship status serves as a primary barrier to HPV vaccination for women in relationships, significant cues to action that permit women to realize actual risk for HPV can facilitate the vaccination process. As of yet, no interventions have been developed for this population to address this specific barrier.

Unvaccinated women who were single and dating reported that their relationship status did not impact their decision for non-vaccination. In fact, these women had more accurate perceptions of their risk for HPV compared to women in relationships who were unvaccinated. Women who were single and dating were more likely to question why they had not yet received the HPV vaccine. Similarly, women who were single and dating and vaccinated reported a more accurate risk perception for HPV and that their decision for the vaccine was not based on their

relationship status. Both groups of women acknowledged the advantage of getting the HPV vaccine was the uncertainty of future sexual partners. Women who were single and dating were more heterogeneous than the other relationship status categories. This particular group's variability is often overlooked in other study designs since they are lumped into the "single" or "never married" category (Anhang Price et al., 2011; Ford, 2011; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichter, et al., 2012; Lindley et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013).

In contrast, women who were unvaccinated and single only perceived themselves at zero risk for HPV, which was attributed to lack of sexual activity. Most of these women recognized their potential risk for HPV once commencing a relationship or sexual activity; however, stated they would wait until that point to receive the vaccine. Cohen and Head (2013) reported a similar argument from young adult women who were not sexually active. While these women stated that their current relationship status did not impact their decision to get the HPV vaccine, the fact that they were single and not sexually active was their primary reason for not getting the vaccine now. Thus, in a sense, these women's relationship statuses were the primary barrier for not getting the HPV vaccine, much like women who were in relationships and unvaccinated. Gerend, Shepherd, and Shepherd (2013) evaluated the multidimensional nature of perceived barriers to HPV vaccination among young adult women. This study found one of the barrier dimensions was perceived lack of need, which included the clustering of *not sexually active* and *monogamous relationship*. In contrast, women who were single and vaccinated stated that their relationship status did not impact their decision for vaccination, but much like women in relationships and vaccinated, they had a variety of cues to action for getting the vaccine, including recommendations from providers and parents.

These findings suggest that among unvaccinated young adult women, women were framing their risk for HPV and perceived need for the HPV vaccine based on their *current relationship statuses*. Yet, there was some discussion of the potential need or lack of need if relationship statuses were to change in the future among unvaccinated women. For example, women in relationship said that the vaccine would be more important if they were no longer in a monogamous partnership. In contrast, women who were single and dating said the vaccine would be less important if they did enter a long-term monogamous relationship. While these women were cognizant of the potential change in risk for HPV based on changing relationships, these were not motivating factors when the women evaluated their potential risk for HPV. In other words, women were evaluating their current risk for HPV, rather than recognizing the potential for that risk to change in the future. The low risk perceptions of women in relationships due to monogamy observed in this study are similar to the HIV risk perceptions among women in close relationships. The concept of knowing their partner and engaging in monogamy supersede any other risk behaviors the couple may be engaging in, for example, sex without condoms (Misovich et al., 1997). These findings should be considered in the context of the potential lifetime risk for HPV among a woman, which underscores the need for HPV vaccination. The average lifetime risk of HPV among women with one opposite sex partner is 85% (Chesson, Dunne, et al., 2014). Recent evidence suggests the prevalence of HPV is approximately 17% among heterosexual couples who did not have any other sexual partners (Burchell et al., 2014).

Triangulation

The findings from Phases I and II were complementary and both confirmed the hypothesis the relationship status is influential to HPV vaccination among young adult women.

The findings from Phase I described differences in reasons for non-interest in HPV vaccination based on relationship status groups using a nationally generalizable and large sample. While this suggested that differences do exist by relationships status, this survey was limited by not expanding upon the reasons for non-interest and non-vaccination. Phase II's qualitative methodology permitted an in-depth understanding of reasons for not receiving the HPV vaccine among a smaller sample of young adult women. To assist in the comparison between phases, the relationship status categories from Phase I were redefined to be Married or Living with a Partner and Never Married to mirror the relationship status categories from Phase II (see Table 19, Page 97).

The quantitative data indicated that more women who were Married or Living with a Partner reported "does not need vaccine" compared to Never Married women (45.3% and 34.7%, respectively). This is similar to the findings among unvaccinated women in Phase II that women who were married or living with a partner reported not needing the vaccine due to monogamy or other protective sexual practices in their relationship. In contrast, women who were single and dating were more likely to state that they were unaware of the vaccine as a reason for non-vaccination.

Another key difference observed between the relationship status groups from the survey data were women who were Married or Living with a Partner reported a lack of doctor recommendation more often compared to Never Married women (9.5% and 6.3%, respectively). In the interview sample, vaccinated young adult women were asked their reasons for receiving the HPV vaccine as a young adult. Women who were single and dating or single only were more likely to report a doctor recommendation as a cue to vaccination, whereas women in relationships did not cite this as a reason.

These results provide evidence of the importance of mixed methodology for public health research, especially for a complicated topic, such as HPV vaccination. The qualitative data supplemented the quantitative results by expanding upon the reasons for non-vaccination with narratives from the target population. Furthermore, these narratives were not constricted to closed-ended questions, but based on the diverse perspectives of the participants. Moreover, while the quantitative and qualitative painted a picture of the barriers to HPV vaccination, the qualitative data enriched these findings by also evaluating the facilitators to vaccination among already vaccinated women. However, there are limitations to these comparisons due to differences in samples and recruiting methods, as well as categorizations of relationship status. The quantitative data were more restricted in relationship status types for an 18 to 26 year old population, whereas the interview sampling disentangled the “Never Married” group into three distinct strata (i.e., Long-term Monogamous, Single and Dating, and Single Only), which was found to have significant variability in responses.

Informational Needs

Knowledge about a health behavior is often recognized as a key step in the behavior change process (Brewer & Rimer, 2008). Awareness about the HPV vaccine was found to be a significant predictor of interest in HPV vaccination among young adult women in the NHIS sample (PR = 1.58, 95% CI 1.46-2.05). In examining the primary reasons for non-interest in vaccination, not knowing enough about the vaccine was only reported by 13% of sample. Women in the Phase II sample had adequate knowledge about HPV and the HPV vaccine. Compared to a 2008 sample of college women using the same knowledge scale, the 2015 sample had higher scores, 14.1 and 15.3, respectively (Daley, Vamos, et al., 2010). This coincides with

other literature indicating that awareness about the HPV vaccine have increased over time (Schmidt & Parsons, 2014).

In the Phase II sample, women demonstrated a surface level awareness and knowledge of HPV and the HPV vaccine, but had difficulty elaborating on details. Women were generally aware of what HPV was and that it could cause cervical cancer. However, they were more uncertain about other outcomes associated with HPV, such as genital warts or other HPV-related cancers. This may be due to the heightened focus on the link between HPV and cervical cancer through popular media campaigns rather than on outcomes with more sexual connotations (Pisciotta, 2012). An additional area where women were lacking information was the mode of transmission of HPV. In the interviews, women stated that HPV was transmitted sexually; however, were generally unable to elaborate on modes of transmission (i.e., vaginal-penile, oral, skin to skin). Previous research among young adult women has also documented the lack of knowledge regarding routes of HPV transmission (Sandfort & Pleasant, 2009). If women are unaware of these modes of transmission, they may have the false belief that protected sex with a condom *alone* may prevent HPV, therefore underestimating their risk for acquiring the virus.

Of most concern were the misperceptions women have about the timing and target population for the HPV vaccine. A subset of the vaccinated and unvaccinated women both reported that HPV vaccination should occur after onset of sexual activity. Similarly, approximately 7% of the NHIS sample reported that they did not need the vaccine because they were not sexually active. This is contrary to the evidence supporting that the vaccine is most effective prior to exposure to HPV and onset of sexual activity (Markowitz et al., 2014). Moreover, it perpetuates the public's focus on the connection of this vaccination with sexual activity of adolescents and young adults (Zimet, Rosberger, Fisher, Perez, & Stupiansky, 2013).

Additionally, despite the introduction and approval of a 9-valent vaccine immediately prior to the commencement of data collection (Food and Drug Administration, 2015; Petrosky et al., 2015), none of the participants described this change in vaccine availability. It is anticipated that health messages surrounding the HPV vaccine will become increasingly complicated with options of a quadrivalent and 9-valent vaccine.

Despite many of these misperceptions about HPV and the HPV vaccine, women reported hearing about the HPV vaccine from a variety of sources, such as healthcare providers, family members, partners, TV, and the Internet. Among these sources, women stated that they trusted their healthcare provider the most for information about HPV and the vaccine. It is important to identify the agent most trusted as previous research has indicated the more valued the information source, the more likely the woman may be to prioritize that specific information (Redmond et al., 2010; Worsley, 1989). Moreover, it is evident from the literature how valuable a provider recommendation for the HPV vaccine can be, especially for young adult women (Rosenthal et al., 2011).

Women also reported that they would prefer to learn more information in the future about HPV and the vaccine from a healthcare provider and the Internet. Internet sources, while easily accessible by this population, may also produce negative and mixed messages about the HPV vaccine (Ruiz & Barnett, 2015). Other modes of information were less consistently cited as sources of HPV vaccination information, including the television and radio. Identifying the information-seeking preferences of this demographic can inform the agents or modes used in future health interventions.

Motivation

Motivating factors for HPV vaccination, which included attitudes, social influences, and risk perceptions, were explored. Significant differences in motivations were observed for attitudes about the HPV vaccine between vaccinated and unvaccinated women. Additionally, risk perception varied based on relationship status, as previously described.

Attitudes

Overall, women reported positive attitudes about vaccines generally, stating that they protected the population and personal health from diseases. Surrogate markers for attitudes about other vaccines were measured in the NHIS sample; specifically women who had received a flu shot in the last 12 months or received the Hepatitis B vaccine were more likely to be interested in the HPV vaccine. This is supported by previous research as well (Anhang Price et al., 2011; Jain et al., 2009; Laz et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013).

Yet, women in the interview sample differed in attitudes about the HPV vaccine based on vaccination status. Women who were vaccinated had more favorable opinions about the HPV vaccine compared to women who were unvaccinated. This may reflect true differences in attitudes impacting vaccine behavior, or may be indicative of changes in attitudes after engaging in the behavior. Higher perceived importance and positive attitudes about the HPV vaccine have been cited as being associated with vaccination or intent for vaccination among young adult women (Bendik et al., 2011; Bennett et al., 2012; Dillard, 2011; Ratanasiripong et al., 2013; Rosenthal et al., 2011; Schaefer Ziemer & Hoffman, 2013). However, similar retrospective adjustments have been reported in the literature for risk perceptions and recall bias (Brewer et al., 2007). Thus, the differences in attitudes about the HPV vaccine between vaccination groups may be attributed to experience with the vaccine. Women who were unvaccinated cited more

often that side effects were a negative aspect about the vaccine; however, these women were unable to describe these side effects in any detail. This is congruent with the NHIS sample, which estimated that 12% of unvaccinated young adult women were worried about the safety of the HPV vaccine. In contrast, women who had received the vaccine were able to describe any side effects experienced, such as pain at the injection site, which is reported in the literature as a common side effect with this vaccine (Reiter, Brewer, Gottlieb, McRee, & Smith, 2009a).

An explanation for the disparity observed between the attitudes about vaccines generally and the attitudes about the HPV vaccine may be attributed to women classifying the HPV vaccine as a separate type of vaccine. For instance, women stated it is not similar to required vaccines, such as the MMR vaccine, but is more important than completely optional vaccines, such as the influenza vaccine. Analogous perceptions have been reported by providers who administer adolescent vaccines; specifically, that the HPV vaccine is more burdensome to discuss with patients compared to other required vaccines (e.g., Tdap and meningococcal) (Gilkey et al., 2015).

Social Motivation

There were no major differences between social motivators for HPV vaccination across vaccination status and relationship status. The key motivator was/is a healthcare provider. Previous literature repeatedly emphasizes the importance of a healthcare provider recommendation for HPV vaccination initiation (Daley, Vamos, et al., 2010; Klosky et al., 2015; Licht et al., 2010; Marchand et al., 2012; Rosenthal et al., 2011; Zimet et al., 2010); however, this study also elicited the salience of a trusting or established relationship with a healthcare provider. This confirms findings from Joseph et al. (2014) that a diverse sample of young adult

women reported trust in a provider was important for HPV vaccine decision-making; however, while it significantly predicted intent for vaccination, it was not statistically significant for receipt of the HPV vaccine. Moreover, in this study, some women reported that providers reassured them that the vaccine was best for them, and personalized it to their particular circumstances. While this may appear as a facilitator to HPV vaccination, it can also negatively affect HPV decision-making for this particular population. Women in college may not wish to establish care with a new provider and prefer returning “home” to see a provider they have a relationship with. Thus, while in college, women may not see a trusted provider due to logistics and thus do not receive this recommendation during the catch-up years for HPV vaccination.

Additional influential others included friends, family members, and spouses. Previous literature studying young adult college women has found peer norms impactful for HPV vaccination (Hopfer & Clippard, 2011); however, in this study, peers were less important than other agents. Peers were only seen as significant if they could share their experiences with HPV vaccination as a model that it was safe and acceptable. Family members, specifically mothers, were also important in encouraging or discouraging vaccination, which is previously found in the literature (Cohen & Head, 2013; Hopfer & Clippard, 2011). However, this study found that mothers’ roles in the HPV vaccination process were more salient during adolescence compared to young adulthood. Moreover, women reflected that their mothers were one of the primary barriers to vaccination in adolescence. In comparison, the NHIS sample found that a family member or spouse against the HPV vaccine was a primary reason for non-vaccination in less than 2% of the sample. Therefore, these agents may not necessarily be barriers to vaccination, but rather facilitators.

The final group examined as social motivators were partners. Interestingly, women reported that these were not significant agents in HPV vaccination decision-making, in fact, partners tended to be indifferent. Moreover, women reported that they thought their partners should be vaccinated as well, while some women stated it was important to receive the vaccine to protect their partner's health. Both of these statements are consistent with previous literature (Harper, Alexander, et al., 2014; Patel et al., 2013). This coincides with the notion that sexual health prevention practices are often relegated to women's health. Women often take on the sexual and reproductive health prevention behaviors (e.g., birth control pills) to keep the heterosexual partnership safe. This may also be the product of societal norms of masculine hegemony resulting in men believing they do not need protection (Evans, Frank, Oliffe, & Gregory, 2011). Perhaps this is a consequence of the feminization of the HPV vaccine, which ultimately over-identified the vaccine as a women's rather than men's health behavior (Daley, Buhi, Vamos, et al., 2012).

Previous literature among university women has indicated that attitudes toward HPV vaccination and perceptions of social support predicted intention of HPV vaccination (Fisher, Kohut, Salisbury, & Salvadori, 2013), which is supported by this study. However, one factor that is understudied in the current literature emerged, the idea that HPV vaccination is a personal decision. Women repeatedly mentioned that while outside information or people were influential, women ultimately wanted to make the decision on their own with all the available information. In other words, women were deciding if the vaccine was right for them. This personalization of the vaccine for individual use has implications for future health messages targeted at this newly autonomous group of young adults. Women desire to know that the HPV vaccine is best for their health given their medical and social history. This contradicts the

literature that reports social norms from peers and family members being influential for HPV vaccine decision-making (Allen et al., 2009; Bennett et al., 2012; Hopfer & Clippard, 2011; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013). While these multiple spheres of influence may be significant, women wish to reconcile the overwhelming amounts information and perspectives with their own beliefs and judgement.

Reasons for Non-Vaccination as an Adolescent

Since the HPV vaccine has been available for females since 2006 and this study's sample comprised females 18 to 26 years old, women were questioned about the reasons they did not receive the HPV vaccine as an adolescent, as these factors may influence current HPV vaccination behavior. Major reasons were lack of awareness of the HPV vaccine and parental beliefs about the HPV vaccine. For many of these women, lack of awareness perpetuated until young adulthood. Similarly, approximately 30% of the NHIS 2010 sample of women had not heard of the HPV vaccine. However, parental influence, while significant in adolescence, does not have the same weight in young adulthood. This provides evidence to the statement that young adulthood is a period of autonomous decision-making for sexual and reproductive health. Furthermore it emphasizes the need to continue to target women in the catch-up range for HPV vaccination, since their parents' beliefs may have been an obstacle to vaccination at an earlier age.

Reasons for (Non-) Vaccination as a Young Adult

Vaccination decision-making in young adulthood revealed that parental beliefs were no longer primary drivers in this process. In examining the primary reasons for non-vaccination

among unvaccinated women, two key themes emerged: (1) lack of awareness of the vaccine, and (2) perceptions of low risk for HPV. As previously stated, the perceptions related to risk of HPV varied based on relationship status groups, which impacted reasoning for not needing the vaccine at that time. The lack of awareness of the HPV vaccine was a significant barrier to vaccination among this sample, while similarly it affected interest in HPV vaccination in the NHIS sample. These two barriers were also previously identified in the literature as contributing to low uptake of the HPV vaccine (Anhang Price et al., 2011; Cohen & Head, 2013; Gelman et al., 2013; Hodge et al., 2011; Hopfer & Clippard, 2011; Joseph et al., 2014; Laz et al., 2013; Ratanasiripong et al., 2013; Schaefer Ziemer & Hoffman, 2013; Schmidt & Parsons, 2014).

In contrast, women who were vaccinated cited a variety of reasons for getting the HPV vaccine as a young adult. These cues to action, while quite heterogeneous, could be simplified to addressing the primary barriers: lack of awareness and perceptions of low risk for HPV. For some women, a recommendation from another individual or awareness generally contributed to uptake of the vaccine. For others, it was the realization of the actual risk for HPV in their lifetime, which stemmed from HPV diagnosis, family history of cancer, becoming sexually active, or other changes in relationship status.

Consequences

Similar to the findings from the informational needs, the majority of women focused on cervical cancer as the primary consequence to HPV. Again, this may be attributed to popular media and health messages' focus on this connection (Pisciotta, 2012). Women repeatedly mentioned cervical cancer to be the most severe outcome, while genital warts were seen as inconvenient and aesthetically displeasing. Correspondingly, previous studies have found that the

perceived severity of cervical cancer predicted HPV vaccination (Bendik et al., 2011; Krakow et al., 2015). Findings from the knowledge survey confirm that women were less aware of HPV's connection to genital warts (60%) compared to cervical cancer (94%).

An additional consequence reported by a smaller proportion of the sample was the emotional responses to an HPV diagnosis. Previous literature has reported on emotional responses expressed by women who are HPV positive, including anger, self-blame, fear, and stigma (Daley, Perrin, et al., 2010; Perrin et al., 2006). This consequence may be even more salient in women compared to men since women have screening tests throughout their adult lives to identify the presence of HPV (US Preventive Services Task Force, 2014a), whereas a comparable test is not approved for use among men. Therefore, women may experience these emotional responses on a greater scale due to increased testing. Yet, Daley, Buhi, Marhefka, et al. (2012) found in a natural history study of HPV infection in men, that men who tested positive for HPV experienced more negative emotional responses compared to HPV negative men. The only instance where the emotional responses to HPV may be similar across sexes is with the presence of genital warts, which may cause shame and affect self-esteem (Jeynes, Chung, & Challenor, 2009), or potentially oropharyngeal cancer.

Behavioral Skills

Vaccinated and unvaccinated women had similar procedural knowledge for obtaining the HPV vaccine. This is reassuring to confirm that unvaccinated women are aware of the process for accessing, financing, and following up with the HPV vaccine. Additionally, women reported similar facilitators to vaccination, including ease of logistics, cost/insurance, and healthcare provider established or trusted. Yet, unvaccinated women desired additional information prior to

vaccination. Another facilitator described was a fewer number of shots for the vaccine series. This is reassuring as current research is evaluating the efficacy of a two-dose rather than three-dose vaccine (Markowitz et al., 2014), which may ease the vaccination process for women.

In contrast, unvaccinated women reported more barriers to vaccination, such as cost and insurance. However, the frequency of barriers reported in this group may be inflated compared to vaccinated women due to addressing a hypothetical situation, whereas vaccinated women recalled the situation. Some of the barriers described by unvaccinated women were stated in reference to women generally, not necessarily personally experienced barriers. In the NHIS sample of unvaccinated women, the cost of the vaccine as a reason for non-vaccination was only cited by 3% of the sample. Yet, the presence of cost and lack of insurance coverage as a barrier to vaccination is congruent with previous literature among this population (Anhang Price et al., 2011; Dempsey et al., 2011; Ford, 2011; Head & Cohen, 2012; Hodge et al., 2011; Jain et al., 2009; Joseph et al., 2014; Laz et al., 2013; Lindley et al., 2013; Rahman et al., 2015; Tiro et al., 2012; Wei et al., 2013; Zimet et al., 2010).

Macro Factors

The macro factors assessed in this study were healthcare interaction, economic factors (i.e., insurance coverage and poverty level), and social and cultural factors.

Healthcare Interaction

The interview sample reported high levels of healthcare interaction; visiting a gynecologist or general practice physician approximately once a year. This indicates that access to a healthcare provider is not an issue; rather these women have many clinical opportunities to

discuss the HPV vaccine with providers. In fact, women mentioned needing to go to a healthcare appointment for annual exams for preventive screening, such as Pap tests, as well as getting birth control refills. Florida data from 2008-2009 indicate that approximately 24% of women reported using short-acting reversible methods of contraception, such as pills, injectable, patches, and 5% using long-acting reversible methods, such as intrauterine devices, and implants (Hernandez, Sappenfield, Clark, & Thompson, 2012), all of which requires some level of healthcare interaction. These simultaneous sexual and reproductive health behaviors may offer the opportunity for increased vaccination among catch-up young adult women. However, one barrier reported among college women was the desired to return to a familiar or trusted healthcare provider “back home.” This may reduce the number of annual visits in the catch-up period for some women since the logistics are less feasible. Efforts are needed to understand how to engage college women with health services available in a university setting, which would ultimately decrease logistical barriers for vaccine uptake.

Economic

Additionally, most women in the sample reported having some form of insurance coverage, which may also contribute to the high healthcare interaction for this sample. Insurance has been found to be a significant barrier in the literature (Anhang Price et al., 2011; Dempsey et al., 2011; Ford, 2011; Hodge et al., 2011; Jain et al., 2009; Laz et al., 2013; Lindley et al., 2013; Rahman et al., 2015; Tiro et al., 2012; Wei et al., 2013; Zimet et al., 2010), because without insurance, there is a high out-of-pocket cost for the HPV vaccine (American Cancer Society, 2014b; Planned Parenthood, 2014). In contrast, insurance coverage was not a significant predictor of HPV vaccine interest in the NHIS sample. In addition, certain economic factors may

contribute to HPV vaccination in young adult women. In the NHIS sample, being less than 100% of the poverty ratio was a significant predictor for interest HPV vaccination. This may be attributed to the impending changes in Medicaid Eligibility across the United States at the time of the survey (2010), which would create a national Medicaid minimum eligibility of 133% of the federal poverty level (Centers for Medicare and Medicaid, n.d.). Additionally, young adults were permitted to stay on their parent's insurance coverage until age 26, as of 2010 ("Patient Protection and Affordable Care Act," 2010). Previous research has reported that low income or being below the federal poverty level was associated with non-vaccination among young adult women (Chao et al., 2010; Jain et al., 2009; Laz et al., 2013; Rahman et al., 2013; Wei et al., 2013). With the changing healthcare landscape and availability of health coverage for young adults, it is anticipated that insurance coverage for this demographic will increase (Claxton, Levitt, Brodie, Garfield, & Damico, 2014; Rudowitz, Snyder, Smith, Gifford, & Ellis, 2014).

Social and Cultural Factors

One of the more nebulous factors reported by women were the social and cultural factors impacting HPV vaccination. These may be more difficult for participants to recall since they are in the periphery of their influence. The most prominent theme that emerged throughout the interviews was the discussion of the anti-vaccination movement. As a result, the discussion about vaccines became politicized with participants stating they were "pro-vaccine" or did not understand people who were "anti-vaccine." The social context of this movement is necessary to consider for this health behavior as public commentary and figures (e.g., celebrities) can have an influence on a preventive behavior (Bean, 2011; Hoffman & Tan, 2015).

Some women described media messages about the HPV vaccine that they have seen. The majority were characterized as negative or mixed/incomplete messages. Similarly, a content analysis of web media has revealed the majority of the HPV vaccine webpages also have a negative spin (Ruiz & Barnett, 2015). Moreover, popular media, such as the television show *Girls* on HBO, may provide unfocused or problematic messages about HPV and HPV vaccination (Rogers, 2015). Overall, the women reported a level of skepticism of the messages seen. While mass media campaigns or other sources of media may be used as a tool to reach a broad audience, this may not necessarily be the best option to target young adult women.

Finally, the NHIS sample revealed that region of the United States impacted interest in HPV vaccination. While previous literature has indicated that the South region has lower uptake in the HPV vaccine (Rahman et al., 2013; Schmidt & Parsons, 2014), this analysis found that women living in the Midwest were less likely than women living in the South to be interested in the HPV vaccine.

Strengths and Limitations

For any research project, the strengths and limitations of the study design must be evaluated in context of the results reported. For this study, these were assessed by phase of the study due to the mixed method design.

Phase I – Validity and Reliability

Utilizing the NHIS 2010 dataset for a secondary data analysis had advantages to achieve this research aim. First, the survey used a nationally-representative sample based on the population characteristics from the U.S. Census. The analysis procedures incorporated the

primary sampling units, strata and clustering variables to appropriately weight the survey data according to the complex sampling design. Thus, the external validity of this sample could extend to the larger United States population of unvaccinated women 18 to 26 years of age.

Despite the benefits of conducting a secondary data analysis (e.g., feasibility, generalizability), there were limitations. First, given that this was a cross-sectional survey, there was the concern for issues with self-report for responses, specifically for HPV vaccination, one of the sub-setting variables used to develop the samples for analysis. Previous studies have estimated the reliability of self-report of HPV vaccination. One study has shown that the sensitivity for recall among adolescent girls 13 to 17 years to only be 54%, and for mothers of those girls 76%. Alternatively, the specificity was 100% (Stupiansky, Zimet, Cummings, Fortenberry, & Shew, 2012). A study conducted among women 18 to 26 years old reported that there was 94.5% agreement between recall and electronic medical records for the first dose of the HPV vaccine series (Kharbanda et al., 2013). The remaining variables included in the analysis were also self-reported and may have suffered from recall bias by the individual. Moreover, the reliability of these survey questions was not reported on publically available reports from the National Center for Health Statistics. However, the questions are periodically revised by experts in health statistics and health content areas (Centers for Disease Control and Prevention & National Center for Health Statistics, 2012). Also, because these data were from a secondary source, the analysis was limited to the population who had the option to respond to the psychosocial questions about the HPV vaccine, which were women un-interested in the vaccine. As a result, a comparison of vaccinated to un-vaccinated women was not within the scope of this analysis.

An additional limitation of this dataset was the response rate. While participants were drawn from a random sample, nearly 40% refused to participate. In 2009, the nonresponse bias for the sample adult and sample child files were assessed. In the sample adult file, non-respondents were more likely to be younger and Hispanic, but have a similar health status. As a result of this analysis, an adjustment was made and implemented in the 2010 NHIS file weights to account for nonresponse bias associated with geographic area, sex, age, and race/ethnicity (Moriarity, 2009). Another issue faced was the large amount of missing data for the income variable in the NHIS 2010 dataset. To address this issue, the NHIS has developed imputed values for income based on demographic and health-related variables (Division of Health Interview Statistics & National Center for Health Statistics, 2011b). As a result, multiple imputation was used in the analysis to estimate income's impact on HPV vaccine intention.

An additional limitation of using secondary, cross-sectional data was the ability to assess causality between the exposure and outcome. While women may report no interest in the HPV vaccine while in a particular relationship status, this only infers an association between relationship status and HPV vaccination interest. Additional qualitative research elucidated women's specific decision-making for HPV non-vaccination.

The statistical analysis methods also must be considered. This study used logistic regression to estimate the odds ratio. While this is the most commonly used methodology for measuring the strength of association in cross-sectional data (Szklo & Nieto, 2007b), this particular analysis was limited by the fact that the outcome variable of interest may not be rare (i.e., ~35%) (Schmidt & Parsons, 2014). The odds ratio asymptotically approaches the relative risk with small probabilities; however, when an event is not rare (>10%), then the odds ratio will overestimate the relative risk (Szklo & Nieto, 2007a). To assist in this overestimation of the

relative risk, an ad hoc adjustment of the odds ratio was used to derive a closer estimate of the relative risk by accounting for the prevalence (Zhang & Yu, 1998).

The final statistical consideration was the use of survey-weighting procedures and the availability of Exact tests in the statistical software program. The primary reasons for non-interest in HPV vaccination compared to relationship status revealed multiple cells with frequencies less than five. While chi square tests are not equipped to handle small cell numbers (Rosner, 2006), Fishers Exact test is not available in SAS 9.4 with survey-weighting procedures (SAS Institute Inc., 2015). As a result, smaller categories were combined into an “other” category to permit the use of a chi square test. This ultimately resulted in a reduction in the variability of responses for reason for non-vaccination.

Phase II - Trustworthiness of Data

Qualitative methodology does not have the traditional methods for assessment of validity and reliability. Rather data can be assessed for *trustworthiness*, the truth value of the findings, using the following criteria: *credibility*, *dependability*, *confirmability*, and *transferability* (Ulin, Robinson, & Tolley, 2005) In this context, the *credibility* of the interpretations of the data was assessed by looking for negative cases for emerging hypotheses in the data, as well as seeking explanations for inconsistencies in the data from outside sources (e.g., Phase I results).

Dependability refers to the ability to replicate the process for obtaining the results, which was documented throughout the research process and reported in dissemination pieces. Due to the subjective nature of data analysis, it was important for the researcher to be reflexive throughout the project. This occurred through writing memos during the interview and analysis processes, as well as debriefing with committee members and colleagues. Additionally, having a second coder

establish the reliability of the coding process ($\kappa = 0.88$) improved the dependability of the analysis process. *Confirmability* of the results was achieved by utilizing an audit trail for all research processes (e.g., raw data, data analysis process, memos). Finally, *transferability* is the degree to which the results can be applied or transferred to groups of people beyond this project. Results are more likely to be transferable when utilizing a theoretical framework to guide the research, making it more likely to be adaptable to other populations (Ulin et al., 2005). To assist in the transferability of the results, the IMB Model was used as a guiding theoretical framework. To assist in the evaluation of the transferability of the results, the characteristics of the final sample was assessed to allow for comparison with other types of populations (Denscombe, 2010). The student population at the University of South Florida is more racially/ethnically diverse than most universities in the United States. Data from the NCHA 2013-14 surveys indicate that USF had more black and Hispanic respondents (11.3% and 21.1%, respectively) compared to the reference group (6.6% and 13.9%, respectively). Furthermore, these racial and ethnic groups have increased at the University of South Florida from 2011 to 2014 (University of South Florida, n.d.-a). Among the eligible sample completing the initial survey, 19% of respondents were Hispanic and 19% were black. It may be that these results are only transferable to similar college populations and not representative of women 18 to 26 years in the general population. Moreover, the data from the knowledge questions will most likely be different in this college population compared to a general population since one study found that knowledge about the HPV vaccine was strongly associated with college educational attainment (Kennedy et al., 2011).

Using qualitative methods to answer the proposed research question was an appropriate scientific approach. The research question asked “why” and “how”, which qualitative

methodology permits a greater level of detail and depth compared to quantitative methodology (Hennink et al., 2011b). Additionally, this approach was an extension of what has been previously documented using survey-based research indicating that married or monogamous women are less likely to be vaccinated (Anhang Price et al., 2011; Bernat et al., 2013; Ford, 2011; Joseph et al., 2014; Laz et al., 2013; Liddon, Hood, et al., 2012; Liddon, Leichliter, et al., 2012; Lindley et al., 2013; Rahman et al., 2013; Schmidt & Parsons, 2014; Wei et al., 2013; Williams et al., 2013; Zimet et al., 2010). This form of data collection was suitable for investigating how people make decisions, their personal beliefs and perceptions, motivations for behavior, and for sensitive issues (Hennink et al., 2011a). Furthermore, this design of having two segments for the sample allowed for a *description* of the variability of HPV informational needs, motivations, and behavioral skills across these groups, rather than *quantifying* the variation, which is typical of quantitative research.

An additional benefit of conducting in-depth interviews was the less-restrictive form of data collection. The open-ended nature allowed for participants to add additional information that may have not been explicitly asked for, thus permitting the generation of new findings. The iterative process of qualitative data analysis allowed for adjustments to interview guide material throughout the study to account for emergent findings (Hennink et al., 2011b). These characteristics are typically not attributes of quantitative methodologies. Additionally, this study design permitted women to self-identify their relationship status without any specific criteria. Through the in-depth interview, descriptions about length of time, monogamy, and sexual behavior were gathered to provide context to these relationship status categories, which may be beneficial for future studies.

While the knowledge scale was not the main focus of this research phase, the study benefited from utilizing an HPV knowledge scale that had high reliability with an intraclass correlation coefficient equivalent to $\alpha = 0.92$. Moreover, this knowledge scale has been previously applied among a college sample of women, confirming the content validity of the scale (Daley, Vamos, et al., 2010).

This methodology was the most appropriate for the research question; however, there are limitations that must be considered. Firstly, a major criticism of qualitative data analysis is the subjectivity of the process, that is argued to affect the internal validity of the findings (Hennink et al., 2011b). In order to make any potential subjectivity transparent, I engaged in reflexivity, which is self-reflection on the research throughout the research project (Hennink et al., 2011b). By documenting the potential biases I have as a researcher, this helped me be more aware of any subjective bias introduced in the study. For example, I am a public health, female researcher who perceives vaccination as a benefit to the public's health. Also, I have received the HPV vaccine, underscoring my personal preference for this vaccination. During interviews, participants sometimes asked my personal opinion about the HPV vaccine; however, I asked that we wait until the end of the interview to discuss information about me. This was an attempt to not allow my beliefs to influence the participants' perceptions of the HPV vaccine.

The mode of the interview administration via telephone may have impacted the social desirability bias of the data collected. Compared to questionnaires, telephone interviewing has been found to underestimate severity of health status due to respondents reporting better health outcomes (Brewer, Hallman, Fiedler, & Kipen, 2004). However, a comparison of perceived risk for cancer was compared for interview administered telephone surveys and mailed surveys found there was no difference between these modes of data collection (Persoskie, Leyva, &

Ferrer, 2014). To ameliorate the effect of social desirability bias on the data collection process, the researcher attempted to establish rapport with the participants. This was implemented by demonstrating gratitude to the participant for their time and honesty of their answers. Moreover, the more sensitive questions regarding HPV risk were layered in the middle of the interview to allow time for the participant to be more comfortable with the interviewer.

An additional potential source of bias that may have been present in this study is sampling bias. Recruitment materials (Appendix A) stated the purpose of this study was to "... investigat[e] the knowledge, attitudes and opinions of young adult women about HPV vaccination." As a result, women included in the sample may have had more of an interest or more knowledge of the HPV vaccine compared to non-participants. Additionally, recruitment in this phase was stratified only by vaccination status and relationship status in order to assess the variability in HPV vaccine decision-making among these groups. This stratification alone may prevent equivalent comparisons of known risk factors or associated sociodemographic factors for HPV vaccination (e.g., age, sexual orientation), which may slightly bias these results.

Findings from the qualitative data indicated that there may have been recall bias for women who already received the HPV vaccine. Certain constructs, such as attitudes about the HPV vaccine and barriers to vaccination, may have been adjusted for women after receiving the HPV vaccine compared to unvaccinated women. While the research design advertised that women could be eligible to participate if they received the first dose of the vaccine within the last six months, it became clear during the interview process that many women did not accurately recall this length of time. Once the study concluded, it was determined that overall the vaccinated women received at least one of the three doses for the vaccine in the last year, rather

than the first dose in the last six months. Conducting the follow-up interviews after the survey was permitted the elucidation of this difference.

One interesting finding in two of the interviews was women reporting that the HPV vaccine was required for admittance to the university or living in residence halls. These women were probed to describe the vaccine and the purpose of the vaccine to ensure it was the HPV vaccine they were referencing. Additionally, these women were asked to clarify if it was the HPV vaccine and not the meningococcal vaccine, which is often required for living on campus. Everything stated by the participants indicated that they received the HPV vaccine with the exception that it was required, which was incorrect. During the analysis, the USF Student Health Services webpage was reviewed to determine if any confusion could occur for students. While the webpage clearly delineates those vaccines required for documentation (e.g., MMR, Hepatitis B, and Meningitis if living on campus), it does provide information on the HPV vaccine in addition to these other vaccines (University of South Florida, n.d.-b). Future work should examine how college entry policies could impact HPV vaccination behavior for catch-up groups.

The goal of Phase II was to compare the informational needs, motivations, and behavioral skills for HPV vaccination among young adult women across relationship status groups and vaccination status groups in congruence with the research questions proposed (Table 2). While conducting these comparisons, it was evident that women who were married/living with a partner or in a long-term monogamous relationship shared similar factors for HPV vaccination. Thus, these two sampling groups were consolidated into one group for the analysis. It was hypothesized that the single and dating, and single only groups would also be similar; however, it was evident that these two sampling groups were distinct in their factors contributing to HPV vaccination. As a result there were uneven numbers in the sampling categories for the data

analysis. However, this study underscored the importance of finer categorizations of relationship status for scientific study. Previous research has stratified samples by sexual activity (active or never active) (Hopfer & Clippard, 2011); yet this oversimplification removes the heterogeneity present within these groups as evidenced by this study.

Implications

This research study established that relationship status plays an integral role in HPV vaccine decision-making for young adult women. Primarily, it identified that women's risk perceptions regarding HPV were moderated by their relationship status; specifically, women in long-term relationships were less likely to see themselves at risk for HPV due to monogamy. A potential mechanism to address this discrepancy between actual and perceived risk is the use of *health literacy*. Health literacy is the process of finding, understanding, evaluating, communicating and using health information to make informed health decisions (Coleman et al., 2011). Returning to the IMB Model, women in this study were found to have adequate levels of knowledge regarding HPV and HPV vaccination, such as identifying HPV as sexually transmitted, the potential ways to prevent HPV, and that a vaccine does exist. Moreover, the women also reported having the behavioral skills necessary to perform the behavior, such as procedural knowledge and facilitators. The high level of healthcare interaction and insurance coverage also facilitates the ability of these women to have opportunities for vaccination. However, the motivations for vaccination served as obstacles, specifically risk perceptions. Therefore, the missing step in the health literacy process is the accurate *evaluation* of this health information regarding risk for HPV and how it applies to women's personal health (Coleman et al., 2011).

A key social motivator identified by women was the healthcare provider. While previous literature reports that a healthcare provider recommendation is an essential step in the HPV vaccination process (Rosenthal et al., 2011), this study expanded these findings by emphasizing the importance of provider reassurance that the vaccine is best for the individual. Healthcare providers can be agents in the health literacy process to assist women in evaluating the true risk for HPV, not only based on current relationship status, but also future risk for HPV. Currently, US Preventive Services Task Force recommends sexually transmitted infection behavioral counseling for sexually active adolescents and adults. This comprises providing essential health information about STIs and transmission, assessing individual risk for STIs, and skill building (e.g., condoms, communication, and goal-setting) (US Preventive Services Task Force, 2014b). While this type of behavioral counseling is recommended generally for all STIs, specific health messages are required for HPV, as well as for the HPV vaccine, for women not already vaccinated. These messages can assist women in understanding individual risk for HPV in the context of relationship status and potential future risk.

While healthcare providers are integral to the health literacy process for young adult women and HPV vaccination, an assessment regarding current provider practices and HPV vaccination should occur. Previous research has reported that providers have biases regarding prioritization of HPV vaccination and young adult female patients' relationship statuses (Zimet et al., 2011); however, these were based on hypothetical scenarios. As such, it may be necessary for healthcare providers to be recipients, in addition to agents, of health literacy to equip them with the skills needed to assist patients in the evaluation process for the HPV vaccine (Vamos, 2011). Moreover, research with healthcare providers could identify the tools or methods that would facilitate this process with patients, for example, patient decision-making aids,

informational brochures, Internet websites, brief motivational interviewing or eHealth technology. Previous research reported that providers rely on secondary sources (e.g., handouts) to facilitate HPV vaccine discussions and also preferred to follow professional organization recommendations (Vadaparampil et al., 2013). Integrating previous findings with formative consumer-based research can inform the development of resources that would be acceptable and feasible for providers in a clinic setting.

Ultimately tailoring health messages to young adult women's specific risk misperceptions about HPV can promote patient-centered, individualized care to reassure women about the HPV vaccine. This connects with the women's reported desire for personal decision-making about HPV vaccination. By reinforcing the health literacy process, women will ultimately be able to make an informed decision based on all evidence. The findings from this mixed-methods study provide the formative research to inform future intervention development. In fact, this study design aligns with the elicitation phase of the IMB Model intervention development sequence (Fisher & Fisher, 2002). These findings can be used in future research in three specific manners: (1) develop a quantitative instrument guided by the IMB Model to assess risk perceptions and relationship status as a barrier to HPV vaccination among a larger sample and more diverse population (e.g., community sample, 4-year college sample, 2-year college sample); (2) develop health messages from the qualitative responses from women regarding their risk perceptions for HPV and perceived need for the vaccine; and (3) evaluate developed health messages in multiple settings. The proposed quantitative survey should include a measure of sexual behaviors to compare actual and perceived risk for HPV. It can also be utilized to evaluate future interventions. Findings from future research with the target population and healthcare providers can inform the development of theory-based interventions using IMB Model and Intervention

Mapping methodologies (Bartholomew et al., 1998; Fisher & Fisher, 2002) (Figure 10). In addition to planning and preparing for future research endeavors, a dissemination plan has been developed to share these results with scientific and community audiences (Appendix C).

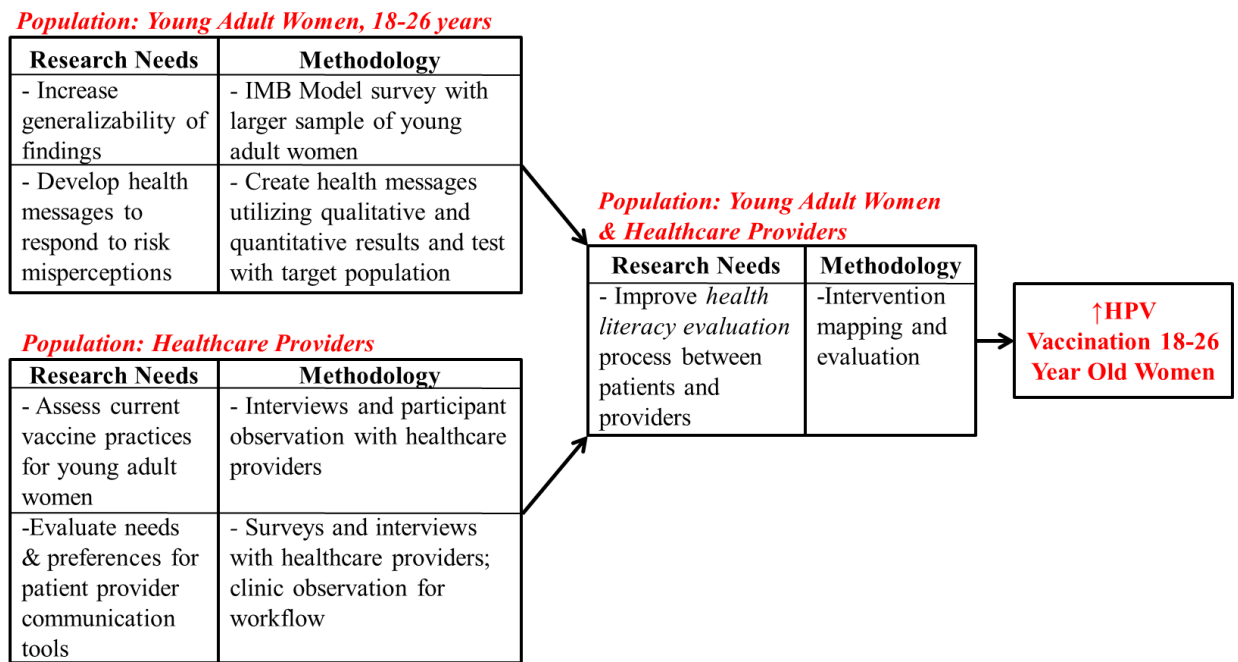


Figure 10: Proposed Future Research to Improve HPV Vaccination

Additionally, this proposed future research aligns with a number of public health priorities, including Healthy People 2020 objectives to: (1) Improve the health literacy of the population; (2) Increase the proportion of patients whose doctor recommends personalize health information resources to help them manage their health; (3) increase the proportion of persons who report that their health care providers always involved them in decisions about their health care as much as they wanted; (4) reduce the proportion of females with HPV infection; (5) reduce invasive uterine cervical cancer cases; and (6) reduce the death rate from cancer of the uterine cervix (Healthy People 2020, 2015a, 2015b, 2015c, 2015d).

A final issue to address is the need for continued targeted efforts to improve HPV vaccination rates among young adult women in the United States. The two major barriers identified for HPV vaccination as an adolescent were unawareness of the vaccine and parental refusal. As unvaccinated adolescents transition into young adulthood, they should be given the opportunity to make individual health decisions to prevent HPV and HPV-related diseases, outside the prevue of their parents' beliefs. Future research aimed at improving HPV vaccination among young adult women aligns with the Centers for Disease Control and Prevention call for additional research to increase HPV vaccine coverage by engaging patients and providers to eliminate missed clinical opportunities (Markowitz et al., 2014). Thus, young adults should not be discounted from continued research on HPV vaccination.

Conclusion

This study found that relationship status impacts HPV vaccine decision-making and reasons for non-vaccination among young adult women. Specifically, it operates by modifying risk perceptions for HPV and perceived need for the HPV vaccine, which serve as barriers to vaccination. Young adult women have the knowledge and behavioral skills necessary to access and understand the importance of HPV vaccination, as well as the reinforcing macro factors in place. However, women are unable to accurately perceive their individual risk for HPV, resulting in impaired motivation for vaccination. A potential mechanism to address this issue is the use of *health literacy*. Future research should integrate health literacy techniques with healthcare providers serving this population to assist in the *evaluation* process for risk of HPV among young adult women. This will facilitate shared decision-making and patient-provider communication surrounding the HPV vaccine.

If current trends in HPV vaccination continue in the United States, there will continue to be a substantial proportion of women who are in the catch-up range of 18 to 26 years old, yet are not vaccinated. Continued research is needed to target this specific group of unvaccinated women who have the opportunity to make autonomous sexual and reproductive health decisions. By promoting HPV vaccination among young adult women, it will ultimately reduce the morbidity and mortality of HPV-related diseases, including genital warts and HPV-related cancers.

CHAPTER 6: REFERENCES

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APPENDIX A: PHASE II RECRUITMENT EMAIL LANGUAGE

IRB

Study Title: HPV Vaccination among Young Adult Women

PI: Erika Thompson, MPH

Volunteers Needed for Research Study

Description: We are investigating the knowledge, attitudes and opinions of young adult women about HPV vaccination. Your participation would take about 5 minutes to complete an initial online survey. You would then be contacted to schedule a follow-up 30 minute telephone or Skype interview at a time that is convenient for you.

Who Can Participate?

- female,
- age 18 to 26 years,
- student at the University of South Florida, and
- meets *one* of these criteria:
 - has not received any HPV vaccine shots
 - has received the first HPV vaccine shot within the last 6 months

Incentives for Participation: Participants who schedule and complete the telephone/Skype interview will receive a \$10 gift card.

How to Participate? Start the process by clicking on this link to complete the initial short survey.

[HYPERLINK FOR SURVEY](#)

To learn more, contact the Principal Investigator, Erika Thompson at XXX-XXX-XXXX or at ethomps1@health.usf.edu.

APPENDIX B: PHASE II INSTRUMENTS

Eligibility Survey

Thank you for your interest in the *HPV Vaccination among Young Adult Women* study. To determine if you are eligible to participate, please complete the following questions.

1. What is your gender?
 - a. Female
 - b. Male
 - c. Transgender
 - d. Other

2. What is your current age? _____

3. A vaccine to prevent the human papilloma virus or HPV infection is available and is called the cervical cancer or genital warts vaccine, HPV shot, Gardasil or Cervarix. Have you EVER received an HPV vaccine shot?
 - a. No (Continue to Question 6)
 - b. Yes (Continue to question 4)
 - c. Don't know (End survey)

4. Did you receive your first HPV vaccine shot in the last 6 months?
 - a. No (End survey)
 - b. Yes (Continue to question 5)
 - c. Don't know (End survey)

5. (Question 4 = Yes) Thinking back to when you received your first dose of the HPV vaccine, please identify your relationship status *at that time*:
 - a. Married or living with a partner
 - b. Single, but in a long-term monogamous relationship
 - c. Single and dating
 - d. Single, but not in a relationship or dating

6. (Question 3 = No) Please identify your *current* relationship status:
 - a. Married or living with a partner
 - b. Single, but in a long-term monogamous relationship
 - c. Single and dating
 - d. Single, but not in a relationship or dating

Informed Consent

Informed Consent to Participate in Research Information to Consider Before Taking Part in this Research Study

IRB Study #

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

HPV Vaccination among Young Adult Women

The person who is in charge of this research study is Erika Thompson. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. Erika Thompson is being guided in this research by Dr. Ellen Daley. If you have any questions about this research please contact Erika Thompson at ethomps1@health.usf.edu (XXX-XXX-XXXX) or Dr. Ellen Daley at [email address](#).

The research will be conducted via an online survey and a follow-up telephone or Skype interview.

Purpose of the study

The purpose of this study is to assess and understand the information needs, motivations, and skills required for HPV vaccination among college females. You are being asked to participate because you are enrolled at the University of South Florida and met the eligibility criteria.

Study Procedures

- If you take part in this study, you will be asked to spend approximately 5-minutes answering questions about your knowledge of HPV and HPV vaccination. There are no right or wrong answers to any of the questions. Your responses will be averaged with the responses of other participants. All responses will remain anonymous and individual responses will not be identified.

No identifiable information, including your name or email address, will be associated with your responses. However, you will be asked to report information on your age, gender, race/ethnicity, relationship status, and sexual orientation. In order to schedule a follow-up interview, you will be asked to provide your name, email, and telephone number. These items will not be connected to any of the information you share.

- You will only complete the survey once. There will only be a follow-up interview.

This research is being conducted at the University of South Florida, during March to April 2015.

Total Number of Participants

About 48 individuals will take part in this study at USF.

Alternatives

You do not have to participate in this research study.

Benefits

We are unsure if you will receive any benefits by taking part in this research study.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

You will receive a \$10 gift card for participating in the survey and interview for this study.

Cost

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

Conflict of Interest Statement

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely

confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, Co-Investigators, study advisors, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, staff in the USF Office of Research and Innovation, USF Division of Research Integrity and Compliance, and other USF offices who oversee this research.
- It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may not be possible as the researcher may not be able to extract anonymous data from the database.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. The decision to participate or not to participate in the study will not affect your student status (e.g., course grades, etc).

New information about the study

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

You can get the answers to your questions, concerns, or complaints

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638.

By completing the survey, you are agreeing to participate in research.

Demographic Questions

Thank you for agreeing to participate in this study. All of your responses will be confidential. Please complete the following questions.

1. Which category(ies) best describes your race? (Check all that apply)
 - a. American Indian/Alaskan Native
 - b. Asian
 - c. Native Hawaiian/Pacific Islander
 - d. Black or African American
 - e. White or Caucasian
 - f. Other: _____

2. Are you Hispanic or Latina?
 - a. Yes
 - b. No

3. Are you an international student?
 - a. Yes
 - b. No

4. What is your primary source of health insurance?
 - a. Private
 - b. School-sponsored
 - c. Medicaid
 - d. Other: _____
 - e. Don't have insurance
 - f. Not sure if I have insurance

5. What sexual orientation do you most identify with? (Check one)
 - a. Bisexual
 - b. Homosexual
 - c. Heterosexual
 - d. Unsure
 - e. Other: _____

Knowledge Questions

For each of the following questions, please answer True or False as a response. If you are unsure, you can select Unsure. Please do not use any outside resources to assist you in answering these questions.

1. There are many types of HPV (T)
2. Antibiotics can cure HPV (F)
3. Only men can get HPV (F)
4. Using a condom decreases the chance of HPV transmission (T)
5. There is a vaccine for women that prevents certain types of HPV (T)
6. You can have HPV without knowing it (T)
7. HPV can be cured (F)
8. Some types of HPV cause cervical cancer (T)
9. HPV can cause HIV/AIDS (F)
10. You can always tell when someone else have HPV (F)
11. HPV can cause abnormal Pap smears in women (T)
12. HPV can cause herpes (F)
13. HPV can affect a woman's ability to get pregnant (F)
14. HPV is a virus (T)
15. HPV can cause genital warts (T)
16. HPV is spread on toilet seats (F)
17. Only women can get HPV (F)
18. HPV is a sexually transmitted infection (T)
19. Transmission of HPV can occur through sexual contact with another person (T)
20. HPV can be passed to a newborn at birth (T)
21. Even if you do not see a wart, you can transmit HPV (T)
22. HPV is a bacterial infection (F)
23. Most HPV infections clear up within a short time (T)

24. Where have you heard about the HPV vaccine? (Check all that apply)
 - a. Healthcare provider
 - b. Family
 - c. Friends/Peers
 - d. Partner/Spouse
 - e. Radio
 - f. Television
 - g. Internet
 - h. Other source: _____
 - i. I have not heard about the HPV vaccine until today

Interview Guide

Hello, my name is Erika Thompson, and I am a researcher and doctoral candidate at the University of South Florida. May I please speak to _____.

Thank you for completing the initial survey for this study and agreeing to participate in this interview. This interview should only take about 30 to 40 minutes. As you may recall, you consented to this interview when you initially completed the survey. Your participation is completely voluntary and we can stop the interview at any time. Everything you state will be confidential and not linked to your name or any other identifiers. Finally, there is no right or wrong answer to each of these questions. I just ask that you answer the questions as honestly as you can.

Would you mind if I audio-recorded our conversation?

So to start, what do you think about the HPV vaccine?

Construct	Sub-Group	Interview Question
Information: Knowledge	All	<p>What are some of the things you know about HPV? [Probe: Transmission Probe: Outcomes – cancer, genital warts, herpes, HIV Probe: Curability and length of infection] <i>Added after pilot testing</i></p> <p>What are some of the things you know about the HPV vaccine? [Probe: Who can get it? Probe: When should you get it? Probe: Any negative effect associated with it?] <i>Added after pilot testing</i></p> <p>[People mention __[insert from knowledge questionnaire]__ about HPV (HPV vaccine). What do you think about this statement? Why?] <i>Removed after pilot testing</i></p> <p>[I see you mentioned on your survey that you heard of the HPV vaccine from _____. Is there one of these sources that you trust the most?] <i>Added after pilot testing</i></p> <p>[If you wanted to receive more information about the HPV vaccine, where would you want to get it from?] <i>Added after pilot testing</i></p>
<p>Human papillomavirus or HPV is a sexually transmitted infection. The HPV vaccine can protect females and males against types of HPV that can cause genital warts and cancers, such as cervical cancer. The vaccine includes three doses or three shots provided over the course of six months typically.</p>		

Motivation: Personal	Unvaccinated	<p>How do you feel about vaccines in general? Probe: How important do you think they are? Why?</p> <p>How do you feel about the HPV vaccine? Probe: How important do you think it is? Why?</p> <p>What are some good things about getting the vaccine? Why?</p> <p>What are some bad things about getting the vaccine? Why?</p> <p>What are the reasons for not getting HPV vaccinated?</p> <p>Why didn't you get the vaccine when you were younger?</p>
	Vaccinated	<p>How do you feel about vaccines in general? Probe: How important do you think they are? Why?</p> <p>How do you feel about the HPV vaccine? Probe: How important do you think it is? Why?</p> <p>What are some good things about getting the vaccine? Why?</p> <p>What are some bad things about getting the vaccine? Why?</p> <p>What are some of the reasons why you decided to get the vaccine now?</p> <p>Why didn't you get the vaccine when you were younger?</p>
Motivation: Social	Unvaccinated	<p>Which people in your life do you think would impact your decision to get the vaccine? Probe: How would they impact your decision? (Positive or negative) Probe: Parents, peers, partners, providers?</p> <p>Based on your response to the initial survey, I see that you are in a [relationship category]. Can you talk a little bit about your current relationship status? Probe: Length of time? Probe: Mutually monogamous? (if applicable) Probe: Future together? (if applicable)</p> <p>How does your current relationship status impact your decision to be HPV vaccinated? Why?</p> <p>How do you think it might change if your relationship status changes in the future?</p>
	Vaccinated	Which people in your life do you think impacted your

		<p>decision to get the vaccine? Probe: How did they impact your decision? (Positive or negative) Probe: Parents, peers, partners, providers?</p> <p>Based on your response to the initial survey, I see that you were in a [relationship category] at the time you were vaccinated. Can you talk a little bit about your relationship status at that time? Probe: Length of time? Still in this relationship? Probe: Mutually monogamous? (if applicable) Probe: Future together? (if applicable)</p> <p>How did your relationship status at that time impact your decision to be HPV vaccinated? Why?</p>
Motivation: Perceived Vulnerability	Unvaccinated	<p>What do you think your risk of HPV is, without the vaccine? Probe: What influences this risk? Probe: Does your relationship status impact this risk?</p> <p>Do you think your risk would change if you got the vaccine? Probe: How so?</p> <p>What do you think are the consequences of getting HPV? Probe: How serious is the condition?; How severe is the condition?; How significant is the condition?</p>
	Vaccinated	<p>What do you think your risk of HPV is, without the vaccine? Probe: What influences this risk? Probe: Did your relationship status impact this risk?</p> <p>Do you think your risk has changed now that you got the vaccine? Probe: How so?</p> <p>What do you think are the consequences of getting HPV? Probe: How serious is the condition?; How severe is the condition?; How significant is the condition?</p>
Behavioral skills	Unvaccinated	<p>Walk me through the steps you would need to do to get the HPV vaccine. Probe: access, communicate, complete</p> <p>What would make it easy to get the vaccine?</p> <p>What would make it difficult to get the vaccine? Probe: How confident do you feel to overcome these barriers?</p>

	Vaccinated	<p>Walk me through the steps you took to get the HPV vaccine. Probe: access, communicate, complete</p> <p>What made it easy to get the vaccine?</p> <p>What made it difficult to get the vaccine? Probe: How confident did you feel to overcome these barriers?</p>
Macro factors	All	<p>How frequently do you visit your healthcare provider? Probe: How often did you go in the last year?</p> <p>You have mentioned [list here] barriers and facilitators to HPV vaccination, are there any other social or cultural factors that impact your opinion or ability to get the vaccine? Probe: Distrust government or pharmaceuticals Probe: Media messages Probe: Vaccine culture</p> <p><i>Insurance status question in demographics section.</i></p>

Is there anything else you would like to share with me about HPV or HPV vaccination?

Thank you for your participation and contribution to this research.

APPENDIX C: DISSEMINATION PLAN

1. Manuscripts

Brief Title	Target Journals (Impact Factor)	Description
IMB Model Findings	American Journal of Public Health (4.552) Vaccine (3.624) Health Education and Behavior (2.229)	The purpose is to compare the information, motivation, behavioral skills, and macro factors for HPV vaccination between vaccinated and unvaccinated women. Methods will be from Phase II of the dissertation.
Risk Perceptions	American Journal of Public Health (4.552) American Journal of Preventive Medicine (4.527) Women's Health Issues (2.330)	The purpose is to describe how relationship status impacts risk perceptions and perceived need of the HPV vaccine. Methods will be from Phase II of the dissertation.
NHIS 2010 Analysis	Sexually Transmitted Diseases (2.594)	The focus on this paper is to describe the differences in primary reasons for non-vaccination by relationship status. This manuscript will likely be a Brief Report.
HPV Knowledge and Information	Health Education and Behavior (Impact Factor 2.229) Women's Health Issues (2.330)	The purpose of this paper is to compare how knowledge items are measured for the quantitative and qualitative components of Phase II.

2. Conference Abstracts

Brief Title	Conference	Description
IMB Model Findings	American Academy of Health Behavior 2016 Due: Sept 19 2015	The purpose is to compare the information, motivation, behavioral skills, and macro factors for HPV vaccination between vaccinated and unvaccinated women. Methods will be from Phase II of the dissertation.
Risk Perceptions	Society for the	The purpose is to describe how relationship

	Scientific Study of Sexuality 2015 Due: Sept 1 2015	status impacts risk perceptions and perceived need of the HPV vaccine. Methods will be from Phase II of the dissertation.
NHIS 2010 Analysis	American Public Health Association 2016 Due: Feb 2016	The focus on this abstract is to describe the differences in primary reasons for non-vaccination by relationship status. This manuscript will likely be a Brief Report.
HPV Knowledge and Information	American Public Health Association 2016 Due: Feb 2016	The purpose of this abstract is to compare how knowledge items are measured for the quantitative and qualitative components of Phase II.
HPV Vaccine Attitudes	American Public Health Association 2016 Due: Feb 2016	The purpose of this abstract is to describe how women frame the HPV vaccine as a separate vaccine from required and optional vaccinations, as well as reconcile these attitudes with the anti-vaccination movement.

3. Community Reports

An executive summary of the findings from this dissertation will be drafted and shared with the USF Student Health Services staff. This report will translate the research into implications for practice.

APPENDIX D: IRB APPROVALS



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX(813) 974-7091

3/4/2015

Erika Thompson
Epidemiology and Biostatistics
12901 Bruce B Downs Blvd, MDC56
Tampa, FL 333612

RE: **NOT Human Research Activities Determination**
IRB#: Pro00021130
Title: Secondary Analysis of National Health Interview Survey (NHIS) for HPV Vaccination

Dear Ms. Thompson:

The Institutional Review Board (IRB) has reviewed the information you provided regarding the above referenced project and has determined the activities do not meet the definition of human subjects research. Therefore, IRB approval is not required. If, in the future, you change this activity such that it becomes human subjects research, IRB approval will be required. If you wish to obtain a determination about whether the activity, with the proposed changes, will be human subjects research, please contact the IRB for further guidance.

All research activities, regardless of the level of IRB oversight, must be conducted in a manner that is consistent with the ethical principles of your profession and the ethical guidelines for the protection of human subjects. As principal investigator, it is your responsibility to ensure subjects' rights and welfare are protected during the execution of this project

Also, please note that there may be requirements under the HIPAA Privacy Rule that apply to the information/data you will use in your activities. For further information about any existing HIPAA requirements for this project, please contact a HIPAA Program administrator at 813-974-5638.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

A handwritten signature in blue ink that reads "V Jorgensen MD". The signature is written in a cursive style.

E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

March 11, 2015

Erika Thompson
Epidemiology and Biostatistics
12901 Bruce B. Downs Blvd
MDC 56
Tampa, FL 33612

RE: **Expedited Approval for Initial Review**
IRB#: Pro00021133
Title: HPV Vaccination among Young Adult Females

Study Approval Period: 3/11/2015 to 3/11/2016

Dear Ms. Thompson:

On 3/11/2015, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

Approved Item(s):

Protocol Document(s):

[Study Protocol - Version 1](#)

Consent/Assent Document(s)*:

[Informed Consent Language for Online Survey Version 2](#) **granted a waiver

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s). **Waivers are not stamped.

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review

category:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,



Kristen Salomon, Ph.D., Vice Chairperson
USF Institutional Review Board