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# HPV Vaccine Decision-Making among Male Sexual Minorities: An Integrative Theoretical

Framework for Vaccine Promotion

by

Christopher W. Wheldon

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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Keywords: Male Sexual Minority, HPV Prevention, Mixed Methods, Integrative Model

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# DEDICATION

This research would not have been possible without the support of the participants who volunteered their time and shared their thoughts and opinions. I dedicate this dissertation to them and to the larger community that they represent.



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# ABSTRACT

Men who have sex with men (MSM) are at increased risk of anal cancer as a result of anal HPV infection. Routine HPV vaccination is recommended for all MSM up through age 26; however, vaccine uptake among this population is low. The Integrative Model of Behavioral Prediction (IM) was used to identify, describe, and explain psychosocial factors related to HPV vaccine decision-making for young MSM. A sequential mixed-methods approach consisting of semistructured interviews, a quantitative survey, and a qualitative open-ended survey was used to address the following aims: (1) Determine salient outcome, normative, efficacy, and control beliefs related to HPV-vaccination among young MSM; (2) Identify information needs and trusted sources of information regarding HPV vaccination among young MSM; and (3) Develop and test a structural equation model guided by the Integrated Model of Behavioral Prediction. The purpose and objectives of this research address priorities outlined in the Institute of Medicine's report on health disparities among lesbian, gay, bisexual, and transgender (LGBT) populations. Results highlight the lack of information and knowledge regarding HPV prevention in this population. The majority of respondents had heard of the HPV vaccine but generally perceived it as a women's health issue. Attitudes toward vaccination were generally positive, as was behavioral intention to get vaccinated within the next 12 moths. Salient behavioral beliefs described physical benefits such as lowering risk and promoting overall health. Psychological benefits were described as protecting sex partners and providing peace of mind. There was some concern regarding the risks of vaccination including contracting HPV from the vaccine, not



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knowing if it would be effective, and potential side effects. Normative influences on decisionmaking were minimal. Availability, cost, and convenience were among the most salient external control factors. Issues surrounding disclosure of sexual minority status influenced control factors including self-efficacy. Addressing the specific beliefs and concerns expressed by MSM can help to improve the effectiveness of health education interventions promoting vaccination. Empirical findings support the proposed behavioral model of vaccine decision-making.



# **CHAPTER 1: INTRODUCTION**

The incidence of anal cancer is increasing in the U.S. and men who have sex with men (MSM) are disproportionally at risk (Daling et al., 2004; Johnson, Madeleine, Newcomer, Schwartz, & Daling, 2004; Joseph et al., 2008). Between 1973 and 2000, the incidence of anal cancer in the U.S. increased among both men and women; however, the incidence among men increased at a higher rate (160% vs. 78%) (Johnson et al., 2004). The incidence rates of anal squamous cell carcinoma (SCC), the dominant histologic anal cancer type in the U.S., increased an average of 2.6% per year between 1998 and 2003 (Joseph et al., 2008). The demographic trends in anal cancer changed after 2000, when the combined incidence of SCC and carcinoma in situ were higher in men than in women (Nelson, Levine, Bernstein, Smith, & Lai, 2013). Most of this increase, however, has been attributed to the HIV epidemic and the disproportional risk faced by MSM (Cress & Holly, 2003; Daling et al., 2004; Nelson et al., 2013).

It is estimated that the incidence of anal cancer is approximately 12.5-36.9 cases per 100,000 MSM compared to just 1 case per 100,000 heterosexual males (~ 20 times higher for MSM) (D'Souza et al., 2008; Daling et al., 1987). This rate is substantially greater in MSM infected with HIV. Since 1996, the anal cancer incidence of HIV-positive MSM was estimated to range from 59.4-96.2 cases per 100,000 (Machalek et al., 2012).

Further evidence indicates that a sizable proportion of MSM exhibit anal squamous intraepithelial lesions (ASILs), which are considered biological precursors of anal cancer. In their investigation of HIV-negative MSM recruited from four U.S. cities, Chin-Hong and



colleagues (2005) found that 20% of MSM had ASILs, with 5% of these classified as high-grade lesions (i.e., invasive cancer precursors). A study of HIV-positive MSM found the prevalence of ASILs to be approximately 81% with 13% classified as high-grade lesions (Palefsky et al., 2005). Similar rates of ASILs were reported in studies of MSM residing in European countries (Kreuter et al., 2010; Piketty et al., 2004). The high rate of ASILs among populations of MSM, as well as the increase risk of invasive anal cancer, suggests that anal cancer prevention targeting MSM is of significant public health importance.

Overall, the current risk for anal cancer for MSM is comparable to women's risk for cervical cancer prior to widespread implementation of cytological screening (Qualters, Lee, Smith, & Aubert, 1992). While most attention has focused on the well-established link between human papillomavirus (HPV) and cervical cancer, infection with oncogenic HPV types (e.g., HPV -16 and -18) is also a primary causal factor in the etiology of anal cancer (Grulich et al., 2012). In a meta-analysis of anal HPV-related disease, the prevalence of anogenital HPV infection was as high as 92.6% and 69.9% in studies of HIV-positive and HIV-negative, MSM, respectively (Machalek et al., 2012). The prevalence of oncogenic high-risk types was also high in these populations, averaging 73.5% in HIV-positive and 37.2% in HIV-negative MSM. These infections are effectively prevented through prophylactic vaccination (Giuliano et al., 2011).

In 2009 the U.S. Food and Drug Administration approved the quadrivalent HPV vaccine, Gardasil, for the prevention of genital warts in males ages 9-26. Indications of Gardasil were extended in 2011 to include the prevention of anal cancer and anal intraepithelial neoplasia in both males and females. The Centers for Disease Control and Prevention (CDC) recently recommended routine vaccination of males aged 11 and 12, and catch-up vaccination in males between the ages of 13 and 21. Permissive use was recommended for men between the ages of



22 and 26; however, the Advisory Committee on Immunization Practices (ACIP) recommended *routine* vaccination of MSM up through age 26 (Centers for Disease Control and Prevention, 2011b). There is a paucity of behavioral research focusing on adult MSM ages 18-26 regarding their readiness to initiate HPV vaccination.

Preliminary research suggest that a reasoned action approach, as represented in the Integrative Model of Behavioral Prediction (IM), is a viable theoretical framework from which to understand HPV vaccine decision-making and to design tailored interventions. According to this model, health education interventions must address the salient HPV-related outcome, normative and control beliefs expressed by young MSM in order to effectively promote vaccination among this population. These beliefs and perceptions cannot be generalized *a priori* from other research domains or study populations but require careful formative elicitation research conducted with the priority population. The salient beliefs elicited in the current study can be used to create innovative culturally appropriate interventions promoting HPV vaccination among young MSM.

#### **Statement of Need**

There is limited theory-based research on HPV vaccine acceptability and intentions among men in general, and even fewer studies focusing on MSM for whom the need is even greater. Overall, men have been found to have limited knowledge about HPV (Gerend & Magloire, 2008; Klug, Hukelmann, & Blettner, 2008), to be largely unaware of the link between HPV infection and cancer in men (Gerend & Barley, 2009), and to have widely varying attitudes toward HPV vaccination (Liddon, Hood, Wynn, & Markowitz, 2010). The few studies that have focused on MSM have reported a wide range of HPV awareness, knowledge, and vaccine acceptability in MSM (Reiter, Brewer, McRee, Gilbert, & Smith, 2010; Simatherai et al., 2009; Tider, Parsons, & Bimbi, 2005; Wheldon, Daley, Buhi, Nyitray, & Giuliano, 2011). Much of this



research is limited by its focus on MSM living in a few large metropolitan cities, and by measures that did not assess knowledge of the oncogenic risk of HPV infection in men. One national study of MSM found high awareness of HPV but limited knowledge about the direct health effects of HPV infection on males (Gilbert, Brewer, Reiter, Ng, & Smith, 2010). For example, although 79% of men in this study had heard of HPV, only 32% knew HPV could cause anal cancer.

Collectively, the utility of this body of research for intervention planning is limited by three important caveats: (1) most of this data were collected with regard to a hypothetical HPV vaccine since, at the time, no vaccine had been approved for the prevention of HPV in males; (2) participants were on average much older than males who are in the current recommended age range for HPV vaccination; and (3) social and cultural beliefs and perceptions salient to young MSM were not explored. These limitations in the extant literature limit the ability of public health professionals to tailor health education interventions to the specific needs of gay, bisexual, and other MSM. Widespread acceptance and uptake of the HPV vaccine is needed in order for prophylactic vaccination to be an effective—both in terms of reach and cost—public health strategy to decrease the burden of HPV-related cancers among male sexual minorities. Health education research aimed at promoting vaccination is therefore an essential component of such a strategy.

#### **Research Plan**

#### **Purpose of the Study**

The long-term goal of this research is to decrease the incidence of anal cancer and other HPV-associated diseases among MSM by preventing infection of HPV types -6, -11, -16 and -18 through vaccination. The purpose of this study was to understand the factors important to young



MSM when making decisions about HPV vaccination. A multi-phase, multi-method study was conducted in order to develop measures of relevant theoretical constructs and to test an integrative model of HPV vaccine intentions in a sample of young MSM. The following aims were addressed: (1) Determine salient outcome, normative, efficacy, and control beliefs related to HPV-vaccination among young MSM; (2) Identify information needs and trusted sources of information regarding HPV vaccination among young MSM; and (3) Develop and test a structural equation model guided by the Integrated Model of Behavioral Prediction that identifies the psychosocial determinants of young MSM's HPV vaccine intentions. The specific aims and associated research questions are summarized in Table 1.

The goal of this research is to inform health education interventions that will increase HPV vaccine uptake among young adult MSM; however, since the vaccine has only recently been approved for males, and the number of young MSM who have actually received the HPV vaccine is very small, it is not possible at this time to study vaccine uptake directly. Therefore, the main outcome of interest for this research is intent to receive the HPV vaccine, which is theoretically the most proximal determinant of future vaccination (Montano & Kasprzyk, 2008).

The target population for this research includes (1) men between the ages of 18 and 26, (2) who reside in the United States, (3) are able to read and comprehend English, (3) who have not initiated the HPV vaccine series, and (4) who have ever engaged in sexual contact with another male or who identify as gay or bisexual. This conceptual population includes both gay identified and non-gay identified MSM in order to be inclusive of all those who engage, or may engage at some point, in similar behaviors that increase the risk of HPV infection. It also focuses on adult males who do not need parental permission to receive the vaccine.



# *Rationale for the study*

The use of empirically supported behavioral models of HPV vaccination specific to MSM will increase the efficacy of health education messages and interventions targeting MSM, which will result in greater rates of vaccination and decreased risk of anal cancer and other HPV-associated diseases. By identifying the salient psychosocial factors associated with HPV-vaccination among young MSM and testing a theoretical behavioral model that identifies specific beliefs and perceptions that can affect intentions to get vaccinated, the outcomes of this research can be used to develop tailored health education programs aimed at increasing vaccine uptake among this population. The strategies for behavioral change, for example, would differ significantly if this research identifies normative influences as the strongest predictor of vaccine intentions and attitudinal factors as largely unimportant. Furthermore, by eliciting salient influential individuals or groups, and measuring indirect effects of normative influences (normative beliefs and motivation to comply), the final model will provide a rich source of information to plan behavior change strategies.

Future directions include the use of Intervention Mapping to apply the determinants of HPV vaccine intentions identified in the current study to the creation of specific change objectives, which represent empirically validated "pathways" that can yield the most immediate changes in motivation and behavior (Bartholomew, 2011). This approach will also involve the identification of relevant stakeholders and community resources that can be leveraged to disseminate health education messages and programs, with the ultimate goal of increasing HPV vaccine awareness, acceptability, and uptake among diverse populations of young MSM.



Research Aim	Research Question
Research Aim #1: (a) Describe salient outcome, normative, efficacy, and control beliefs related to HPV-vaccination among young MSM	1. What do YMSM believe are the advantages and/or disadvantages of receiving the HPV vaccine?
(b) Determine factors that underlie these beliefs	2. (a) How do YMSM perceive others who receive the HPV vaccine? (b) Who are the individuals and/or groups that influence YMSM decisions regarding HPV vaccination?
	3.What factors or circumstances would enable YMSM to initiate HPV vaccination and what factors or circumstances would inhibit their ability or willingness to get vaccinated?
Research Aim #2: Identify information needs and trusted sources of information regarding HPV vaccination among young MSM.	4. What sources of health-related information do YMSM access and trust? What information would help influence their HPV vaccine decisions?
Research Aim #3: Develop and test a structural equation model guided by the Integrated Model (IM) of Behavioral Prediction that identifies the psychosocial determinants of young MSM's HPV vaccine intentions	5. What are the structural relationships between factors from the IM and what is their relationship to HPV vaccine intentions?

Table 1: Aims and Research Questions



# **CHAPTER 2: LITERATURE REVIEW**

#### Human papillomavirus as a public health problem

Human papillomavirus (HPV) is a common infectious agent that infects the epithelial tissues after abrasion or trauma (Schiller, Day, & Kines, 2010). Though there are many types of HPV, it is principally known and described as a sexually transmitted infection (STI). Currently there are more than 40 known HPV types that infect epithelial tissues in anogenital regions of males and females. Assessment activities surrounding the study of HPV as a public health problem include epidemiological investigations designed to quantify the distribution and determinants of HPV infection and HPV-related diseases. These types of surveillance activities are essential to inform policy development and the assurance of provisions and resources.

It is estimated that 6.2 million sexually active Americans between the ages of 15 and 44 will acquire HPV every year (Weinstock, Berman, & Cates, 2004). Given that cross-sectional studies often find a 50% prevalence of HPV infection, it's likely that a larger proportion of the population gets HPV infection during the lifetime (Dunne et al., 2007; Dunne, Nielson, Stone, Markowitz, & Giuliano, 2006). The majority of HPV infections will spontaneously regress with only a small percent of HPV infections persisting beyond two years (Baseman & Koutsky, 2005). Prevalence estimates of HPV in the U.S. vary as a result of geographic variations in study samples, anatomical sites from which specimens were collected (e.g., cervicovaginal, glans, corona, prepuce, anus, etc.), as well as the processing methods used to analyze the samples (Dunne et al., 2006; Nielson et al., 2007; Smith & Travis, 2011). Estimates range from just 1.3%



to 72.9% in studies assessing multiple anatomical sites (Dunne et al., 2006). Because of the wide-ranging prevalence estimates across populations, an overall estimate of HPV infection is not useful. This is further substantiated when one considers sex differences in HPV prevalence and persistence.

Unlike patterns of HPV infection in females, the prevalence of genital HPV in males does not concentrate as highly in younger age cohorts indicating sex differences in persistence or reinfection (becoming infected with same HPV-type after initially clearing the infection) (Smith, Melendy, Rana, & Pimenta, 2008). These sex differences may also be reflected in observations of lower antibody prevalence for specific HPV types and lower titer levels in males compared to females (Giuliano et al., 2008). Therefore, age does not appear to be as strongly associated with genital HPV prevalence in males, in general, as it is in females. It is still unknown if age-based sex differences exist in anal HPV infection.

Results are more conclusive, however, with regard to determinants of infection. Sexual behavior is consistently associated with HPV prevalence in both males and females. A greater number of lifetime and recent sex partners increase risk of HPV (Svare et al., 2002). Having multiple sex partners is also positively associated with co-infection with multiple HPV types (Nielson et al., 2009; Rousseau et al., 2003). For men, multiple-type HPV infections may be more common in particular anatomical sites such as the penile shaft and to a lesser extent the glans penis/coronal sulcus; whereas other sites such as the perianal and anal canal may be less likely to harbor multiple type infections (Nielson et al., 2009).

Therefore, the prevalence and type of HPV infection also appears to vary across men based on their history of same-sex sexual behaviors. Men with a history of oral and/or anal sex with men have been shown to have a higher prevalence of specific anal HPV genotypes when



compared with men without a history of same-sex behavior (Nyitray, da Silva, Baggio, Lu, Smith, Abrahamsen, Papenfuss, Quiterio, et al., 2011). For example, the prevalence of combined genotypes 6/11, the two HPV types responsible for the majority of anogenital warts, were found to be more common in men who have sex with men (MSM) and men who have sex with men and women (MSMW) when compared to men who have sex with women (MSW) (Nyitray, da Silva, Baggio, Lu, Smith, Abrahamsen, Papenfuss, Quiterio, et al., 2011). Similarly, the prevalence of any HPV type at the perianal region or in the anal canal is strongly associated with a history of same-sex sexual behavior. And while anal HPV infection among MSW is not uncommon, these type-specific infections tend to co-occur at anal and genital sites in MSW, but less so among MSM (Nyitray, da Silva, Baggio, Lu, Smith, Abrahamsen, Papenfuss, Quiterio, et al., 2011). This pattern of infection suggests self-inoculation between anatomical sites among MSW (Hernandez et al., 2008).

Among MSM and MSMW, there are a number of factors associated with the prevalence of anal HPV infection. One of the strongest behavioral factors is history and frequency of receptive anal intercourse (Chin-Hong et al., 2004; Vajdic et al., 2009). Infection with HIV also increases risk of HPV. MSM seropositive for HIV were significantly more likely to be infected with both oncogenic and nononcogenic HPV types compared to HIV seronegative MSM (Vajdic et al., 2009; van der Snoek et al., 2003).

Anal HPV infection is also common among females. In a recent cohort study of women, the period prevalence over an average of 1.3 years for anal HPV infection was 70% (Goodman et al., 2008). The incidence of infection (inclusive of 18 high-risk HPV DNA types) was nearly 20 per 1,000 woman-months after a year of follow-up. A greater number of sexual partners and baseline cervical HPV infection was positively associated with anal HPV infection among



women in this cohort study; however, anal intercourse was not significantly associated with anal HPV infection. This finding is in accordance with some previous research on anal HPV infection in women that failed to find an association between anal HPV infection and receptive anal intercourse (Palefsky, Holly, Ralston, Da Costa, & Greenblatt, 2001). In contrast, research among MSM has consistently found strong associations between receptive anal intercourse and anal HPV infection (Chin-Hong et al., 2004; Vajdic et al., 2009). Collectively, these findings suggest divergent routes of transmission responsible for the acquisition of anal HPV infection in heterosexual men and women, compared to homosexually active men.

#### High-risk and low-risk HPV

A better approach to the surveillance and monitoring of HPV infections is to focus on those specific types that result in the greatest disease burden given the wide variation in the distribution of HPV infection among diverse populations, the various determinants that lead to these infections, and the differences observed in persistence of infection. A small subset of genotypes is responsible for the largest proportion of clinical diseases such as anogenital warts and certain cancers. Those associated with anogenital warts are considered low-risk, as they do not result in malignant cancers. Two types of low-risk HPV (type -6 and -11) cause approximately 90% of genital warts. In contrast, 12-18 types of HPV are considered high-risk because of their relationship with invasive cancer (Muñoz et al., 2003).

#### HPV-associate disease burden

# Genital warts

Genital warts, or Condylomata acuminate, occur at multiple anogenital sites in both men and women. They can also develop in the larynx, eyes, and nose. The majority of genital warts are caused by HPV type -6 or -11 (Garland et al., 2009). Infection with these HPV types is very



common in the United States. In a recently published study, the seroprevalence of HPV types 6/11 was 20.8% for females and 7.3% for males (Markowitz, Sternberg, Dunne, McQuillan, & Unger, 2009); however, these are likely lower bound estimates due to lower antibody response and titer levels for specific HPV types in males (Giuliano et al., 2008).

Despite the high prevalence of infection with these HPV types in the population, the majority of infections do not result in genital warts because the infections are cleared by the body's immune system. Analysis of private insurance claims estimate the incidence density rate of genital warts in the United States to be approximately 1.7 per 1,000 person years (Insinga, Dasbach, & Myers, 2003). Self-report data from a population-based sample of men and women aged 18 to 59 residing in the US indicated approximately 6% of this population has ever been diagnosed with genital warts (Dinh, Sternberg, Dunne, & Markowitz, 2008). There is some indication that the rate of genital warts is increasing in the United States and is highest among men and women in their twenties (Insinga et al., 2003; Koshiol, Laurent, & Pimenta, 2004). Furthermore, anogenital warts may be more prevalent among MSM, and are associated with certain sexual behaviors and tobacco use (Hansen et al., 2010; Fengyi Jin et al., 2007; Wiley et al., 2009).

Though anogenital warts are relatively benign, treatment options and the likelihood of reoccurrence result in significant health care costs and utilization (Giuliano, 2007). Developing anogential warts also exerts a significant psychosocial burden in both men and women and negatively impacts their quality of life (Jeynes, Chung, & Challenor, 2009; Scarbrough Lefebvre, Van Kriekinge, Gonçalves, & de Sanjose, 2011; Skaaby & Kofoed, 2011). Furthermore, anogenital warts may increase the risk for HIV infection among high-risk populations of men (Jin et al., 2010).



# Cervical cancer

Initial assessments of the public health impact of HPV began in the 1970s when genital warts was linked to HPV infection in returning war veterans; however, it was not until the 1980s that HPV infection was linked to squamous cell carcinomas of the cervix (Boshart et al., 1984). It is now well understood that HPV infection is a necessary cause of cervical cancer (Walboomers et al., 1999), which is the second most common type of cancer in women worldwide and is estimated to develop in approximately 8.1/100,000 women every year in the United States (Howlader et al., 2011). This rate is far less than the rate of cervical cancer in previous decades, as the incidence in the United States has decreased almost 70% among white women due to the widespread implementation of cytological screening (Devesa et al., 1987; Kitchener, Castle, & Cox, 2006). Despite the success of these prevention efforts, cervical cancer is still a significant cause of cancer-related morality in the United States, particularly among Black and Hispanic women (Barnholtz-Sloan et al., 2009). Infection with a high-risk type of HPV is a necessary cause of cervical cancer. Specifically, HPV-16 and -18 account for the highest proportion of cervical cancers (Clifford, Smith, Plummer, Munoz, & Franceschi, 2003). Other HPV-associated cancers

These same HPV types have also been implicated as primary causal agents of anal cancer (Carter et al., 2001; Frisch et al., 1999; Melbye & Frisch, 1998), and are strongly associated with cancers of the oropharynx, vulva, vagina, and penis (Gillison, Chaturvedi, & Lowy, 2008). Collectively, these noncervical HPV-associated cancers result in over 19,000 cancers per year in the United States. Among these, anal and oropharyngeal cancers represent the largest burden of noncervical HPV-associated cancers. Furthermore, as shown below, there are notable disparities



in the incidence of these cancers, particularly with regard to incidence among men (Palefsky, 2010b).

## Head and neck cancer

In contrast to the declining rates of cervical cancer in the United States, rates of noncervical HPV-associated cancers are static or increasing (Gillison et al., 2008). For example, persistent infection with high-risk HPV types can result in a series of invasive cancers in both men and women including anal and head and neck cancers. Cancers of the head and neck include all of those cancers developing in the oral cavity, salivary glands, sinus and nasal cavities, pharynx, or larynx. The role of HPV infection in the development of head and neck cancer depends largely on the site of the tumor. The association of HPV infection is strongest for cancers of the oropharynx with approximately 60% of these cancers attributable to HPV infection (Gillison et al., 2008). The burden of these HPV-related oral cancers has increased over the last two decades, particularly among younger men (Chaturvedi et al., 2011; Marur, D'Souza, Westra, & Forastiere, 2010; Westra, 2009). There are an estimated 7,000 cases of oropharyngeal cancer annually in the US, with approximately 5,600 of those cases occurring among men (CDC, 2011). Similar to cervical cancer, HPV -16 and -18 are the most prevalent HPV types found in oropharyngeal cancers (Giuliano et al., 2008).

#### Anal cancer

There is a growing body of evidence that suggests most anal cancers (more than 90%) are caused by HPV infection (Gillison et al., 2008). In 2009, an estimated 5,290 men and women in the U.S. were reported with cancers of the anus, anal canal, or anorectum (Jemal et al., 2009). And while overall survival rates from anal cancer are similar to survival rates from other cancers of the digestive system, there is a significant quality of life lost depending upon the



recommended treatment (Allal, Sprangers, Laurencet, Reymond, & Kurtz, 1999). Furthermore, the incidence of anal cancer is increasing, and certain subpopulations are at disproportional risk of this disease. Between 1973 and 2000, the incidence of anal cancer in the United States increased among both men and women; however, the incidence among men increased at a higher rate (160% vs. 78%) (Johnson et al., 2004). The incidence rates of anal squamous cell carcinoma (SCC), the dominant histologic anal cancer type in the U.S., increased an average of 2.6% per year between 1998 and 2003 (Joseph et al., 2008). The demographic trends in anal cancer changed after 2000, when the combined incidence of SCC and carcinoma in situ were higher in men than in women (Nelson et al., 2013).

Most of this increase, however, has been attributed to the disproportional risk faced by MSM (Cress & Holly, 2003; Daling et al., 2004). Epidemiological evidence strongly suggests that MSM are at increased risk of developing anal cancer. The incidence of anal cancer in MSM was estimated to be approximately 12.5-36.9 cases per 100,000 MSM compared to just 1 case per 100,000 heterosexual males (Daling et al., 1987). A prospective cohort study of married same-sex partners in Denmark found that homosexually partnered men had over 31 times the risk of anal cancer compared to the rest of the general population (Frisch et al., 1997).

The prevalence of anal squamous intraepithelial lesions (ASILs), some of which are likely biological precursors of anal cancer, provides additional evidence of anal cancer risk in MSM. Analysis of anal cytology results among sexually active HIV-negative MSM determined that 5% of the men had biological precursors of anal cancer (Chin-Hong et al., 2005). The risk of ASILs increase significantly for HIV infected individuals. Prevalence estimates of ASILs from a study of HIV-positive MSM were as high as 81% (Palefsky et al., 2005). These findings are consistent with the incidence of anal cancer found in HIV-positive MSM (D'Souza et al., 2008).



At nearly 80 cases per 100,000, HIV-positive MSM are nearly 40 times more likely to develop anal cancer than HIV-negative MSM. Overall, risk estimates for anal cancer among MSM are comparable, and even exceed, women's risk for cervical cancer prior to widespread implementation of cytological screening (Qualters et al., 1992).

#### Penile cancer

HPV infection is also associated with a number of penile cancers, which are rare compared to other HPV-associated cancers. The estimated average annual number of HPVassociated cases of penile cancer in the US is 298 (Gillison et al., 2008). This low occurrence equates to less than 1 case per 100,000 men. Unlike cervical cancer, in which HPV is a necessary cause, penile cancer is a histologically heterogeneous disease where approximately 40-50% of cases are associated with HPV infection (Giuliano et al., 2008). The association of HPV infection with penile cancer is clarified when stratified by histology with a much larger proportion of warty/basaloid cancers testing positive for HPV DNA (~75-80%) compared to the more common squamous cell carcinomas (~30-60%) (Giuliano et al., 2008; Palefsky, 2010). Of these HPV-associated penile cancers, the majority (~87%) can be attributed to infection with HPV type 16 and/or 18 (Gillison et al., 2008).

#### **HPV Prevention**

The prevention of HPV infection among males has garnered increased attention in recent years, both because of the indirect benefit to females resulting from lower population prevalence, as well as the growing awareness of the health sequelae of HPV infection in men. Identifying factors associated with the increased risk of HPV transmission provides targets for primary prevention efforts. The primary modes of transmission of HPV include vaginal and anal intercourse (Burchell, Winer, de Sanjosé, & Franco, 2006). Prevalence of HPV infection is



commonly associated with a greater number of lifetime and recent sexual partners (Dunne et al., 2006). Significantly decreasing exposure through the modification of sexual behaviors is unlikely given the highly transmissible nature of HPV and increasingly permissive social norms regarding sexual behavior (Thornton & Young-DeMarco, 2001).

In addition, the protective effect of condom use against HPV transmission during sexual intercourse is undetermined (Manhart & Koutsky, 2002) and is likely site specific. Consistent condom use with female partners seems to offer some degree of protection from genital HPV infection, particularly at covered sites such as the penile shaft and glans (Baldwin et al., 2004; Nielson et al., 2010). Always using condom was also found to be protective against anal HPV infection among MSM (Nyitray, da Silva, Baggio, Lu, Smith, Abrahamsen, Papenfuss, Villa, et al., 2011). Despite these findings, condom use was not associated with risk of anogenital warts among men in a previous study (Wiley et al., 2005). The association between condom use and HPV prevalence appears to be moderated in part by biological sex differences, given that women appear to benefit less from condom use than men (Manhart & Koutsky, 2002; Vaccarella et al., 2006). Studies investigating the association of condom use and HPV have several methodological limitations (e.g., HPV sites measured) that limit our ability to draw valid and reliable conclusions; however, it is clear that the overall impact of condom use as a viable HPV prevention strategy is limited by the potential for transmission during noncoital sexual actively.

The data regarding the protective effects of male circumcision is more definitive. A recent meta-analysis reviewed 23 articles published through September of 2010 and found consistent evidence for reduced risk of HPV among circumcised men (Larke, Thomas, dos Santos Silva, & Weiss, 2011). The strongest effect was for reduced prevalent infections, particularly at the glans/corona and sites more proximal to the foreskin. There was further



evidence indicating that circumcision is protective against incident infections and may result in increased clearance of acquired infections. There is some related evidence that the protective effect of circumcision may decrease the prevalence of HPV-associated diseases. For example, childhood circumcision is associated with reduced risk of invasive penile cancer (Larke et al., 2011); and, among men with a history of multiple sex partners, a decreased risk of cervical cancer has been observed in their female partners (Castellsagué et al., 2002). No data is available regarding circumcision risk of anal HPV infection or anal cancer.

Circumcision as a population-based HPV prevention strategy is limited, however, by its overall impact on HPV transmission as well as limited modifiability. Based on current data, circumcision can reduce HPV transmission by an estimated 43% (Larke et al., 2011); however, there is wide variation in this estimate and may be as low as 29%. Furthermore, the overall prevalence of male circumcision in the United States has steadily decreased since the 1970s (Xu, Markowitz, Sternberg, & Aral, 2007), and is associated with strong cultural values and increasingly negative attitudes that may be resistant to modification (Zoske, 1998).

More recent efforts to prevent HPV infection involve prophylactic vaccination as a primary prevention strategy. A quadrivalent HPV vaccine has been shown to have high efficacy for preventing infection of HPV types -6, -11, -16, and -18, and also clinical diseases such as anogenital warts and external genital lesions (Giuliano et al., 2011). The reported efficacy of the quadrivalent vaccine in preventing infections (types -6, -11, -16, and -18), external genital lesions, and genital warts was found to be approximately 90% in vaccinated males who were naïve to the four HPV genotypes prior to vaccination. A bivalent HPV vaccine (types -16 and -18), Cervarix, is also available and is indicated for the prevention of cervical cancer; however,



the efficacy of Cervarix in preventing HPV 16/18 and associated cancers in males is currently unknown.

In 2009, the U.S. Food and Drug Administration approved an HPV vaccine, Gardasil, for the prevention of genital warts, and in 2010 approved the vaccine for the prevention of anal cancer and anal intraepithelial neoplasia in both males and females. The most recent expansion of the ACIP's HPV vaccine recommendations to include *routine* vaccination of boys aged 11 or 12, catch-up vaccination of young men 13 through 21 years who have not been previously vaccinated, and *permissive* vaccination of males 22 through 26 (Centers for Disease Control and Prevention, 2011b). The ACIP also issued a risk-based recommendation for the *routine* vaccination of MSM through age 26 (a nonavalent vaccine was approved by the FDA in 2014 but at the time of this writing this vaccine had not been recommended for adult males).

It should be noted that these recommendations create a 5-year period between the ages of 22 and 26 in which *routine* vaccination of males is not recommended unless the male belongs to the "risk population" defined as "men who have sex with men" or if he is infected with HIV. It is unclear if this risk population includes men who identify as a sexual minority (e.g., gay or bisexual) but who have not yet been sexually active with men. Implementing these divergent policy recommendations require population-based vaccine promotion programs targeting male sexual minorities.

In order for the vaccine to be an effective strategy at reducing the incidence of HPV and HPV-associated diseases, widespread acceptance and uptake of the vaccine is necessary. The most recent estimates indicate low uptake of HPV vaccine among adult MSM. In 2011, just 5% of MSM surveyed as part of the National HIV Behavioral Surveillance System had received one



dose of the HPV vaccine. A Harris LGBT Interactive Panel survey conducted in 2013 reported a 13% uptake among MSM 18 to 26 years old.

## HPV vaccine behavioral research

Currently there is little consensus in the extant research literature on the acceptability of HPV vaccination in adult males. The results are difficult to compare given the differences in methodology, the populations sampled, as well as whether the data were collected prior to the FDA's approval of the use of Gardasil in males. In addition, the age at which vaccination is sought, either by the individual adult or his parent/guardian, determines who should be the focus of the research. The research reviewed here will focus on studies from the perspective of adult men, compared to the parents or guardians of adolescent males, due to the lack of research on the latter. Furthermore, these two groups of males—those in the target age vs. those in the catch-up group—will require unique interventions with divergent targets and strategies to increase vaccine uptake.

Early studies on the acceptability of vaccination against sexually transmitted infections among college students suggest that this population is overwhelmingly supportive of such vaccinations (Boehner, Howe, Bernstein, & Rosenthal, 2003). These findings suggest that adult college students have positive attitudes toward new vaccine technologies targeting sexually transmitted infections and may adopt such technologies in large numbers; however, it is well established that general attitudes toward a broad set of behaviors (e.g., vaccination against a class of diseases) are poor predictors of actual behavioral performance compared to more specific attitudes toward a well-defined behavior (Fishbein & Ajzen, 2010). Therefore, the major weakness of this early work is the focus on hypothetical vaccines.



The degree to which men are even aware and knowledgeable about HPV and the HPV vaccine will significantly impact the likelihood that they will be receptive to vaccine recommendations. A meta-analysis of research published between 1992 to 2006 found a wide range of awareness and knowledge about HPV in both men and women (Klug et al., 2008). Since the quadrivalent vaccine was not available to females until 2006, the research surveyed reflects the awareness and knowledge of participants prior to widespread media coverage and marketing of the vaccine. The authors found that awareness of HPV ranged from 13% to 92% and was generally higher among women than men.

There is a widespread lack of knowledge that infection with HPV causes diseases such as anogenital warts and cancers (Klug et al., 2008). This lack of knowledge was most evident prior to the implementation of the HPV vaccination campaigns. In a survey of college freshmen conducted in 2000, the majority of men (96%) and women (95%) had heard of genital warts, but only 4% of men and 12% of females knew that HPV causes genital warts (Baer, Allen, & Braun, 2000). Similarly, students in this study were unaware of the etiological connection between dysplasia of the cervix and penis and HPV infection, and expressed a poor understanding of the transmission of HPV relative to that of genital warts. These findings are not limited to this single study but are consistent with findings from a large body of research conducted during this time period (Klug et al., 2008).

Limitations inherent in sex education programs that rely on the dissemination of "simple messages of prevention" have been identified as one possible explanation for the wide-spread lack of basic information about HPV (Braun & Phoun, 2010, p.50). The transmission dynamics of HPV limit the ability to construct simple messages around preexisting "safer sex" discourses, such as those applied to the prevention of HIV/AIDS. As a result, HPV as an important sexually



transmitted infection was largely ignored (Braun & Phoun, 2010). Others have identified incomplete media coverage of HPV that systematically lacked information about sexual transmission and the relationship of HPV infection to clinical diseases (Anhang, Stryker, Wright, & Goldie, 2004). These larger social phenomena provide a context from which to understand public perceptions of HPV and identify potential barriers to vaccine promotion among men.

A series of media reports and a direct-to-consumer advertising campaign shortly followed the initial FDA approval of Gardasil in 2006. In what was seen as an attempt to deemphasize the sexual nature of HPV in order to limit the opposition of vaccinating young girls, the majority of the initial media coverage and related advertisements failed to provide information about HPV including its transmission, prevalence, and clinical manifestations other than cervical cancer (Braun & Phoun, 2010; Mamo, Nelson, & Clark, 2010). As a result, the predominant focus on Gardasil as cancer prevention technology is thought to have created unrealistic perceptions of the probability of HPV infection resulting in cervical cancer—a proposition that has some empirical support (Munsell, Gray, Reed, Vasquez, & Vlasak, 2010)—and may foster a general lack of susceptibility or concern about HPV infection among men.

A number of studies have assessed men's awareness of HPV and the HPV vaccine following the licensure of the vaccine for females and the ensuing mass media attention (Allen, Fantasia, Fontenot, Flaherty, & Santana, 2009; M. A. Gerend & Barley, 2009; M. A. Gerend, Shepherd, & Monday, 2008; Jones & Cook, 2008; Nielsen, Munk, Liaw, & Kjaer, 2009). As previously described, however, much of the reporting on the vaccine, as well as the formal direct-to-consumer advertising campaign implemented by Merck, framed Gardasil almost exclusively as a technology to prevent cervical cancer while omitting information about HPV as a sexually transmitted infection (Braun & Phoun, 2010). As a result—though awareness of HPV



increased among men following the availability of the vaccine for females—men's knowledge of HPV remained low (Klug et al., 2008). In fact, the initial marketing of Gardasil may have actually created the perception that HPV is only of concern for females (Wailoo, Livingston, Epstein, & Aronowitz, 2010).

After more than two years following the availability of Gardasil, male students participating in a series of focus groups at a large urban university were well aware of HPV and the HPV vaccine (Allen et al., 2009). However, there was a general sense expressed in these groups that men were not susceptible to HPV or that HPV infection in men was not serious. In fact, many of the men referred to HPV as a "women's disease" (Allen et al., 2009). As late as 2009—just prior to the FDA's approval of Gardasil for males—as many as 45% of male college students in one survey believed that males could not even acquire HPV, and 74% of those who were aware that men could become infected with HPV were under the impression that HPV infection in men was rare (Katz, Krieger, & Roberto, 2011). The majority of these men reported commercials and advertisements as the primary source of their information regarding HPV, whereas few men had received information about HPV through health education programs or healthcare providers (Katz et al., 2011).

Results from these studies demonstrate that awareness of HPV increased following the initial licensing of Gardasil for females, but men continued to have poor knowledge of HPV in general, and specifically regarding clinical manifestations of HPV infection in men (Liddon et al., 2010; Nadarzynski, Smith, Richardson, Jones, & Llewellyn, 2014). Information about the etiological relationships between HPV infection, genital warts and cancers in men was largely absent from initial public discourse surrounding HPV. To date, behavioral surveys continue to indicate that a large proportion of men remain unaware of the potential clinical manifestations of



HPV. For example, in a series of recent studies men were largely unaware that genital warts are caused by HPV infection (Gilbert et al., 2010; Nandwani, 2010; Tider et al., 2005; Wheldon et al., 2011) and even fewer were aware that HPV is associated with oral, penile or anal cancers (Gerend & Barley, 2009; Gilbert et al., 2010; Wheldon et al., 2011).

Brewer, Ng, McRee, and Reiter reported that a majority of heterosexual (62%) and gay/bisexual (79%) men participating in a national survey of men in the United States were aware of HPV but had low knowledge about HPV-related diseases (Brewer, Ng, McRee, & Reiter, 2010). And while findings from this study suggest that gay and bisexual men—who were hypothesized to be more sensitized to sexual health concerns—were more aware of HPV and had higher knowledge of HPV-related diseases than heterosexual men, their level of knowledge was still quite low (Brewer et al., 2010; Gilbert et al., 2010). For example, only 15% of gay/bisexual men knew HPV infection can cause anal cancer. Furthermore, the majority of men in this study expressed the belief that HPV vaccine would not benefit men.

There have been very few studies that have surveyed men about HPV following the initial approval of Gardasil for men in late 2009. A recent study of Australian college students found moderate knowledge of HPV but highlighted important misconceptions held by many of the men sampled. Most men correctly identified that HPV causes cervical cancer, but few were aware of HPV-related diseases in men (Petrovic, Burney, & Fletcher, 2011). Similarly, young gay and bisexual men in the US exhibited high awareness of HPV as a cause of cervical cancer, but were much less aware of the possible clinical manifestations in men (Wheldon et al., 2011). More than 40% of men participating in this survey were unaware that genital warts are caused by HPV infection, and less than half were knowledgeable about the link between HPV and oral, anal, or penile cancers. In addition, more than a year following the approval of Gardasil for



males, only a quarter of the men in this sample were aware that an HPV vaccine was available to them.

## Barriers to HPV vaccine uptake among men

There are a number of important barriers to widespread uptake of HPV vaccine among adult males in the catch-up age range of 18 to 26. Key among these, as previously outlined, is a widespread lack of knowledge and awareness of HPV and HPV-associated disease in men. Men consistently demonstrate lack of basic information about HPV and HPV vaccination. Furthermore, while knowledge is not consistently predictive of HPV vaccine acceptability (Daley et al., 2010; Ferris et al., 2009; Gerend & Barley, 2009; Gilbert et al., 2010; Reiter et al., 2010) or intentions among men (Petrovic et al., 2011; Wheldon et al., 2011; Young et al., 2011), knowledge and awareness are considered fundamental or background factors that operate indirectly through more salient perceptions and beliefs (Fishbein & Ajzen, 2010). For example, knowledge of the high prevalence and transmissibility of HPV may result in greater perceived susceptibility to HPV infection among men. This is important because perceived susceptibility of HPV or HPV related diseases has been shown to positively correlate with HPV vaccine acceptance and intentions (Crosby, DiClemente, Salazar, Nash, & Younge, 2011; Daley et al., 2010; Gerend & Barley, 2009; Gilbert et al., 2010; Reiter et al., 2010; Wheldon et al., 2011). Therefore, the existing research that suggests men, particularly those in the vaccine-licensed age cohort, do not feel susceptible to HPV is concerning and is a significant psychosocial barrier to widespread vaccine uptake among this population.

In a recent study, the majority of young men (~54%) who were surveyed two months after the approval of Gardasil for males expressed low perceived susceptibility to HPV (Crosby et al., 2011). In turn, men with low perceived susceptibility to HPV were found to be



significantly less likely to express a desire to receive an HPV vaccine. The association between perceived susceptibility to HPV infection and positive intent to receive an HPV vaccine has been found in a number of other studies in diverse populations of men (Daley et al., 2010; Gerend & Barley, 2009; Reiter, McRee, Kadis, & Brewer, 2011).

These results suggest that health education interventions focusing on correcting widespread misperceptions that HPV infection among men is rare may result in greater perceptions of susceptibility and in turn create positive motivation for HPV vaccination. However, it is well established that perceived susceptibility of a given health condition will increase intrinsic motivation only if that health condition is also perceived as being a serious threat to physical and or psychological well being (Fishbein & Ajzen, 2010).

Men's general lack of knowledge regarding the clinical manifestations of HPV infection would suggest that they would express ambiguous beliefs with regard to the seriousness of such an infection. In fact, a wide range of perceptions regarding the seriousness of HPV infection has been reported (Brewer et al., 2010; Bynum, Brandt, Friedman, Annang, & Tanner, 2011; Crosby et al., 2011; Daley et al., 2010; Gerend & Barley, 2009; Katz et al., 2011; Wheldon et al., 2011; Young et al., 2011). Presumably, the perceived severity of HPV infection would be higher among men who are knowledgeable about the potential health consequences of such an infection; unfortunately, these associations have not yet been reported in any of the published literature. There is some indirect support for this hypothesis in the consistent finding that men who express a positive belief in the potential health benefits of HPV vaccination—suggesting that they perceive negative health consequences from HPV infection—have higher vaccine intentions (Gerend & Barley, 2009; Gilbert et al., 2010; Wheldon et al., 2011).



Concerns about the overall safety of HPV vaccination have also been identified as a significant barrier to vaccine uptake in men (Liddon et al., 2010). In a recent study immediately following the approval of Gardasil for use among males, a majority of men (67%) expressed concern about the vaccine's safety (Crosby et al., 2011). There was a general consensus among the men in this survey that they did not have enough information about Gardasil and that they should "wait awhile before deciding about getting vaccinated" because the vaccine was "too new" (Crosby et al., 2011).. Men's concerns about side effects associated with HPV vaccination are commonly reported (Daley et al., 2010; Gerend & Barley, 2009; Young et al., 2011), but it is unclear to what degree these concerns about safety are actually specific to HPV vaccination, in contrast to more general concerns about vaccinations. Unfortunately, these studies typically measure safety concerns specific to HPV vaccination (Crosby et al., 2011; Gerend & Barley, 2009; Reiter et al., 2011; Wheldon et al., 2011) safety concerns about vaccinations in general (Daley et al., 2010; Ferris et al., 2009). Without measuring both indicators of safety concerns within the same study, the subsequent analyses are unable to empirically determine the collinearity of these factors.

Consequently, there is some evidence to suggest that while men commonly express concerns about vaccine safety, these concerns are not very salient in their appraisals of their overall vaccine intentions. This is evidenced by consistent null findings for safety concerns in multivariable statistical models of HPV vaccine intentions (Daley et al., 2010; Gerend & Barley, 2009; Reiter et al., 2011; Wheldon et al., 2011). Studies that do find positive associations between safety concerns and vaccine intentions typically limit their analyses to zero-order correlations, and are therefore unable to control for spurious relationships (Ferris et al., 2009).



In addition, expressed concern about vaccine safety may actually be an indicator of a more general negative attitude toward recommended health behaviors. In a recent study assessing the associations between HPV vaccine intentions and a variety of health behaviors, there was a positive association between wearing a seatbelt and vaccine intentions. In this same study, vaccine intentions were not associated with being "extremely concerned" about vaccine safety (Ferris et al., 2009). Instead, one of the more significant differences between these men was the degree to which they believed that vaccines are important. The majority (67%) of men who wanted the HPV vaccine believed that it is "extremely important" to get vaccinated for all recommended vaccines. Collectively, these findings suggest that concerns over vaccine safety are of less importance in HPV vaccine-related decision-making than are more positive dispositions toward health behaviors (e.g., general vaccinations, seatbelt use).

Other barriers, such as the actual or perceived cost of vaccination, demonstrate much more stable associations with HPV vaccine intentions (Gerend & Barley, 2009; Wheldon et al., 2011; Young et al., 2011). The current cost of the HPV vaccine series (approximately \$400.00) is far greater than the out-of-pocket cost men found to be acceptable for this vaccine (Gilbert et al., 2010). Consequently, men have indicated that the high cost of the vaccine series is a primary reason that they would not be immunized (Crosby et al., 2011). The negative association between cost and HPV vaccine intention was also commonly reported as a barrier to vaccination among women (Brewer & Fazekas, 2007). But recent research that controlled for cost in the study design has demonstrated that cost may actually be of less concern than indicated by statistical models (Vanderpool, Casey, & Crosby, 2010). Additional research needs to clarify this relationship but it is clear that third party payers will play an important role in ensuring vaccine uptake across socioeconomic strata.



An often-overlooked barrier to vaccine promotion among young men is the lack of healthcare utilization by this demographic (Mansfield, Addis, & Mahalik, 2003). Men, independent of age, are much less likely than women to utilize routine medical services such as an annual physical exam (Chabot, Lewis, de Bocanegra, & Darney, 2011; Vaidya, Partha, & Karmakar, 2012). The lack of interaction with the healthcare system limits the opportunities of healthcare providers to counsel eligible men about HPV vaccination. This is a significant barrier considering that provider recommendation has been shown to be one of the strongest predictors of HPV catch-up vaccination among women (Brewer & Fazekas, 2007; Rosenthal et al., 2011) and there is growing evidence that men are generally more accepting of vaccination when recommended by a healthcare provider (Daley et al., 2011; Ferris et al., 2009; Reiter et al., 2011). Furthermore, providers have indicated a willingness to recommend HPV vaccination to their male patients and are therefore a vital resource in vaccine promotion efforts (Zimet & Rosenthal, 2010). Future studies should assess the ability to overcome access barriers by offering vaccine in informal settings where men are more likely to be engaged (Kierans, Robertson, & Mair, 2007).

### Psychosocial issues surrounding HPV vaccination of male sexual minorities

There is a growing amount of behavioral research focused specifically on HPV vaccination among gay, bisexual, and other men who have sex with men referred to as "MSM" from this point forward) that warrants further consideration (Nadarzynski et al., 2014). It has been argued that MSM—as a subpopulation of men—stand to receive the greatest direct benefit from HPV vaccination due to their increased risk of anal cancer (Palefsky, 2010a, 2010b). As early as 2005, researchers began assessing HPV-related knowledge and beliefs among MSM



living in large urban cities (Tider et al., 2005). This research demonstrated a general lack of knowledge about HPV infection similar to that found among men in general.

Collectively the body of behavioral research on HPV and MSM demonstrate low levels of knowledge and concern about HPV (Nadarzynski et al., 2014). Comparisons of MSM with heterosexual men have found that a greater proportion of MSM had previously heard of HPV and had greater awareness of HPV related diseases in men (Brewer et al., 2010). Despite these statistically significant differences, the overall knowledge of HPV in this study was low. The most poorly understood aspect of HPV infection in men is the clinical manifestations of HPV with regard to non-cervical HPV-associated cancers (Reiter et al., 2011; Wheldon et al., 2011).

Despite the limited information about HPV and HPV vaccination reported by the majority of MSM surveyed, the acceptability of HPV vaccination among this population widely varies from study to study (Nadarzynski et al., 2014). Two studies operationalizing vaccine intentionality as a multidimensional construct, reported disparate rates of vaccine intentions among MSM (Reiter et al., 2011; Wheldon et al., 2011). Wheldon et al. reported (2011) that only 36% of the men in their study were considered likely to get vaccinated even after they were provided basic information about HPV-vaccines and HPV-associated diseases. By comparison, Reiter and colleagues found 74% of MSM in their study were willing to receive HPV vaccine (Reiter et al., 2011). There are a few possible explanations for these findings. For instance, there are notable differences in the age of respondents in these studies. Older men with a greater number of lifetime sexual partners may perceive themselves at greater risk of HPV-related diseases and therefore may express more willingness to receive HPV vaccine. Lower vaccine intentions were found in the study that sampled MSM between the ages of 18 and 29 (Wheldon et al., 2011); whereas, the higher estimate of vaccine acceptability resulted from a sample



inclusive of men as old as 59 (Reiter et al., 2011). In fact, Thomas and Goldstone (2011)—in their study of off-label HPV vaccination of MSM attending an anorectal surgical clinic—reported high demand for HPV vaccination among MSM in their mid-to-late 30s.

Another important difference between these two studies is that Gardasil was approved and available for use in men at the time of data collection of the latter investigation. This enabled the researchers to specify a timeframe (i.e., within the next 12 months) in which participants rated their intentions to get vaccinated (Wheldon et al., 2011). In the prior study, intentionality was measured with regard to a hypothetical vaccine in which participants rated the likelihood that they would get vaccinated at some point in the future (Reiter et al., 2011). Research across a variety of health domains has consistently found better predictive validity from measures of intention that specify a time-based context as it relates to the performance of a target behavior (Fishbein & Ajzen, 2010). Therefore, the more precise measure of vaccine intentionality is theoretically more predictive of actual vaccination. In this case, the more precise measure revealed lower vaccine intentions (Wheldon et al., 2011).

Secondary prevention efforts aimed at decreasing morbidity and mortality of HPV-related diseases may be of particular value given the limited efficacy of prophylactic vaccination of men who have likely been previously exposed to multiple HPV types. Gay men's health advocates who identified anal cancer as a gay health threat in the late 1990s proactively advocated for secondary prevention options, such as the anal Pap smear (Epstein, 2010). The social and political organizations that emerged from the HIV/AIDS epidemic were brought to bear against "heteronormative medical assumptions" that rendered anal cancer as an invisible disease for which no preventive interventions were available (Epstein, 2010, p. 69). To date, there is no official indication with regard to the use of anal Pap smear for the screening of anal cancer or



precancerous lesions; although, there is a growing body of research which suggests that regular cytological screening is a useful and cost effective measure for the secondary prevention of anal cancer in both HIV-negative and –positive MSM (Park & Palefsky, 2010). Other studies have examined the addition of HPV reflex testing to screening protocols to increase the detection of anal cancer development (Goldstone, Enyinna, & Davis, 2009); however, the exiting literature is limited by observational study designs (Chiao, Giordano, Palefsky, Tyring, & Serag, 2006) and lack a clear understanding of the most important outcome to measure. Randomized clinical trials are still needed in order to determine the efficacy of anal cytology screening and to inform screening guidelines for the secondary prevention of anal cancer.

Based on the available research it is clear that prophylactic HPV vaccination represents the most viable and effective prevention strategy currently available to reduce the future incidence of HPV and its associated diseases among younger generations of MSM (i.e., those under age 27 years). Due to elevated risk for anal cancer, a concerted effort to vaccinate MSM up through age 26 years is warranted; however, secondary prevention through early detection of anal disease will remain important for a large number of MSM who will not benefit from vaccination. Health behavior research is needed in order to assess the acceptability of these prevention efforts among MSM and to create vaccine promotion programs tailored for this population.

#### **Preliminary Data**

A preliminary study was completed to identify psychosocial correlates of HPV vaccine intentions among young MSM (Wheldon, Buhi, & Daley, 2013; Wheldon et al., 2011), and to assess the utility of the Health Belief Model (Rosenstock, 1974) and Theory of Planned Behavior (Ajzen, 1991)in predicting intent to receive HPV vaccine. The sample included a total of 179



men between the ages of 18 and 29 years (Mean age = 22) who identified as gay or bisexual or who had a history of sexual activity with men. These men were recruited in the fall of 2010 through gay and lesbian student organizations at 23 colleges and universities across the Southeastern U.S. and through a social networking Internet site.

Similar to previous findings, the majority of young MSM (93%) in this study had heard of HPV prior to participation, but were generally unaware of the causal association of HPV with anal, penile, and oral cancers. Only 26% were aware of the availability of an HPV vaccine for males. Just 12% of young MSM indicated that they intended to get vaccinated within the next year yet 66% indicated that they would like to learn more about the vaccine. Constructs from the Health Belief Model (HBM) and Theory of Planned Behavior (TPB) explained a large proportion of the variance in a composite index of vaccine intentions (48% and 46%, respectively). However, the percent of explained variance changed very little (~5%) in a combined model (HBM + TPB), indicating redundancy in the explanatory power of these theories.

The problem of overlap in constructs from the HBM and TPB has been extensively discussed, and an alternative model has been developed that integrates concepts from the HBM and TPB, as well as from social cognitive theory (Fishbein et al., 2001). The resulting model, called the Integrated Model of Behavioral Prediction (IM), brings together theoretical constructs proven to be proximate determinants of health behaviors. The IM was used as the theoretical foundation for this study. These theoretical approaches will be discussed in more detail below.

### **Theoretical Framework**

It has been well established that health promotion and behavior change interventions are more effective if they are based in behavioral theory (Green, 2000). As a set of interrelated



concepts, definitions, and propositions that present a systematic view of phenomena (Glanz & Rimer, 2005), theory enables researchers and practitioners to condense and organize knowledge, as well as to explain and predict specific behaviors (e.g., HPV vaccination). Thus researchers are able to build generalizable knowledge within a field or discipline by building theory, testing theories, and adjusting theories with findings from empirical investigations. These are the foundational activities of all scientific fields. Therefore, a well-defined theoretical approach is necessary to study HPV-related prevention behaviors if the purpose of that study is to develop and evaluate scientific knowledge needed for prevention activities.

HPV preventive behaviors, such as vaccination, can (and should) be studied from a variety of perspectives including that of the priority population (young gay and bisexual men in this study), health care providers who administer the vaccine, community-based organizations that serve the priority population, as well as through the analysis of social institutions (e.g., media). A first step is to assess what the priority population knows about the health risks and the preventive behavior, as well their readiness or intention to engage in the behavior. Social and behavioral science theories are needed in order identify and understand the psychological and social factors that determine an individual's acceptance of a medical intervention and their readiness to complete that intervention. What follows is a discussion of key health behavior theories focusing on individual decision-making and behavior.

## Theories of health behavior

Intrapersonal level theories posit that the most proximate determinants of a given health behavior are the affect, behavior, and cognitions of the individual actor. A number of intrapersonal health behavior theories have been articulated, each conceptualizing the relationships among a number of key concepts in distinct ways (Noar & Zimmerman, 2005). The



Health Belief Model (HBM), the Theory of Planned Behavior (TPB), and Social Cognitive Theory (SCT) are commonly used theoretical approaches to explain discrete health behaviors and to inform behavioral interventions.

## Health Belief Model (HBM)

The intellectual roots of the HBM stem largely from the field of psychology, and most notably from the German-American psychologist Kurt Lewin and his developmental field theory (Glanz & Rimer, 2005). Lewin, credited as the founder of modern social psychology, emphasized the study of individual-environment interactions as key to understanding human behavior. In contrast to behaviorism, the dominant paradigm at the time, Lewin's Field Theory understood behavior as purposive and a product of an individual's personality, perceptions, and social interactions. The social environment (or "life space") was of particular importance. Lewin conceptualized this environment as a field containing behavioral objects in which the individual actor appraised as either desirable or undesirable (i.e., positive and negative valance) (Rosenstock, 1974). One could then predict an individual's behavior by assessing this appraisal process. Individuals would act in ways to avoid objects perceived as negative and to move toward or engage objects perceived as positive.

In the early 1950s, social psychologists Rosenstock, Hochbaum, and Kegels developed the HBM while working in the U.S. Public Health Service (Rosenstock, 1974). The original intent of the HBM was to explain why individuals were not taking advantage of a free tuberculosis health-screening program. The HBM includes elements from Lewin's field theory and emphasizes the subjective perceptions of the individual in understanding health behavior (Maiman & Becker, 1974). Diseases were understood as objects in which an individual perceived as negative, and would therefore behave in ways that would move the individual away



from that object (i.e., prevent or treat the disease). But in order for this appraisal to occur, the individual must first perceive himself or herself at risk for the disease.

The HBM conceptualizes these cognitive processes into four key constructs: (1) perceived susceptibility, (2) perceived severity, (3) perceived benefits, and (4) perceived barriers. It was proposed that perceived susceptibility (individual's perception of the risk of illness/disease) and perceived severity (beliefs about the physical and social consequences of the illness/disease) form the threat element that motivates action; whereas, perceived benefits (beliefs about the benefits of criterion specific health behavior) and barriers (beliefs about the real or imagined costs of the criterion specific behavior) provide information about the likely path to action. Two additional constructs, cues to action and self-efficacy, are also used in the HBM. Cues to action, although an underdeveloped construct in the model, describe those somatic and/or environmental events that elicit action. Self-efficacy describes an individual's confidence in his/her ability to take action in a variety of situations or circumstances.

The HBM also emphasizes the role of modifying factors that may attenuate the relationship among the constructs. These modifying factors are often conceptualized as sociodemographic influences, but could also include knowledge as well as personality characteristics that may influence individual perceptions. The relationships among the constructs themselves are not well conceptualized in the HBM. In certain circumstances, modifying factors may actually be antecedents to perceived threat, which is often the case with knowledge. Similarly, perceived barriers or benefits may act as modifying variables, or they may mediate the relationship between perceived threat and the desired health behavior. These structural ambiguities have significant ramifications for how this model is applied in research and practice.



# Theory of Planned Behavior (TPB)

The Theory of Planned Behavior (TPB) is the result of an adaptation of the Theory of Reasoned Action (TRA) (Fishbein, Triandis, Kanfer, et al., 2001). Social psychologist Martin Fishbein developed the TRA to overcome the limitations of behavioral research that conceptualized attitudes as the most proximate cause of behavior. The problem was that, across many studies and behavioral domains, attitudes were inconsistently correlated with behavior. Given the equivocal nature of these findings, Fishbein introduced the TRA, which conceptualized behavioral intention as the factor mediating the relationship between attitudes and behavior. The TRA includes three main constructs: (1) Behavioral intentions, (2) attitudes, and (3) subjective norms.

Behavioral intentions are said to capture the motivational qualities that lead to adoption of a behavior, and are theorized to be a function of attitudes and subjective norms. Attitudes are further subdivided into behavioral beliefs and evaluations of behavioral outcomes. Essentially, attitudes are "latent dispositions or tendencies to respond with some degree of favorableness or unfavorableness to a psychological object" (p. 76) and are composed of beliefs regarding the attributes and outcomes of the object (Fishbein & Ajzen, 2010). The evaluation, or appraisal, of these beliefs leads to the formation of attitudes. Similarly, subjective norms are conceptualized as the normative beliefs and the motivation to comply with these beliefs. Normative beliefs refer to the approval or disapproval of others within an individual's social environment. Subjective norms are formed when these beliefs are weighted by an individual's evaluation of how motivated he or she is to comply with those in their network.

The TPB includes these important constructs, with the addition of perceived behavioral control (PBC). Ajzen argued that an individual, despite having positive attitudes and normative



support for a behavior, might be inhibited by external factors (Ajzen, 1991). Therefore, PBC was added to account for individual volition to perform a behavior. Like attitudes and subjective norms, PBC is composed of a belief and an evaluative component. Control beliefs are an individual's beliefs regarding his or her ability to perform a given behavior based on what external factors will inhibit or facilitate their ability to act. In PBC, these beliefs are weighted by the perceived strength of these factors to inhibit or facilitate behavioral performance. It is theorized that the importance of PBC is diminished when there is a high degree of volition associated with a specific behavior (Fishbein & Ajzen, 2010).

The relationships among constructs in the TPB, unlike those in the HBM, are clearly defined. Attitudes, subjective norms, and perceived control are all theorized to have a direct effect on intentions to perform a given behavior, which in turn is said to be a proximate cause of behavioral performance. However, the strength of the relationship between any of the three main constructs and behavioral intention will vary according the specific behavior under investigation. In general, if an individual believes that a given behavior will lead to a desired outcome, that important and respected people in his/her life are supportive of the behavior, and that there are strong external facilitators but few barriers, then it is theorized that behavioral intentions will be strong for the behavior and will lead to behavioral performance.

### Social Cognitive Theory

Alfred Bandura developed Social Learning Theory, now Social Cognitive Theory (SCT), in a response to the limitations of the then dominant behaviorism paradigm. This new approach to learning emphasized the role of the social environment in determining behavior, and in particular, the importance of the interaction between the individual actor and the social environment. The most recent iterations of this theory were heavily influenced by the emergence



of the cognitive paradigm in psychology, which lead to a greater emphasis on the cognitive processes in learning and behavior (Bandura, 2001). The result is the current form of the SCT, which conceptualizes behavior as the product of intrapersonal and interpersonal factors. In other words, individual level factors interact with interpersonal factors to influence behavior; however, the SCT also posits that an individual can affect change in the environment and regulate their own behavior. This relationship is represented by the concept of reciprocal determinism. Other organizing concepts include psychological determinants of behavior, observational learning, environmental determinants of behavior, and moral disengagement.

Psychological determinants of behavior are inclusive of those concepts dealing with individual beliefs and perceptions. There are three key concepts that are grouped into psychological determinants: outcome expectations, self-efficacy, and collective efficacy. Outcome expectations are an individual's beliefs about the outcome of a particular behavior, and the value he or she places on this outcome. This conceptual definition is nearly identical to the concept of behavioral beliefs from the TPB. Self-efficacy describes an individual's confidence in his/her ability to take action in a variety of situations or circumstances. Similarly, collective efficacy in the SCT refers to an individual's confidence in the ability of a group, community, or organization to affect change in some desirable outcome.

Observational learning is learning through observation, or by observing the behavior of others. This can occur by observing someone in real life or through some other media such as video, audio, or text. The SCT proposes four processes involved in observational learning: attention, retention, production, and motivation. Observational learning is facilitated if the learner is attentive to the modeling of the behavior, is able to retain the information observed



(either directly or through interaction with some media), is able to perform the behavior, and is motivated to perform the behavior.

There are two concepts inclusive of environmental determinants of behavior. The first concept, incentive motivation, is adapted from operant conditioning and includes the use of rewards and punishments to inhibit or reinforce behavior. Similarly, facilitation includes the resources, skills, and environmental aspects that are constructed to encourage the adoption of a specific behavior. While operant conditioning and facilitation represent those environmental conditions that either increase or decrease the probability of performing a specific behavior, self regulation is inclusive of cognitive strategies that an individual utilizes to monitor their own behavior, set goals, seek feedback, reward himself or herself, talk through a problem or barrier, and enlist support from others.

And finally, moral disengagement is a concept that represents the means by which individuals divorce themselves from moral standards and expectations in order to justify some ethically questionable behavior. Moral disengagement is said to operate through four cognitive processes: euphemistic labeling, dehumanization and attribution of blame, diffusion and displacement of responsibility, and perceived moral justification. Euphemistic labeling is said to enable moral disengagement by using descriptions or words of morally questionable actions that downplay the emotional or social impact. Similarly, through the dehumanization and construction of an in-group/out-group mentality, individuals are able to justify actions and apply blame that would not be acceptable in other circumstances. Conversely, diffusion and displacement of responsibility attempts to divert or minimize the consequences resulting from one's actions. Perceived moral justification is the attempt to reverse the perception of an action by constructing it as a needed benefit rather than an objectionable act.



## An integrative framework

Despite the similarities among the constructs proposed by these health behavior theories, they are typically understood and applied in research and practice as independent theoretical approaches. There have been surprisingly few attempts to empirically compare the predictive validity of these models or to clarify inconsistent conceptual definitions and measurements, as well as poorly explicated causal propositions (Fishbein et al., 2001; Noar & Zimmerman, 2005; Painter, Borba, Hynes, Mays, & Glanz, 2008; Weinstein, 1993, 2007). The absence of these vital research activities impede the scientific growth of health behavior research, restricts the cumulative body of knowledge created from empirical investigation, and ultimately limits the creation of effective health behavior interventions (Noar & Zimmerman, 2005).

In an attempt to move the science of behavior research forward, key authors of the most widely used health behavior theories convened at a National Institute of Mental Health workshop to discuss issues regarding redundancy in conceptual definitions, appropriate measurement of key constructs, and propositional hypothesis among constructs (Fishbein et al., 2001). The Integrative Model of Behavioral Prediction (IM) is the result of these discussions (Fishbein, 2009).

The IM posits—that given appropriate awareness, knowledge, and skills, and in the absence of significant environmental constraints—behavioral intention, or readiness to act, is the mechanism through which attitudes, perceived norms, and perceptions of personal agency affect behavior (Fishbein, 2009). The intervening role of behavioral intention was previously highlighted in the TRA and TPB, but was absent from the HBM and SCT. As such, the IM conceptualizes behavioral intention as the necessary determinant of any given behavior; and, when measured on a continuum of the strength of a persons intention, it is thought to encompass



the concept of readiness that was previously introduced in stages of change models (DiClemente & Prochaska, 1986). Individual health beliefs and perceptions are therefore understood to influence behavior indirectly through behavioral intention.

The strength of behavioral intentions to either perform or abstain from a given health behavior are proposed to be a function of (1) attitudes toward performing the behavior, (2) perceived normative influence with regard to the behavior, and (3) self-efficacy or perceived control over one's ability to successfully perform the behavior (Fishbein, 2009). These propositions are nearly identical to those in the TPB, except that in the IM Fishbein argues that the concept of perceived behavioral control is identical to self-efficacy as defined by Afred Bandura in the SCT (Fishbein & Ajzen, 2010). As such, these constructs are simply defined as personal agency in the IM. Thus, attitudes, perceived norms, and personal agency are theorized to account for a substantial amount of the variation in behavioral intentions, though the strengths of the relationships are thought to vary across different populations and behavioral domains.

Identifying the underlying beliefs and cognitive processes of these three psychosocial factors are of fundamental importance to designing effective behavioral interventions. As explicated in the IM, attitudes, perceived norms, and personal agency result from a process of cognitive evaluation of salient beliefs regarding the possible outcomes of a behavior, the normative proscriptions, and perceived barriers and/or facilitators. In other words, attitudes are formed from an individual's evaluation of beliefs regarding the outcome expectancies of a behavior including the positive and negative results. Therefore, behavioral beliefs are thought to encompass the physical, psychological, or social outcome expectancies described in the SCT, as well as the perceived benefits and barriers from the HBM. Similarly, normative influences and



personal agency are thought to result from cognitive appraisals of injunctive and describe normative beliefs as well as efficacy-related beliefs, respectively.

There are a number of additional constructs labeled as "background influences" in the IM that were identified during the NIMH theorist workshop (Fishbein et al., 2001). These include socio-demographic factors, knowledge, and other individual difference variables (e.g., perceived threat/risk, personality, mood, and emotions). Background influences, such as perceived threat, are theorized to indirectly affect intentions and subsequent behavior by contributing to underlying mental model regarding a given behavior. This view stands in contrast to the propositions explicated in the HBM that conceptualize perceived threat as a direct predictor of health behavior. The role of perceived threat, or risk perception more generally, as a direct determinant of a given health behavior has also been called into question by other health behavior theorists (Leventhal, Kelly, & Leventhal, 1999) and is equivocal in the empirical literature (Brewer et al., 2007; Floyd & Prentice-Dunn, 2000; Harrison, Mullen, & Green, 1992). However, the importance and causal relationship of perceived threat to health behavior is an empirical question and will ultimately be determined through ongoing research.

The IM is best suited for a study of HPV vaccination in adult men for a number of important reasons. First among these is its conceptualization of behavioral intentions as a mediating variable that can stand as a proxy measure of vaccine initiation. The IM also incorporates key constructs from multiple health behavior theories, which increases its explanatory power and reduces issues of multicollinearity involved in multivariate statistical analyses. Finally, the IM clearly defines causal propositions including intervening relationships that are important for future intervention planning.



#### A theoretical approach to HPV vaccine promotion among male sexual minorities

According to the IM, the most proximate determinant of HPV vaccination among young gay and bisexual men (YMSM) is a strong behavioral intention to receive the vaccine. Thus, behavioral intention is an important outcome measure for HPV vaccination behavioral research given that few men—and even fewer YMSM—will have initiated the vaccine series. Therefore, intention provides the closest proxy measure of vaccination and allows for better estimates of future vaccine uptake in this population.

Understanding the factors that contribute to an individual's intention or readiness to receive the HPV vaccine is also necessary in order to effectively communicate and educate the public in a way that will increase vaccine uptake. The IM has an advantage over other individual-level health behavior theories in that it identifies the most proximal determinates of behavior from decades of empirical research covering a variety of health domains and incorporates them into a comprehensive model. This not only reduces potential issues of multicollinearity among redundant constructs, but it also specifies structural relationships among these constructs, that when empirically validated, can help to identify modifiable factors for targeted interventions (e.g., specific beliefs about HPV vaccination).

According to the propositions present in the IM, in order for gay and bisexual men to form strong behavioral intentions toward receiving the HPV vaccine, they first need to (see Figure 1): (1) have positive attitudes towards HPV vaccination; (2) perceive that valued and respected friends, family, and/or significant others will support and encourage them to receive the HPV vaccine; and (3) feel confident in their ability to perform all of the tasks required to receive the vaccine (e.g., identify a health care provider who can administer the vaccine, discuss the vaccine with a health care provider etc.). Collectively, these three constructs (Attitudes,



Perceived Norms, and Personal Agency/Self-efficacy) represent the most proximate determinants of behavioral intention to initiate HPV vaccination; however, the strength of the relationships between any one of these determents and behavioral intention will vary across populations and within populations depending on relevant background characteristics (See Figure 1). For example, MSM with stronger links to established gay communities might rely more on normative influences than MSM who are isolated from such communities. The objective of empirical research is to determine if the target behavior is primarily under attitudinal, normative, and/or control influences, which is accomplished by quantifying the explanatory power of each construct with respect to behavioral intentions.

In addition, the propositional structure of the IM places special emphasis on the underlying beliefs, or antecedents, of the most proximate determinants of behavioral intention. As indicated by the IM, attitudes are formed through the appraisal of beliefs—or in other words, an individual's evaluation of their beliefs—regarding the perceived outcomes of a given behavior. The valance and weight of these beliefs are the indicators of the attitude toward the behavior. For example, if a young man believes that the HPV vaccine will help prevent him from developing anal cancer later in life, and if he values that outcome, then it is theorized that his attitudes toward the HPV vaccine will reflect these beliefs. However, this is but one example of a series of possible outcome beliefs that collectively contribute to the formation of attitudes toward the HPV vaccine. The same is true for the valances and weights that underlie the formation of evaluative beliefs with regard to perceived norms and personal agency.

Elicitation research is the primary empirical tool used to describe the most salient outcome, normative, and agency-related beliefs relevant to the priority population (Middlestadt, Bhattacharyya, Rosenbaum, Fishbein, & Shepherd, 1996). Interventions aimed at influencing



attitudes, perceived norms, and perceived agency/self-efficacy would therefore attempt to influence these salient beliefs. It is this combination of clearly explicated explanatory constructs and propositions (i.e., the reasoned action approach emphasizing proximal determinants of behavior) with population-specific antecedent beliefs that strengthen the IM as a useful theoretical framework for identifying personal determinants of behavior and describing change objectives for intervention programs.

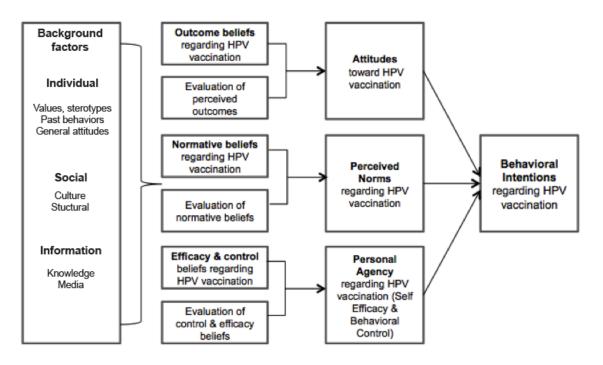


Figure 1: An integrated theoretical model of HPV vaccine promotion



## **CHAPTER 3: METHODS**

The long-term goal of this research is to decrease the incidence of anal cancer and other HPV-related diseases among MSM by preventing infection of HPV types -6, -11, -16, and -18 through prophylactic vaccination. The purpose of this research was to understand the factors that were important to young MSM when making decisions about HPV vaccination. The Integrative Model of Behavioral Prediction (IM) was used as the theoretical framework for this study. The following specific aims were addressed:

- (a) Describe salient behavioral, normative, efficacy, and control beliefs related to HPV vaccination among young MSM; and (b) Determine factors that underlie these beliefs
- Identify information needs and trusted sources of information regarding HPV vaccination among young MSM
- Develop and test a structural equation model guided by the Integrative Model of Behavioral Prediction that identifies the psychosocial determinants of young MSM's HPV vaccine intentions

### **Mixed-Methods Study Design**

A multi-phased, mixed-methods, cross-sectional approach was used to comprehensively address these aims and to build upon the theoretical and empirical research previously described. By combining methods inclusive of both qualitative and quantitative approaches, this research was able to provide an in-depth understanding of the beliefs, perceptions, and sociocultural factors underlying HPV vaccine decision-making. This approach allowed for the elicitation of

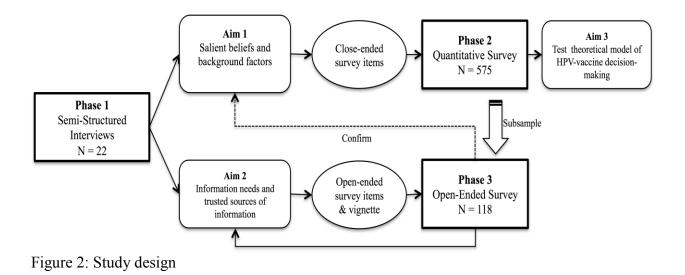


salient beliefs surrounding HPV vaccination specifically, but also allowed the flexibility to explore broader psychosocial issues that may indirectly impact HPV vaccine related attitudes and beliefs. The qualitative methods in this study provided rich descriptions of the theoretical constructs and conceptually extended the integrative model to better understand decision-making processes regarding HPV vaccination among young MSM. The quantitative methods allowed for the systematic testing of the proposed theoretical model and for the identification of those psychosocial factors most predictive of HPV vaccine intentions.

The overall study design is displayed in Figure 2 and includes specific *actions* (i.e., conducting Phases 1, 2, and 3), *inputs/outputs* (i.e., the findings), and the *products* (i.e., how the findings were used). The mixed-method design employed in this study followed a three-phase sequential approach starting with semi-structured qualitative interviews (Phase 1). Findings from these interviews included salient beliefs and background factors that were used to construct the measures used in the *quantitative* survey (Phase 2) and the open-ended survey items used in the *qualitative* survey (Phase 1). Findings from Phase 1 were also used to create a vignette for Phase 3.

The quantitative survey (Phase 2) provided a direct test of the theoretical model, while the qualitative survey (Phase 3) provided confirmation of the salient beliefs and background factors identified in Phase 1 and elicited information regarding sources of HPV-related information and vaccination. Phase 3 consisted of a subsample of participants from Phase 2. A major strength of this research design is that aims 1 and 3—both providing valuable information for health education interventions—are addressed by two distinct methods with two separate samples allowing for the triangulation of data and methods.





### **Priority Population**

The goal of this research is to inform health education interventions that will increase HPV vaccine uptake among young adult MSM; however, since the HPV vaccine has only recently been approved for males, and the number of young MSM who have actually received the HPV is very small (Reiter, McRee, Katz, & Paskett, 2015), it is not possible at this time to study vaccine uptake directly. The main outcome of interest for this research is intent to receive the HPV vaccine (i.e., vaccine intentions) within the next year, which is theoretically the most proximal determinant of future vaccination (Montano & Kasprzyk, 2008). The target population for this research was (1) men from 18 to 26 years of age, (2) who reside in the United States, (3) are able to read and comprehend English, (4) who have not initiated the HPV vaccine series, and (5) who have ever engaged in sexual contact with another male or who identify as gay or bisexual. This conceptual population includes both gay identified and non-gay identified MSM in order to be inclusive of all those who engage, or may engage at some point, in behaviors that



substantially increase the risk of HPV infection. It also focuses on vaccine-eligible adult males who do not need parental permission to receive the vaccine.

## **Phase 1 Methods: Semi-Structured Interviews**

A qualitative descriptive approach was used was used in Phase 1. This approach is less interpretive than other qualitative methods (e.g., grounded theory) but offers a comprehensive summary of an event or phenomena in everyday terms (Sandelowski, 2000). Individual, semi-structured interviews were used to elicit perceptions, attitudes, and beliefs regarding HPV vaccination, including information regarding trusted sources of health information and preferred locations for vaccination. Findings from Phase 1 were used to (1) construct items for the quantitative and qualitative surveys, (2) to fully describe an integrated theoretical model of HPV vaccine decision-making specific to male sexual minorities, and to (3) inform the creation of a vignette used in the open-ended, self-administered survey. The use of multiple methods also allowed for the triangulation of data increasing the authenticity and validity of the findings (Patton, 1999).

## Sampling and recruitment

Purposive sampling was used to maximize variation with regard to HPV vaccine attitudes and related experiences. Maximum variation sampling is an emergent approach that allows initial interviews to guide subsequent sampling strategies rather than predetermining sampling quotas by characteristics of the individual (e.g., age or race) (Sandelowski, 1995). This approach was accomplished by sampling from diverse venues, organizations, and virtual sites. The principal investigator distributed palm cards at community-based organizations that provide services (e.g., HIV testing, treatment, social support) for young adult MSM. Student gay pride organizations at local colleges and universities were sent information about the study and asked to disseminate



this information among their members. In addition to these passive recruitment methods, a direct recruitment strategy was employed using publically available social networking mobile phone applications. The principal investigator (PI) created profiles on social network applications. These profiles contained the PI's name and affiliation with the University of South Florida. All local users of the applications could view the profiles. The PI then randomly selected users by viewing their public profiles (filtered by age) and sending users a personalized study invitation using the native messaging system.

A total of 22 interviews were completed before data saturation occurred. For the purpose of this study, data saturation was defined as "the point in data collection and analysis when new information produces little or no change to the codebook" (Guest, 2006). During the initial phases of data analysis, men infected with HIV expressed different perspectives and experiences with regard to their health, HPV status specifically, so the last five participants were targeted based on self-reported HIV status (an option in the social networking applications).

## Procedure

Interviews were conducted either in person (n = 14) or on the telephone (n = 8), depending on the preference or availability of the participant, and lasted between 20 and 50 minutes. The interviews were conducted in private locations that were convenient to the participants. Most took place at the University of South Florida. A waiver of documentation of informed consent was granted by the USF IRB in order to maintain the confidentiality of participants. Participants were asked to complete a brief pre-screening questionnaire that collected demographic information. Each interview began with a verbal acknowledgment that the participant understood the consent document and agreed to be recorded. Interviews were recorded and transcribed (omitting identifiers).



## Incentive

All participants were remunerated in the form of a \$25 gift card.

## Instrument

A semi-structured interview guide was used for the Phase 1 qualitative interviews. The interview questions (see Appendix 1) were derived from the IM and were used to elicit the beliefs and perceptions that underlie attitudes toward HPV vaccination, perceived norms regarding HPV vaccination, and personal agency with regard to HPV vaccination. Standard questions for formative research using this theoretical approach were included as appropriate (Fishbein & Ajzen, 2010). Additional questions and probes were added as new insights were discovered through successive interviews. Content and face validity were established by eliciting feedback from experts experienced in health behavior theory and qualitative research. The interview questions were also piloted with members from the priority population. Questions were assessed according to the degree to which they were appropriate, given the stated aims of the project.

## Data analysis

Descriptive qualitative content analysis was used to summarize the informational content of the data (Elo & Kyngäs, 2008). Rather than approaching data analysis without *a priori* theoretical framework, as is common in other types of qualitative analyses (e.g., grounded theory), a combination of deductive (or "directed") and inductive content analytic approaches were used (Hsieh & Shannon, 2005). This method provided rich descriptions of the proposed theoretical constructs and conceptually extended the IM specifically with regard to the criterion specific behavior (i.e., HPV vaccination) and the priority population (i.e., young adult MSM).



The directed approach to content analysis is used when an existing theory has demonstrated explanatory power with regard to a given phenomena but needs further description and specification (Hsieh & Shannon, 2005). This type of formative phase, or elicitation phase, is an essential step in the application of the IM for a specific health behavior (Fishbein & Ajzen, 2010). In the current study, directed content analysis was used to frame and understand the experiences and perceptions of the participants—as expressed in the interview text—with regard to HPV vaccination. This process was combined with an inductive approach in order to further define the theoretical constructs, or main categories, of the IM using the words and expressions of the participants.

All interviews were digitally recorded and transcribed verbatim. Transcripts were imported into MAXQDA qualitative data analysis software, which was used for coding and data reduction. No identifying information was retained in the transcripts. A five-step process largely based on the strategies of deductive and inductive qualitative content analysis outlined by Elo and Kyngäs (2008)—was used as the data analytic framework. This included (1) coding the transcripts using the main categories from the IM; (2) using in-vivo coding to identify text within the main categories that exemplify that category; (3) classifying those in-vivo codes into more generic categories as they relate specifically to HPV vaccination; (4) further refining those generic categories into more specific and conceptually meaningful sub-categories; (5) and assessing the trustworthiness of the findings. An example of this data reduction method is presented in Figure 3.

## Trustworthiness

In qualitative research, issues of validity and reliability are often approached in terms of trustworthiness. The trustworthiness of findings from qualitative research centers on issues of



credibility, transferability, dependability, and confirmability (Lincoln & Guba, 1985). These issues were addressed in the current investigation by (1) employing a multi-method qualitative research design that allows for the triangulation of methods and data; (2) maximizing diversity among participants through purposive sampling; and (3) utilizing secondary coders to assess the consistency of the analytic decisions made by the PI.

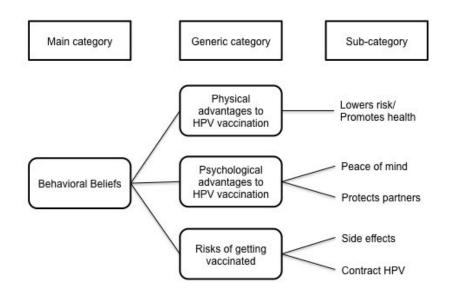


Figure 3: Example of the coding process

Inter-coder agreement was assessed in three distinct ways. First, after coding three randomly selected transcripts, the degree to which the coders used each code in the codebook in a given transcript was assessed, and secondly, the percent agreement on the frequency with which each code was used to describe the text. A criterion of 80% agreement, as recommended by Miles and Huberman (1994), was determined to represent sufficient reliability in the application of the main categories. Agreement ranged from 82 to 98 percent across three interview transcripts. Thirdly, the application of sub-codes to their representative quotes. Two



secondary coders analyzed representative quotes using a revised codebook containing the emergent sub-codes (see step 4 of the data analytic framework). These quotes were extracted from the text and were determined by the PI to represent the fundamental defining characteristic of the sub-category. Inconsistencies in the application of the sub-codes were discussed and the codebook was revised. In the revised codebook, codes with overlapping conceptual definitions were combined and further refined. A third coder coded the data with the revised codebook and the percent agreement was calculated as the proportion of correctly coded text segments. Agreement was determined to be sufficient at 84%.

### Phase 2 Methods: Quantitative Internet-based Survey

### Overview

A cross-sectional, close-ended, self-administered, Internet-based survey provided the data used to quantify the behavioral intentions of young MSM to receive the HPV vaccine. Direct measures of attitudes toward the HPV vaccine, perceived normative influences for vaccination, and perceived behavioral control/efficacy in obtaining the vaccine were described, and the relationships with vaccine intentions were explored. Furthermore, outcome, normative, efficacy, and control beliefs, as well as individual evaluations of these beliefs were investigated in order to better understand the modifiable factors underlying the formation of attitudes, perceived norms, perceived control, and self-efficacy with regard to HPV vaccination.

### Sampling and recruitment

Participants were recruited for the quantitative survey using three distinct approaches: (1) a snowball sampling of college students affiliated with campus-based LGBT student organizations across the Southeast United States; (2) Internet-based recruitment focused on



social media; (3) Paid advertisements targeting young MSM using social and sexual networking sites/apps.

A growing number of studies of young MSM demonstrate that Internet-based recruiting strategies—particularly those focused on social and sexual networking sites—can successfully recruit large diverse samples of sexual minority youth at low cost and in short periods of time (Bolding, Davis, Sherr, Hart, & Elford, 2004; Carter, Ding, & Rose, 2011; Parsons, Vial, Starks, & Golub, 2012; Ross, Månsson, Daneback, Cooper, & Tikkanen, 2005). Internet-based recruitment strategies allow for inclusion of research participants from geographically disparate areas and are better able to reach socially isolated individuals or "hidden" populations that may not be available otherwise. This offers a great advantage when conducting research with young MSM. This is particularly true for those who reside outside of large urban centers without wellestablished gay communities where venue-based recruitment strategies are difficult to implement. Another advantage to conducting Internet-based recruitment is the flexibility of time and resources. Banner advertisements can easily be targeted to specific populations (e.g., age, sexual orientation) using user-generated profile information, and can accommodate small budgets. Banner advertisements were purchased from two networking websites: a social networking site and a sexual networking mobile application. These advertisements were targeted to men who meet inclusion criteria for this study based on the information they entered in their site-specific user profiles (e.g., age, location, and sexual orientation).

## Procedure

Participants recruited from Internet-based social networking sites were directed to the study website through the banner advertisements. Likewise, after successfully making contact with a representative of a LGBT student organization (in most cases this was the organization's



student-elected president), the PI emailed the organization's representative with information describing the study and provided a URL to the study website. They were asked to forward this information to their members who meet inclusion criteria. Participants were directed to the study website containing informed consent information.

All participants were asked to give their consent via the electronic form. If they agreed to participate and gave their electronic consent, they were directed to the survey hosted on a secure server at the University of South Florida. The survey was created using Qualtrics Survey Software and took participants an average of 13 minutes to complete. All study procedures and instruments were reviewed and approved by the USF IRB.

## Incentive

Participants could elect to enter into a drawing for one of ten \$25 gift cards from Amazon. To enter they provided an email address where the gift card could be sent. This email address could not be linked to their survey data.

#### Instrument

A self-administered quantitative survey was developed from the formative elicitation research guided by the IM (Phase 1). Self-administered surveys can be given over large geographic areas and offer a sense of privacy and anonymity for research participants. Internetbased surveys are particularly useful for this research population, which is young and can reasonably be expected to have high computer literacy.

It has been demonstrated that Internet-based surveys can increase a participant's sense of anonymity and help to decrease social desirability bias (Rhodes, Bowie, & Hergenrather, 2003). Furthermore, the use of Qualtrics Survey Software allowed for the implementation of preprogrammed skip patterns and dynamic pages. These features helped to minimize survey



fatigue. Internet-based surveys also increase the privacy and confidentiality of participants by allowing them to complete the survey in a location and time of their choosing and by encrypting responses that are transmitted electronically.

## Measures

Measures were constructed according to the guidelines specified for the measurement of constructs from the IM and from the elicitation research previously described (Phase 1) (Fishbein, 2000; Fishbein et al., 2001; Montano & Kasprzyk, 2008). The full survey instrument can be found in appendix 2. Direct measures of attitude (A), perceived norms (N), and perceived behavioral control (C) were measured according to standard measurement procedures (Fishbein & Ajzen, 2010). The expectancy-value framework was used to measure indirect attitudes, norms, and behavioral control by creating an index of beliefs weighted by their evaluation. For example, a behavioral belief of strength  $b_i$  (e.g., The HPV vaccine will help me to prevent anal cancer) is weighted by a measure of the relevance or importance of that specific outcome  $e_i$  (Preventing anal cancer is important to me). The cross product of these two variables is the expectancy-value score for that specific belief ( $b_ie_i$ ). These scores were summed to represent an index of the salient beliefs ( $\Sigma b_ie_i$ ). This was done to create separate indexes for behavioral beliefs, normative beliefs, and control beliefs. The behavioral, normative, and control beliefs measured in this study were identified in Phase 1 qualitative interviews.

*Intentions (INT).* Three items were used to measure vaccine intentions ( $\alpha = .90$ ). They assess intention to "find out more information about HPV," "make an appointment to talk to a doctor or health care provider about the HPV vaccine," and to "get your first HPV shot." Each item specified a timeframe "within the next 12 months.' Responses were recorded on a 5-point bipolar scale (Unlikely-Likely).



*Attitude (ATT).* Attitudes toward HPV vaccination were measured using a 5-point semantic differential scale ( $\alpha = .86$ ) including the following adjectives (1) not worth it—worthwhile, (2) harmful—beneficial, (3) a bad thing for me—a good thing for me, (4) unimportant—important, (5) ineffective—effective. These items followed the statement, "Overall, I think that getting the HPV vaccine is...." Higher values represent a more positive attitude toward HPV vaccination.

*Perceived norm (Norm).* Three items were used to measure perceived norm ( $\alpha = .70$ ). Two items assessed subjective norms: (1) "In general, people who are important to me would encourage me to receive the HPV vaccine" and (2) "I can think of at least one person in my life who would like for me to get the HPV vaccine." One item assessed descriptive norms: (3) "Most of my gay/bisexual male friends would get the HPV vaccine if it were offered to them free of charge." Responses were recorded on a 5-point bipolar scale (disagree-agree). Higher values represent more supportive norms.

*Perceived behavioral control (PBC).* Three items were used to measure perceived behavioral control ( $\alpha = .70$ ). This construct is believed to consist of perceptions of self-efficacy and controllability (Fishbein & Ajzen, 2010). Thus, one item measured self-efficacy: (1) "I am confident that I can get the HPV vaccine in the next 12 months." Two items were used to measure controllability: (2) "There are factors beyond my control that would prevent me from getting the HPV vaccine in the next 12 months" and (3) "Getting the HPV vaccine sometime in the next 12 months would be...Impossible for me—Possible for me." Items 1 and 2 were recorded on a 5-point bipolar scale (disagree-agree) and item 3 used the 5-point impossiblepossible scale. Higher values indicate higher agency.



Behavioral beliefs (BB). Ten behavioral beliefs were measured representing physical advantages, psychological advantages, and disadvantages/concerns associated with HPV vaccination. For example, "It would prevent me from getting genital and anal warts," "Feel like there is one less thing to worry about," and "I would have side effects from the HPV vaccine." Each belief item was followed by an item measuring its corresponding outcome evaluation (e.g., "Preventing genital and anal warts is..."). Outcome evaluations were recorded on a 5-point bipolar scale (unimportant-important). Belief strength  $(b_i)$  was recording on a 5-point bipolar scale (unlikely-likely). The BB score is equal to  $b_i e_i$ . These scores were summed to create the BB index for physical and psychological advantages ( $\Sigma b_i e_i$ ). Higher scores represent a greater endorsement of positive behavioral beliefs associated with HPV vaccination. The same procedure was used to measure a belief in the side effects of HPV vaccination. In order to avoid items with double negatives, the perceived disadvantages (e.g., "not being completely protected" and "the vaccine may not work for me") were only measured by their belief strength  $(b_i)$ . Responses to these two items were averaged and labeled as "Low efficacy" ( $\alpha = .71$ ). A single item was used to measure the belief that "I will contract HPV from the vaccine itself." This measure was also assessed using a 5-point bipolar scale (unlikely-likely). In total, 5 behavioral belief measures were created: (1) Physical advantages, (2) Psychological advantages, (3) Low efficacy, (4) Contract HPV, and (5) Side effects. The physical and psychological advantages were combined ( $\alpha = .90$ ) for structural equation modeling because of their high intercorrelation.

*Normative beliefs (NB).* Four referents (mother, father, gay male friends, and straight friends) were used to assess normative beliefs. Participants reported on the degree to which each referent would be disapproving-approving of him getting the HPV vaccine  $(n_i)$ . Responses were recorded on a 5-point bipolar scale. Participants could choose "not applicable" in cases where



this person/group was not present. "Not applicable" was recoded to represent the neutral midpoint of the scale so that a scale index could be calculated for each participant. Four subsequent items were used to measure the degree to which responses were motivated to comply with each referent ( $m_i$ ). The question stem read: "When deciding whether or not to get the HPV vaccine, would you seriously consider the advice/opinion of…" Responses were recorded on a 5-point bipolar scale (unlikely-likely). The NB score is equal to  $n_im_i$ . These scores were summed to create the NB index ( $\Sigma n_im_i$ ). Higher scores on this index represent more social influence over HPV vaccine decisions.

*Control beliefs (CB).* Four control beliefs ( $c_i$ ) were assessed: (1) "I can find out where to go to get vaccinated," (2) "I will have health insurance next year," (3) "I can find a place to get vaccinated where I don't need to make an appointment," and (4) "I will get tested for HIV in the next 12 months." The degree to which these control beliefs would make it "more difficult" or "much easier" for respondents to "get the HPV vaccine in the next 12 months" was assessed by weighting the control measured on a 5-point bipolar scale (disagree-agree) with a 5-point bipolar perceived power scale ( $p_i$ ) (more difficult—much easier). The CB score is equal to  $c_i p_i$ . These scores were summed to create the CB index ( $\Sigma n_i m_i$ ). Higher scores on this index represent a greater perception of control over behavioral performance.

Self-efficacy (SE). Two items were used to assess the degree of confidence in getting the HPV vaccine in the event that "you had to talk to your doctor or healthcare provider about your sexual orientation (e.g., that you are gay or bisexual)" and "your sexual behaviors (e.g., your sexual history)." Responses were recorded on a 5-point unipolar scale (not at all confident-extremely confident). Reponses were averaged to form a self-efficacy score ( $\alpha = .90$ ).



*Perceived threat (Threat).* Four indicators of perceived threat—threat of warts on the penis or scrotum, anal warts, anal cancer, and HPV infection—were used to construct the latent threat variable. The indictor variables were composites created by taking the product of perceived susceptibility (e.g., "Without the HPV vaccine, what do you think the likelihood is that you will get anal HPV?") with its corresponding measure of severity (e.g., "How serious would it be for you if you became infected with HPV?"). Responses were recorded on 5-point bipolar scales (unlikely-likely and not at all serious-extremely serious). Therefore, each composite indicator had a theoretical range from 1 to 25 with higher values indicating greater perceptions of a likely and serious threat. A threat scale was created to use in bivariate analyses by averaging all four composite scores ( $\alpha = .96$ ).

*Health information orientation (INFO).* Three items were used to assess health information orientation, which was defined as degree of motivation an individual has to seek out relevant health information and to process that information (Dutta-Bergman, 2009). These items were adapted from a previously developed and validated health information orientation scale (Dutta-Bergman, 2009). Items were found to represent a single latent factor. The items used in the current study were: (1) "When I take medicine, I try to get as much information as possible about its benefits and side effects," (2) "Before making a decision about my health, I find out everything I can about the issue," and (3) "It's important to be informed about health issues affecting gay and bisexual men." Responses were recorded on a 5-point bipolar scale. A scale score was calculated by taking the average of the three items ( $\alpha = .80$ ). Higher values indicate a greater degree of orientation toward relevant health information.

Suspicion of LGBT cultural competence. Four items were used to assess suspicion of LGBT cultural competence, which was defined as having a previously received lower quality



healthcare as a result of sexual orientation, expressing discomfort talking to a doctor about sexual orientation or sexual behaviors, expressing a preference that a doctor or healthcare provider not know one's sexual orientation, and expressing a belief that sexual orientation is not relevant to medical care. Responses were recorded on a 5-point bipolar scale (disagree-agree). A scale was created using the average of the three items ( $\alpha = .71$ ).

Nebraska Outness Scale-Concealment (NOS-C). The concealment subscale of the Nebraska Outness Scale (NOS) was included in the survey with the following item stem: "How often do you avoid talking about topics related to or otherwise indicating your sexual orientation when interacting with members of these groups (e.g., not talking about your significant other, changing your mannerisms)?" This was followed with 5 items: (1) members of your immediate family (e.g., parents and siblings), (2) members of your extended family (e.g., aunts, uncles, grandparents, cousins), (3) people you socialize with (e.g., friends and acquaintances), (4) people at your work/school (e.g., coworkers, supervisors, instructors, students), and (5) strangers (e.g., someone you have a casual conversation with in line at the store). Responses were recorded on a ratio scale ranging from never (0%) to always (100%). In previous research the NOS-C demonstrated good internal reliability, as well as discriminant, convergent and predictive validly (Meidlinger & Hope, 2014). Reliability was acceptable in the current study ( $\alpha = .71$ ). No existing research has investigated the factor structure of the NOS ,so it was included as a measured variable in the structural equation models.

### **Data Analysis**

*Data cleaning*. A total of 806 respondents met inclusion criteria for age (18-26), sex at birth (male), sexual minority status (either self identifying as gay, bisexual, or unsure and/or ever having a male sex partner), location (United States), and HPV vaccine history (did not initiate



HPV vaccination). A total of 225 (28%) participants exited the survey before completion. Survey fatigue is a commonly reported problem in Internet-based surveys and similar, or even higher, rates of non-completion have been noted in MSM Internet research (Krakower et al., 2012). The majority of non-completers withdrew from participation prior to the midpoint of the survey. These participants were excluded from analyses. An additional six cases were removed because they had more than 20% of missing data. The final analytic sample consisted of 575 respondents.

*Data quality*. Invalid data is an issue to consider in web-based surveys (Bauermeister et al., 2012). Automatic validation of survey items—including a mixture of forced and requested responses—was implemented in the survey design to minimize falsification and misrepresentations. In addition, IP addresses were examined to identify duplicate entries. There were no duplicate IP addresses out of the 575 responses in the analytic sample. As an additional check, surveys for participants who completed the survey in less than ten minutes (the lowest quartile of response time) were examined for repeated patterns (e.g., skipped questions, out-of-range responses, or inconsistent responses). Based on these criteria all 575 responses appeared valid.

*Statistical analyses.* The SAS statistical software version 9.1 (SAS Institute, Cary, NC) was used to conduct univariate and bivariate analysis. Univariate analyses were conducted on all of the scale variables to generate measures of central tendency, distribution, and to evaluate distributional assumptions. All of the variables violated assumptions of univariate normality; however, the magnitudes of the sample skewness and kurtosis were small, and none surpassed an absolute value of 2. It is suggested that values less than two represent acceptable amounts of nonnormality (Tabachnick & Fidell, 2007). The sample size is large enough to assume that the



distributional assumptions were met for parametric tests. Non-parametric tests were also conducted for each analysis to check for concordance of results (e.g., Spearman rank order correlations in place of Pearson product moment correlations).

Zero-order correlations were calculated to provide a cursory analysis of the relationships among the scales. Mplus version 7 (Muthén & Muthén, 2007) was used to conduct Structural Equation Modeling (SEM). SEM was used to test and modify the proposed theoretical model of HPV vaccine intentions. SEM is useful in developing and testing theoretical models as it allows for the simultaneous estimation of the associations among latent and measured variables and attempts to remove measurement error from these estimates (Buhi, Goodson, & Neilands, 2007). This allows the complete propositional structure of a theory to be tested, including direct and indirect effects. Mplus offers a variety of features including advanced statistical methods for estimating missing data as well as maximum likelihood estimates that are robust to violations of normality (Muthén & Muthén, 2007). The maximum likelihood estimator with robust standard errors was used to estimate parameters that are robust to non-normality and allowed for the full information maximum likelihood method to handle missing data (Buhi et al., 2007; Buhi, Goodson, & Neilands, 2008).

A two-step approach (Anderson & Gerbing, 1988) was used to build the models starting with estimating the measurement model (fit of only the latent factors regressed on the measured indicator variables) and then adding the structural paths (i.e., the structural model). Model fit was evaluated for all models using the following indices: the chi-square test of goodness-of-fit index, the Comparative Fit Index (CFI), the Standardized Root Mean Square Residual (SRMR), and the root mean square error of approximation (RMSEA) (Hu & Bentler, 1999). Aside from the chi-square test, which is significantly biased by sample size, goodness of fit indices do not



produce asymptotic *p*-values and are thus not statistical tests of overall model fit. Therefore, the interpretation of these indices is less objective. Hu and Benter's (1999) guidelines were used as a basis from which to evaluate model fit in the current investigation; however, absolute cutoff criteria were not used as "golden rules" but as general guidelines in combination with a focus on theoretical relevance of specified models and model modifications (Marsh, Hau, & Wen, 20004). A good fitting model would therefore contain: (1) CFI values close to .95, (2) RMSEA values close to .06, (3) SRMR values close to .10, and (4) provide meaningful theoretical results (Hu & Bentler, 1999).

### Phase 3 Methods: Open-Ended Qualitative Survey

An Internet-based, qualitative survey with open-ended response format and preprogrammed probing questions allowed for the exploration of salient beliefs related to HPV vaccination from a large cross-section of young MSM with a greater degree of anonymity than is possible with individual interviews. This method has been successfully applied in research on stigmatized populations or when studying sensitive issues involving sexuality (Middlestadt et al., 1996). Given the sensitive nature of the current project, increasing a participant's sense of anonymity may result in unique and unexpected findings. Thus this method was used as a supplementary method to the semi-structured interviews (Phase 1).

Internet-based, qualitative surveys also allow for enhanced design capabilities to increase the interactivity and personalization of survey questions tailored for specific respondents. Including interactive, probing questions in Internet-based, self-administered surveys is an innovative way of improving the quality and depth of responses to open-ended questions (Holland & Christian, 2009). A vignette was used to provide context regarding HPV vaccination and guide the Internet-based open-ended survey.



## Vignettes in qualitative research

Vignettes are short stories or scenarios that provide a context to which responds are asked to answer questions (Hughes & Huby, 2002). They can include text, images, and other multimedia to provide stimuli and add further interactions. Vignettes are commonly used in health research to study attitudes, beliefs, and perceptions regarding sensitive issues (Barter & Renold, 2000; Hughes & Huby, 2002). They were employed in the current study to help guide participants through a decision-making process regarding HPV vaccination. It was discovered in Phase 1 that young MSM had very little context in which to understand HPV vaccination; therefore, the vignette was created using finding from those interviews. For example, anogenital warts were a key factor in the decisions and circumstances surrounding the few men who had already initiated HPV vaccination. In addition, men in Phase 1 had very little working knowledge of HPV, and they identified alternative settings to offer HPV vaccination. These points were incorporated into the vignette in the following ways: (1) key information about HPV was provided; (2) anogenital warts were used to increase perceived threat of HPV infection; and (3) alternative settings for vaccination were explored. The vignette can be found in Appendix 3.

### Sampling and recruitment

A subsample of men from Phase 2 was recruited to complete the Phase 3 open-ended surveys. Upon completing the Phase 2 quantitative surveys, participants were asked if they were interested in participating in a follow-up study. They provided an email address through Qualtrics Survey Software if they wanted to receive more information. All participants who provided an email address (n=1,157) were invited to participate in Phase 3. A total of 1,141 of those emails were valid. Of the 1,141 delivered emails, 361 (33%) of participants viewed the study website and 328 began the survey. Two-hundred and forty one (73%) of the starters



completed the survey. Respondents not meeting inclusion criteria (i.e., unvaccinated males between the ages of 18 and 26; n = 125) were removed resulting in 116 completed surveys.

## Procedure

All participants were asked to give their consent via the electronic form. If they agreed to participate and gave their electronic consent, they were directed to the survey hosted on a secure server at the University of South Florida. The survey was created using Qualtrics Survey Software. The survey took an average of 32 minutes to complete. All study procedures and instruments were reviewed and approved by research/institutional review board (IRB).

## Incentive

Participants could elect to enter into a drawing for one of ten \$25.00 gift cards from Amazon. To enter they were asked to provide an email address where the gift care could be sent. This email address could not be linked to their survey data.

### Instrument

Participants completed an open-ended questionnaire based on constructs from the IM (See Appendix 3). The questionnaire was developed by the PI with feedback and recommendations from an expert panel of qualitative researchers. In addition, feedback from 5 members of the study population was used to assess the questionnaire for clarity, the wording of questions, and interest and identification with the vignette. The survey contained a vignette consisting of four main sections: (1) the opening scenario providing HPV information, (2) the decision uncertainty scenario in which a decision to get vaccinated or not is being considered, (3) the anal warts threat scenario, and (4) deciding on where to go to get vaccinated. Open-ended questions followed each of the scenarios.



## Data analysis

Responses to the open-ended surveys were imported into MAXQDA for analysis. The analytical approach from Phase 1 was used in Phase 2 in order to describe responses within the IM framework but allow for emerging categories to be explored (See Phase 1 Data Analysis). The revised codebook from Phase 1 provided the *a priori* codes. Responses to each question were initially coded using this codebook. New codes were created as necessary. A structural coding strategy was also used in order to explore reactions to the specific contexts provided by the vignette. Structural coding is a question-based method that serves to index responses to specific questions and is often used in the analysis of open-ended survey data (Saldana, 2009). For example, responses to the question "What do you thing Brandon should do?" were indexed (i.e., coded) according to specific decisions (e.g., "get vaccinated," "talk to a doctor," etc.). Data were then sorted by decision and analyzed further to uncover more descriptive codes about that decision.

## Trustworthiness

A random selection of responses (10%) to questions from each of the four sections were extracted and recoded by the PI and an independent coder with a Ph.D. in Public Health with expertise in qualitative research among MSM. Discrepancies were discussed and another random selection of responses were extracted and recoded. Agreement was greater than 80%.



## **CHAPTER 4: RESULTS**

#### Overview

Results were presented separately based on the three phases of the current study. A synthesis of the results, and how the various methods assessed the specific aims and research questions, will be provided in the discussion. However, it is useful here to describe the complete study sample across the three phases.

As part of the study design, the age of participants was restricted to range from 18 to 26 encompassing vaccine-eligible adult males. The average age was 22 in each phase, and there were similar proportions of men in the 18-20, 21-23, and 24-26 age groups. The ethno-racial identity of participants varied considerably across the three phases. The proportion of ethno-racial minorities was highest in Phase 1, reflecting the purposive oversampling of these populations. Across all phases approximately three in five were current college students and most had health insurance. Overall there were a small number of self-reported HIV-infected men, but a large percentage of respondents reported never receiving an HIV antibody test.

The majority of participants in all three phases self-identified as gay; however, a sizable number of men identified as bisexual in Phases 2 and 3. Participants in Phase 3 were a subsample of Phase 2 participants; thus, the demographics characteristics of these two phases were similar aside from ethno-racial identity. There was a larger proportion of whites who completed Phase 3.



	Phase 1 (N = 22)	Phase 2 (N = 575)	Phase 3 (N = 116)
Characteristic	n (%)	<u>n (%)</u>	n (%)
Age [Mean (SD)]	22 (2.58)	22 (2.43)	22 (2.11)
18-20	8 (36)	167 (29)	25 (22)
21-23	6 (27)	217 (38)	43 (37)
24-26	8 (36)	191 (33)	33 (28)
Sexual identity	0 (50)	1)1 (55)	55 (20)
Gay	21 (95)	431 (75)	82 (71)
Bisexual	1(5)	127 (22)	31 (27)
Heterosexual	I (5)	2 (0)	51 (27)
Not sure		11(2)	1(1)
Other		5(1)	2(2)
Ethno-racial identity <sup>a</sup>		5 (1)	2 (2)
White	9 (41)	363 (63)	83 (72)
African American/Black	5 (23)	121 (21)	9 (7.8)
Hispanic/Latino	6 (27)	91 (16)	4 (3.4)
Asian	1(5)	34 (6)	8 (7)
Native American	1 (5)	11 (2)	1(1)
Pacific Islander		2(0)	1 (1)
African		10 (2)	
Other			
College student	1 (5)	16 (3)	11 (9)
Yes	13 (59)	329 (58)	68 (59)
No	9 (41)	241 (42)	48 (41)
Educational attainment	9 (41)	241 (42)	40 (41)
Less than high school		16 (3)	
High school / GED	5 (23)		14 (12)
Some college	11 (50)	100 (17) 254 (44)	14(12)
2-year college degree	11 (50)	47 (8)	44 (38)
	5 (22)		11(10)
4-year college degree	5 (23)	132(23)	41 (35)
Graduate/Professional degree Health insurance	1 (5)	23 (4)	6 (5)
Yes	20 (91)	176 (92)	09 (94)
No		476 (83)	98 (84)
	2 (9)	89 (15)	18 (16)
Unsure		10 (2)	
HIV status <sup>b</sup>		292((7))	7((())
HIV-Negative		383 (67)	76 (66)
HIV-Positive	5 (23)	35 (6)	3(3)
Never tested		156 (27)	37 (32)
Missing	17 (78)	1 (0)	
HPV vaccination	5 (22)		
Yes	5 (23)		
No	17 (78)	528 (92)	112 (97)
Not sure		47 (8)	4 (3)

Table 2: Descriptive characteristics of participants by study phase

Note. Percentages may not add up to 100 due to rounding. <sup>a</sup> Some participants identified in more than one Ethnoracial category. <sup>b</sup> HIV status was not asked directly in Phase 1. If participants discussed being HIV positive in the interview, they were counted as positive;

otherwise, they were classified as missing.



#### Phase 1 Results: Semi-Structured Interviews

A total of 22 interviews were completed in 2014 with MSM between the ages of 18 and 26. Characteristics of the study sample are presented in Table 2. Participants were on average 22 years old, and most were in college (59%) or had some type of post-secondary education. They were diverse with nearly 60% identifying as an ethno-racial minority. Most identified as gay, and all had been sexually active with male partners.

Five of the participants were self-reported to be HIV-positive. HIV-status was not addressed systematically in order to determine if HIV-status would emerge during the interviews as a salient factor surrounding HPV vaccination. Five participants identified their HIV-status as positive, and for each of these HIV-infected participants, HIV infection was central to his experience with the healthcare system and his subsequent view on HPV vaccination. The main findings from the interviews are presented according to major categories from the IM along with the more specific subcategories defined through content analysis. In Table 4, the main categories of behavioral, normative, and control/efficacy beliefs are presented along with their generic and subcategories. The beliefs expressed in each of these categories are represented by selected quotes taken from the interview transcripts. Survey items that were created to measure the salient beliefs represented in Table 4 are listed in the last column. Direct quotations are attributed to the participants by referencing their individual participant ID numbers (e.g., P01), age, and ethnoracial identities.



												Main Category	I dole 5. Salient beliefs, representative quotes, and survey items
				Y ACCIDATION	Psychological advantages to				vaccination	advantages to	Physical	Generic Category	ocitors, represente
		Peace of mind			Protects partners				health	risk/Promotes	Lowers	Sub-Category	allye quotes, allu
"It would give me one less thing to worry about." (P17, 22, Black)	"Make me feel safer." (P16, 24, White)	"Feel a little better. A little more protected." (P09, 24, White)	"I don't want to spread anything." (P16, 24, White)	"I could be spreading it without even realizing it." (P15, 20, Latino)	"You wouldn't have to worry about giving it to anyone else." (P08, 19, Black)	"Do you want to have surgery on your ass? If not go get a shot." (P02, 26, White)	"It would be a safe bet." (P18, 24, Multiracial)	"I would be less susceptible to anal cancer at least from HPV." (P12, 24, Latino)		21. Latino)	"You're just healthier and lowering risks." (P04,	Representative Quotes	
	worry about	<ul><li>(5) Feel protected from HPV</li><li>(6) Feel like there is one less thing to</li></ul>		<ul><li>(4) Be less likely to spread HPV to your future sex partners?</li></ul>	If you got vaccinated for HPV within the next year, how true are the following things likely to hannen for you? Would you ?	<ul> <li>(3) It would prevent me from getting anal cancer</li> </ul>	(2) It would prevent me from getting	(1) It would make me healthier (Being healthier is [very important to me-		vear	If I got vaccinated for HPV within the next	Survey Items	

Table 3. Salient beliefs, representative quotes, and survey items

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	Normative beliefs							
	Supportive referents							Risks of getting vaccinated
	Health care providers as referent others			Side effects			Unknown efficacy	Contract HPV
	"My doctor would probably be the onethe first one to say get it." (P20, 23, Black)	" if your body rejects it." (P20, 23, Black)	"So I believe you're taking a chance with getting any type of vaccine." (P18, 24, Multiracial)	"Every vaccine has side effects." (P16, 24, White)	"You still have the possibility that you may get it." (P20, 23, Black)	"I would not feel completely protected. In this world you can't really ever feel completely protected."(P09, 24, White)	"Not knowing if it really works, cause you don't know if you technically have it." (P12, 24, Latino)	"There is always a risk that you can contract it from getting the vaccineit just depends on how it interacts with your body." (P16, 24, White)
What do you think their opinions would be? If you don't have a relationship with the	Listed below are some people in your life who may approve or disapprove of you getting the HPV vaccine.		VACUITO	(10) I would have side effects from the HPV			<ul> <li>(7) I will contract HPV from the vaccine</li> <li>(8) The vaccine may not work for me</li> <li>(9) I would not be completely protected</li> <li>from future HPV infection</li> </ul>	How likely do you think the following things are to happen to you if you got vaccinated? If I got vaccinated for HPV within the next year

(1) Your health care provider

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specific person just choose "not applicable." 1 = Very Disapproving, 3 = Neither Approving/Disapproving, 5 = Very Approving

ì

Table 3 (Continued)

									Table 3 (Continued)
				Immediate family members are				Friends as referent others	
75	"I guess just telling her that, just a conversation you wanna avoid. Like you don't wanna tell your mom that you're sexually active, so you feel like you need to have this shot." (P07, 19, White)	"My father would have had no opinion probably and my mother would have probably encouraged me cause she's in the medical field so you would have probably encouraged it." (P01, 21, White)	"I'm a big momma's boy, so I think she would be very all-pro for it, too." (P12, 24, Latino)	"I don't really talk too much to my family." (P16, 24, White)	"My older gay friend when I met when I was 18 I definitely learned a lot from him. He was the first one that told me I should go get HIV tested." (P04, 21, Latino)	"Well my gay friends, all we do is just go out all the time. So it's not really something like we talk about, you know." (P11, 19, Latino)	"I'm pretty sure most of them are clueless about it." (P04, 21, Latino)	"To be quite honest with you, my gay male friends are very like touch and go. We will meet up for drinks, have a good time, kiki for a little bit, and we leave." (P12, 24, Latino)	
				<ul><li>(4) Your mother</li><li>(5) Your father</li></ul>				<ul><li>(2) Most of your gay male friends</li><li>(3) Your straight friends</li></ul>	
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		Control beliefs								Table 3 (Continued)
		External control factors			Descriptive norms		Unsupportive referents		Supportive referents	nued)
		Availability		YACCINC	Know someone who got HPV vaccine		Judgment from others		General acceptance	
76		"But I think a lot of it is getting the knowledge and information and knowing where to get the test." (P16, 24, White) "If it was available on campus." (P06, 21, White)	"And then there is an HPV shot for women and for men, but like every girl in my high school had it." (P04, 21, Latino)	"The one nursing student had just gotten it and I remember I had met him. One male that I knew, a gay male." (P01, 21, White)	"I know [about HPV vaccine] because my sister got it." (P12, 24, Latino)	"She'd [his mother] be upset, 'oh great now he's gonna be riskier'." (P04, 21, Latino)	"Some of the friends that I do have in particular would probably think that I'm just being extremely promiscuous sleeping around with guys like every night and everything." (P15, 20, Latino)	"Why would anybody disapprove of someone getting a vaccine." (P09, 24, White)	"Everyone would be supportive. I can't see anyone saying, 'Oh you shouldn't do that.' " (P04, 21, Latino)	
	(1) If I could quickly find out where to get vaccinated	What would make it easier for you to get the HPV Vaccine? It would make it to get the HPV vaccine in the next 12 months 1 = more difficult to 5 = much easier for me			(1) Do you personally know someone who has gotten the HPV vaccine?		Not measured		(1) I can think of at least one person in my life who would like for me to get the HPV vaccine.	
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				Efficacy beliefs						Table 3 (Continued)
				Internal control factors						inued)
			disclosing	Feeling uncomfortable		Convenience			Cost	
77	Latino) "I'd be very selective on answering questions. Because a lot of people aren't openlike they will ask the question but they are not ready to receive the answer." (P20, 23, Black)	and I lied. So I kind of wasn't out. I knew I was, and I knew I was doing things, but Iat first I was very uncomfortable, so I kind of almost didn't accept it, so I didn't say anything." (P12, 24,	". "Even when I first came out, they [health care providers] would ask me that [sexual behavior]	"I just feel weird talking to someone like that about those kind of things." (P03, 19, Asian)	"And the location of the place. The time of the day I can get it." (P17, 22, Black)	"I would rather go to Metro Wellness. Especially ifMaybe if I won't like rush to get the vaccine. I'd probably wait maybe until my next HIV test." (P17, 22, Black)	"Money is a big issue!" (P06, 21, White)	"It would be a barrier depending on the cost. I am a poor graduate college student. I'm having trouble paying for school let alone a vaccine." (P12, 24, Latino)	"My insurance paid for it. Had I had to pay for it I probably would have been likenah." (P14, 26, Black)	
	your <u>sexual orientation</u> (e.g., that you are gay or bisexual)?	(2) How confident are you in your ability to get the HPV vaccine if you had to talk to your doctor or healthcare provider about	your doctor or healthcare provider about your <u>sexual behaviors</u> (e.g., your sexual history)?	(1) How confident are you in your ability to get the HPV vaccine if you had to talk to		<ul><li>(3) If I could get it without making an appointment</li><li>(4) If I could get it when I get tested for HIV</li></ul>			(2) If my health insurance covered the vaccine	
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## **Behavioral beliefs**

## Physical advantages to vaccination

When asked to describe the "advantages" or "good things" about getting the HPV vaccine, most participants talked about the *physical* benefits to vaccination. They described how their personal risks would be lower and that they would be doing something to promote their health. For instance, one participant—after reading a brief fact sheet about HPV (See Appendix 4)—endorsed the belief that he would be "less susceptible to anal cancer at least from HPV" (P12, 24, Latino). Others talked about how it would "be a safe bet" and that taking steps to protect the "anus" was "important." Overall, few gave specific details about preventing genital warts or anal cancer, instead relying on general statements about how vaccination "lowers risk" and promotes "immunity." This seemed to reflect their limited knowledge about HPV and HPV vaccination.

For some participants, their perceptions about the health benefits of HPV vaccination were clearly influenced by their prior health issues/concerns. One man who described his experience with reoccurring anal warts and their surgical excision stated, "...if it [HPV vaccination] can prevent you from going through what I've gone through, it's well worth it" (P02, 26, White). Another man, who had experienced reoccurring anal warts, mentioned that he wished he had received it [the HPV vaccine] before and inquired if the vaccine would prevent him from "contracting different strains" (P21, 26, White). One participant reflected on his own family history of cancer and how getting vaccinated would help minimize some of this risk. Overall there was a positive attitude toward getting vaccinated, primarily resulting from perceived health advantages.



## Psychological advantages to vaccination

In addition to the perceived physical health benefits of getting the HPV vaccine, many participants talked about psychological advantages, including protecting future sex partners and giving them "peace of mind." One participant mentioned that he "wouldn't have to worry about giving it to anyone else" expressing a general concern about spreading STIs. The focus of these statements was clearly on the infection itself and not on HPV-related disease. When informed that the majority of sexually active people will become infected with HPV at some point, and that the majority of those infections will clear without any symptoms of disease, one participant responded: "It doesn't matter. It's still an STD. You're still tainted" (P09, 24, White).

Others talked about feeling "safer," "feeling better," and having "one less thing to worry about." The following statement highlights the general focus on wellbeing and the importance of *feeling* that they have taken steps to protect their health:

Knowing if I'm infected or not, you know, that would be concerning. But the fact of knowing, "Ok, well I don't know, but I'm taking steps in case I'm not," that would put my mind at ease (P12, 24, Latino).

Again this statement expresses a general concern about being "infected," with prevention of HPV-related disease as a secondary concern.

## *Risks of getting vaccinated*

When asked about the "disadvantages" or "bad things" associated with getting vaccinated for HPV, respondents reported minimal concerns over side effects. Responses to this question tended to focus on the side effects generally associated with any vaccine or medication. For instance, participants mentioned that "every vaccine has side effects," (P16, 24, White) and that people are "taking a chance with getting any type of vaccine" (P18, 24, Multiracial). There was



also an ambiguous concern of the body "rejecting" the vaccine. The importance or value placed on these concerns was minimal. In fact, many of the comments about side effects where phrased in ways that minimize the concerns. For instance, one participant said, "There's side effects for everything, so that's not a big worry on my plate" (P06, 21, White). Others mentioned that they have not heard anything risky about the HPV vaccine and explicitly stated, "I know there's antivaccine views out there, and I don't agree with those" (P03, 19, Asian).

For the most part, concerns about the vaccine reflected doubts about its efficacy. Given that they were all sexually active and that there is no way to test if they had been previously exposed to HPV, they were unsure if vaccination would confer any direct benefits. Some stated that they would "not feel completely protected" (P09, 24, White) or that they "still have the possibility" (P20, 23, Black) of getting infected. This concern seemed to reflect the larger public health focus on vaccinating young children.

A few participants asked whether the HPV vaccine was a "live virus" and one expressed a concern about contracting HPV from the vaccine itself. One participant made explicit mention of this: "There is always a risk that you can contract it from getting the vaccine...it just depends on how it interacts with your body" (P16, 24, White).

### Normative beliefs

### Supportive referents

When asked what individuals or groups would *approve* of their decision to get the HPV vaccine, the majority of participants expressed a very clear sentiment that this would not be a decision that they would widely discuss with anyone prior to getting vaccinated. Some mentioned that their "doctor would probably be the one" (P20, 23, Black) or that their doctor's opinion was the "only opinion that mattered" (P18, 24, Multiracial) regarding this issue. Probes



about the support of friends or family were countered with general statements about their expected approval or statements diminishing the influence of these individuals. One participant stated, "I'm pretty sure most of them [his friends] are clueless about it" (P04, 21, Latino). This same participant, along with one other, identified an older gay friend as a potential source of health information. He stated that his older friend told him the "HPV shot came out a few months ago" and that he "really should get it." This recommendation was influential in his decision to get vaccinated. In general, similarly aged peers were not considered valuable sources of informational or emotional support regarding HPV vaccination.

Perceived support from family members was even more ambiguous. Some respondents generally accepted that their family would be supportive but it's not something they would discuss with them unless there was a specific reason (e.g., parent was a medical professional). Others rejected the idea, explaining that they didn't talk to or were alienated from their families.

Overall the men in this sample described general perceived support for HPV vaccination among their friends, family and medical providers; however, these referents—aside from health care providers—were not deemed to be valuable in their decision-making process.

# Unsupportive referents

There was not a strong sentiment about unsupportive friends or family, but some participants talked about anticipated negative responses from family, and friends. In particular, they expressed a concern that—because HPV is an STI—their mothers would assume they wanted to get vaccine so they can "be a whore" or be "riskier." One participant talked about potential judgment from his straight friends who might assume he needed the vaccine because he was "being extremely promiscuous" (P15, 20, Latino). When probed about these concerns, all of



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the participants stated that despite these potential negative assumptions, their friends and family would still support their decision to get vaccinated.

## Descriptive norms

No questions in the interview guided asked directly about descriptive norms but knowing someone personally who has gotten the HPV vaccine came up often in conversations about HPV knowledge. Participants were asked how they first heard about HPV (if they had) and the most commonly mentioned source of HPV information was from female friends or family (i.e., sisters) who had gotten vaccinated. Only one participant knew of another gay male who had received the vaccine. In general, the overwhelming perception "about people who receive the HPV vaccine" is that they are female.

## **Control and efficacy beliefs**

#### External control factors

Participants were asked what factors or circumstances would "help you" or "make it easier" to get vaccinated. Their responses centered around three primary reasons including availability, cost, and convenience. Many participants expressed uncertainty about where to go to get vaccinated. In general, participants did not see a primary care provider for regular physicals or checkups apart from HIV testing. They tended not to have established relationships with specific providers who they could ask about HPV vaccination. Therefore knowing where the vaccine was available would make it easier for them to access it.

Convenience was also mentioned on multiple occasions. Participants mentioned clinics they know of close to their homes or places of employment where they would prefer to be vaccinated. Flexibility was highly valued in terms of where and when they could get vaccinated. For students, getting vaccinated on campus was mostly preferred. Walk-in availability was also a



noted facilitator. Overall participants seemed open about where to get the vaccine as long as it fit into their schedule. This sample of men received regular HIV testing which was identified as convenient time to get vaccinated. One participated stated: "I would rather go to metro wellness [a local HIV testing location]. Especially if...maybe if I won't like rush to get the vaccine. I'd probably wait maybe until my next HIV test" (P17, 22, Black). Subsequent participants were probed on this issue and most of them were amenable to getting vaccinated at their HIV testing location.

By far the most significant external control factor was cost. There was a general sense that vaccines are expensive, and participants expressed concerns that they could not afford it. Although the majority of participants had health insurance, many were unsure if the vaccine would be covered. In all five cases where participants were already vaccinated, they had insurance coverage and explicitly stated that they would not have been vaccinated if they had to pay the out-of-pocket costs.

## Internal control factors

After participants were asked general question about control beliefs, they were probed regarding their perceived self-efficacy in getting the HPV vaccine if they had to discuss aspects of their sexuality (i.e., sexual behaviors and/or identity). For some participants, this presented no issue at all and they described themselves as having high self-efficacy to ask for the HPV vaccine even if they had to discuss issues of sexuality. However, other participants expressed feeling uncomfortable disclosing their sexuality to healthcare providers. One participant stated, "I just feel weird talking to someone like that about those kind of things" (P03, 19, Asian) Others said they would feel "uncomfortable" and would be "very selective" about answering questions regarding their sexual behavior.



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# **Background factors**

Background factors were explored through general questions about health, healthcare experiences, sexuality, and HPV. Through these open-ended discussions the PI gained a nuanced understanding of potential background factors that underlie HPV-related beliefs and subsequently, HPV-vaccination. A series of generic categories and sub-categories were identified that represent these factors and allowed for the extension of the IM to included propositions regarding the ways in which these factors might influence HPV vaccine decision-making among young MSM. This extended framework is depicted in Figure 4 and described in detail below.

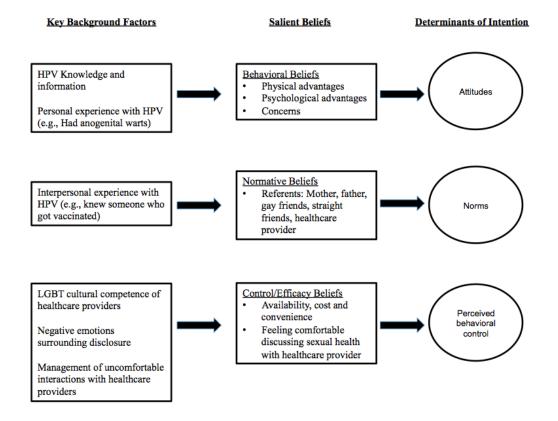


Figure 4: Extended Integrative Model of HPV vaccine decision-making among young male sexual minorities



Main Category	Generic Category	Sub-Category	Representative Ouotes	Survey Items
Background Factors	HPV Knowledge and Information	Reaction to HPV	Interviewer: What are your initial reactions about the vaccine after hearing this information?	Information-Orientation Scale
			"Other than what are the side effects and where the hell can I get this thing as fast as possible." (P12, 24, Latino)	(1) When I take medicine, I try to get as much information as possible about its benefits and side effects
			"I would definitely want to go get it, like right now!" (P11, 19, Latino)	(2) Before making a decision about my health, I find out everything I can about the issue
			"Ironically I have a doctor appointment next Thursday so I'm gonna ask him about." (P20, 23, Black)	(3) It's important to me to be informed about health issues affecting gay and bisexual men
		Information needs	Interviewer: What more information do you need about this vaccine before you think you can make a decision?	(Adapted from Dutta-Beggman, 2009)
			"Just think little fact sheet right here kind of likea wake up call to say like hey maybe it's time for ya'll to get tested for these diseases to get vaccine for it. I mean you knowlike I said that little small fact sheet told so much. It told what it iswho can get itwhat it can cause. Given all the information you need." (P20, 23, Black)	
			"I'd be interested in knowing whether the vaccine would actually kind of prevent me from contracting different strains." (P21, 26, White)	
			"Is it still as effective as you go up in age?" (P15, 20, Latino)	
			"It's passed by skin-to-skin contact. Even using protection doesn't protect you? What kind of skin to skin contact?" (P17, 22, Black)	

Table 4: Background factors important to HPV vaccination among young MSM

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					Table 4 (Continued) Perceived threat
					HPV-related susceptibility
88	"Moderate because I've been with men who are older than me, no more than like ten years though, older than me, but umm I don't know. Like if they've really done like what they've done, compared to what I've done." (P07, 19, White)	"I don't really have a partner and I don't sleep around a lot. I thought it was pretty low but it only takes one time for you to get it so" (P14, 26, Black)	"Well the fact that it only takes one sexual partner that automatically puts you at a 10 I think. Do I want to water it down and say maybe six or seven just to make myself feel better?then yeah. It only takes one." (P15, 20, Latino)	"Well I was already infected with HPV at one point. Not genital warts but a different type of HPV. I didn't really feel like I was much at risk. I had more than one boyfriend that had genital warts. Not at the time I was dating them butand I never caught any of that stuff so I was really happy that I didn't and I guess I really didn't feel threatened by like genital warts." (P18, 24, Multiracial)	"To be honest with you I really don't think I have it you know because I've been tested and I don't know what tests I was being tested for but I know I was getting tested for everything." (P12, 24, Latino)
				<ul> <li>anus</li> <li>(3) If you developed warts on your penis or scrotum</li> <li>(3) If you developed anal cancer</li> <li>Without getting the HPV vaccine, what do you think the chances are that you will</li> <li>(1) Get HPV</li> <li>(2) Get warts on your penis or scrotum</li> <li>(3) Get anal warts</li> <li>(4) Get anal cancer</li> </ul>	<ul> <li>Please indicate on a scale of 1 to 5 how serious you feel the following events would be for you.</li> <li>(1) If you became infected with HPV</li> <li>(2) If you developed warts on or inside your</li> </ul>
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		Anogenital warts							Table 4 (Continued)
		s Had anogenital warts						HPV-related severity	
87	"HPV can come in many different forms actually. Most common would be in genital warts. That's personally what I have. Well I guess I don't have it cause I've had it removed, but it still in my system." (P02, 26, White)	"He had anal warts. He had set up an appointment with a doctor to had his removed so after he had his removed I noticed the first one for me." (P21, 26, White)	"you could be carrying something that you technically don't know you have, and you could have sex with like somebody who you've been together for a long time and incidentally pass it on to them. You know what I mean? So that's kind of alarming." (P12, 24, Latino)	"It's kind of crazy, it stands out too, that, you know, most men who get HPV never develop symptoms or health problems. So it's kind of like just like a sitting virus kind of thing inside of you." (P12, 24, Latino)	"Oh my God it has no symptoms! So how do you know if you got it?!" (P12, 24, Latino)	"Well it's just, that's scary. You know, you just don't know if you have it or not." (P11, 19, Latino)	"And I was surprised that most men who get it never develop any symptoms. That's startling." (P03, 19, Asian)	"Nobody wants cancer so it's scary that how a virus can go undetected of symptoms and it causes these things" (P03, 19, Asian)	
	(2) Has a health care provider ever told you that you had genital or anal warts?	Personal experience with anogenital warts (1) Has a health care provider ever told you that you had human papillomavirus or HPV?							
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		Negative emotions surrounding disclosure	
		motions Felt judged by ng HCP	Know someone who had anogenital warts
88	"I feel like he [his primary care physician] judges me. I feel like if I had a provider or somebody who is a little more open-minded my doctor is a staunch Republican, white dude who is like 65 and I'm sitting there like a gay little Puerto Rican kid, and you know, it is just always awkward when I go to my doctor. We come from opposite ends of the earth." (P12, 24, Latino)	"I just think that, in general, females don't judge as much, I guess you could say with gay men. Umm, I always think it's awkward to go in and tell like a heterosexual male that I'm different than what he is. I like to have sex with guys and anal sex, and stuff like that, that is a difficult conversation to have with a hetero-even if they're completely and fully understanding of it, to me it's still embarrassing. And I can relate more and I'm probably more willing to give information to a female than a male." (P12, 24, Latino)	"I believe I was talking about my friend who had genital warts but I'm not sure. I want to say I probably said I heard there is some sort of vaccine and then I'm sure she talked about it from there. I don't remember exactly." (P01, 21, White) "No the guy that I was dating at the time. He actually had warts at the time and so we thought we were being really careful to keep me from contracting it but we weren't very successful, obviouslywe had one sexual encounter before he told me and I think for him he thought that condom use would protect me against it, which isn't actually the case." (P21, 26, White)
	sexual orientation or sexual behaviors with a doctor or healthcare provider (4) There is no reason why my doctor or healthcare provider would need to know that I have sex with men	<ul> <li>Suspicion of healthcare providers</li> <li>(1) I have received lower quality healthcare services as a result of my sexual orientation</li> <li>(2) I prefer that my doctor or healthcare provider does not know that I am gay/bisexual</li> <li>(3) I feel uncomfortable talking about my</li> </ul>	<ul><li>(1) To the best of your knowledge, do you personally know someone who has had genital or anal warts (other than yourself)?</li><li>(2) To the best of your knowledge, do you personally know someone who has had HPV (other than yourself)?</li></ul>
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Bias toward LGBT	LGBT Cultural Lacks knowledge Competence about gay health issues	
"I would just feel weird talking to someone about that [HPV vaccine], and I would not know their views on LGBT people. So I feel like there may be some bias in the information that they could give me. Even though it's unprofessional." (P03, 19, Asian)	<ul> <li>White)</li> <li>ledge "A gay provider would be more into or up-to-date with newer things that are coming out. Especially like with the threats that are more for the gay lifestyle. Because I really don't think that my health provider would know about HPV." (P12, 24, Latino)</li> </ul>	"I'm not a real big person on discussing orientation because usually if you discuss orientation with people they tend to start shoving you away. There is not doubt in my mind he [his primary care physician] knew but he learned to like form a relationship with me and my family before he started judging me" (P20, 23, Black) "I'm very uncomfortable receiving, especially specialty likewhen I went to go see like umm, a gastroenterologist about issues, when he was straight. I felt like they were judging me, I felt like I was very singled out, I felt like they assumed that it was cause I was gay, that's the first question they asked, like when I was having issues with my colon and everything, they were like what's your orientation I almost didn't want to tell them, because I wanted them to treat me as if I was a straight person and not have those preconceived notions in their head." (P06, 21,
		<ul> <li>Nebraska Outness Scale- Concealment How often do you avoid talking about topics related to or otherwise indicating your sexual orientation when interacting with members of these groups (e.g., not talking about your significant other, changing your mannerisms)?</li> <li>(1) Members of your immediate family (e.g., parents and siblings)</li> <li>(2) Members of your extended family (e.g., aunts, uncles, grandparents, cousins) (2)</li> <li>(3) People you socialize with (e.g., friends and acquaintances) (3)</li> <li>(4) People at your work/school (e.g., coworkers, supervisors, instructors, students)</li> <li>(5) Strangers (e.g., someone you have a casual conversation with in line at the store)</li> </ul>

Table 4 (Continued)		
Management of disclosure	Anonymity	"And typically that is where I go [Public Health Department]. I guess until recent where I can go to this care center thing. But I don't like that because it doesn't really give the anonymity that the health department doesit is a lot better than going to my employer health clinic where I am sitting in a waiting room full of people. It's different for me because I feel like my health care providerI understand there is HIPA and all that stuff and they are suppose to keep my stuff confidential. But I live in a pretty small town and I know how that stuff works. So I'd rather not. I go to the health department and every time I go it is somebody different. It never gets personal. I've never built rapport with them." (P12, 24, Latino)
	Not relevant	"I don't think it is any of their [health care provider] business really [his sexual behavior], but I would've answered truthfully. Wait, would I have answered truthfully? I think I would have. if you are having sex you are having sex. You are being exposed to these diseases when you're having sex. It's a fact of lifelikewhatever. It is just likeit is none of your business who I am having sex with. There is the whole stigma about being gay that we are promiscuous people we just go around having sex with every guy we see and therefore are at higher risk that you knowstraight guys do that all the time too." (P15, 20, Latino)

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## HPV knowledge and information

Nearly all of the participants had heard of HPV and typically described it as a sexually transmitted infection that has multiple "strains" and mostly affects women. The majority (55%) mentioned a vaccine, though most were not aware that males could be vaccinated. Approximately 41% (n = 9) of men listed genital warts as a distinctive characteristic of HPV infection and 36% (n = 8) cancer. When cancer was mentioned it was usually limited to a generic explanation (e.g., "life threatening diseases like cancer") or an explicit mention of cervical cancer. No participant mentioned anal, oral, or penile cancer (not even the 5 vaccinated men). The main sources of HPV-related information came mostly from female friends, formal sex education classes, and Gardasil advertisements. One participant recalled:

I know that there is a vaccine. I feel like there is the stupid commercial, well it's not stupid it's informative. It was like...primarily for girls but now they are doing it for guys as well...the HPV vaccine. (P15, 20, Latino)

After providing basic information about HPV and HPV-vaccination for males (see Appendix 4), participants were asked: "What are your initial reactions about the vaccine after hearing this information?" Some of the men expressed a high level of interest and enthusiasm for getting vaccinated: "...what are the side effects and where the hell can I get this thing as fast as possible" (P12, 24, Latino)! Others expressed intention to speak with their doctors about the vaccine in the near future.

To probe more about their information needs, they were asked: "What is the minimal amount of information you need about this vaccine before you think you can make a decision?" Some of the men asked basic questions about HPV or the vaccine. These questions typically related to: (1) the effectiveness of the vaccine in older males, in males who have already been



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sexually active, or in males who have already been exposed to HPV; (2) the side effects associated with getting vaccinated; and (3) the types of sexual behaviors that spread HPV. Telling them that HPV can be transmitted from "skin-to-skin" contact was too ambitious and usually prompted more questions about specific behaviors. Despite these inquires during the interviews, collectively this sample of men exhibited a high degree of acceptability and willingness to initiate HPV vaccination.

## Perceived threat of HPV infection and disease

Perceptions regarding susceptibility to HPV infection were mixed. Some men described their risk as high considering that it "only takes one sexual partner" (P15, 20, Latino). Others reflected on their sexual histories and relationship status. One participant responded that it was hard for him to assess his risk because he was with his "boyfriend-partner, for almost four years" and that they "rarely" have other sexual partners (P12, 24, Latino). It was common for respondents to discuss their own risk in general terms like "I always use protection to keep myself healthy" (P01, 21, White) or "I don't sleep around a lot" (P14, 26, Black). After reading the fact sheet one respondent stated, "I don't really think that most people are going to have HPV. I mean...maybe gay men who don't practice safe sex" (P09, 24, White). Overall participants seemed unsure on how to respond to questions about their susceptibility to HPV. When asked to rate their risk of having been exposed on a scale of 1 to 10 (with 10 being the highest risk), most of them indicated that they were at average risk (between 4 and 6). There was also a tendency to focus on anal sex as the only risk behavior.

When informed that HPV can cause anal cancer and that MSM are at a higher risk of anal cancer, most of the respondents described their reaction in emotional terms. They used words like "surprising," "sad," "concerning," "scary," and "shocking." There was also a strong



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tendency to describe the infection itself—even in the absence of disease—as distressing. In fact, the absence of symptoms in most cases of infection was commonly noted as concern. One respondent expressed fear saying "Well it's just, that's scary. You know...you just don't know if you have it or not" (P11, 19, Latino). Some of this worry was expressed as concern for "spreading" HPV to their sex partners or as discomfort with the idea of a "sitting virus kind of thing inside of you" that may cause future disease.

## Anogenital warts

Personal experience with anogenital warts—either having had anogenital warts or having had a sexual partner with anogenital warts—was closely tied to some of the participants' attitudes and beliefs surrounding HPV and HPV vaccination. Four out of the five participants who had received HPV vaccine described anogenital warts as a primary reason for getting the vaccine. In each of these cases, the men, or their sex partner at the time, were being treated for anogenital warts when a doctor recommended vaccination.

#### Sexuality and the patient-provider relationship

The majority of the young men in this sample had previous experience talking about their sexual behaviors in a health care setting—mostly while receiving STI testing. In almost all cases, the healthcare provider asked them questions about their sexual behaviors. In some cases these interactions were described as negative, affecting their expectations surrounding disclosure, their confidence in their healthcare providers, as well as the ways in which they managed disclosure in future interactions.

### Negative emotions surrounding disclosure

Feeling ashamed, awkward, and judged were some of the emotions associated with discussing sexual behaviors with a healthcare provider. These feelings stemmed in part from the



degree to which they felt their provider was comfortable with them. One participant captured this sentiment in his comments about his primary care physician:

I feel like he judges me. I feel like if I had a provider or somebody who is a little more open-minded... my doctor is a staunch Republican, white dude who is like 65 and I'm sitting there like a gay little Puerto Rican kid, and you know, it is just always awkward

when I go to my doctor. We come from opposite ends of the earth. (P12, 24, Latino) These negative experiences, or even the anticipation of a negative reaction, play a detrimental role in the relationship between these young gay males and their healthcare providers. This is particularly true when they are seeking treatment or information on sexual health related issues such as HPV vaccination.

## LGBT cultural competence of healthcare providers

Previous negative interactions with a health care provider influenced future expectations and perceptions regarding the overall cultural competence of healthcare providers in dealing with LGBT patients. There was a sense of having to know where a provider stands on issues related to sexuality for fear that he or she may be biased or even not competent in providing care. One participant stated:

I would just feel weird talking to someone about that [HPV vaccine], and I would not know their views on LGBT people. So I feel like there may be some bias in the

information that they could give me. Even though it's unprofessional. (P03, 19, Asian) Other participants questioned whether or not they would rely on their health care provider for information about HPV. For participants who felt confident in their providers, they tended to talk about the established rapport and trust that was proven over the course of multiple interactions. Some men expressed feeling more comfortable with female providers, noting that female



providers are more comfortable with gay men. Others thought they would get better care with a gay provider, one rationale being:

A gay provider would be more into or up-to-date with newer things that are coming out. Especially like with the threats that are more for the gay lifestyle. Because I really don't think that my health provider would know about HPV. (P12, 24, Latino)

The degree to which the patient-provider relationship would impact HPV vaccination was less clear. This relationship was important if it was perceived that asking for the vaccine would prompt a discussion of sexual behaviors. It was less important if the vaccine could be obtained without discussion of sexual history. In other words, the relationship was important for their comfort level regarding their sexuality, not in accepting a recommendation for vaccination. *Management of disclosure* 

When looking for sexual health services, some of the men I talked to will go to a clinic focused on STI testing (e.g., public health departments, planned parenthood, university medical services) even if they have an established relationship with a primary care provider. Because of the perceived stigma and fear of judgment, they value the privacy and anonymity provided by these venues when seeking sexual health services (including HPV vaccination). One participant stated:

Because I feel like my health care provider...I understand there is HIPA and all that stuff and they are suppose to keep my stuff confidential. But I live in a pretty small town and I know how that stuff works. So I'd rather not. I go to the health department and every time I go it is somebody different. It never gets personal. I've never build rapport with them. (P12, 24, Latino)



He actively manages situations in which he expects to be asked questions about his sexual behavior favoring the impersonal nature of some public health clinics. A similar concern was mentioned in another interview when the participant expressed worry that his family doctor could not be trusted to main his confidentiality.

Another strategy that participants used to manage discussions of sexuality with healthcare providers is to lie. If they felt particularly uncomfortable or if they believed their sexual behaviors were irrelevant, they reported being "selective" about what they disclosed or lying about their behaviors. Some men struggled with the idea that their sexuality was ever medically relevant citing "sex is sex" no matter the sex of their partners:

It is just like, it is none of their business who I am having sex with. There is the whole stigma about being gay that we are promiscuous people we just go around having sex with every guy we see and therefore are at higher risk...straight guys do that all the time too. (P15, 20, Latino)

While HPV did not come up directly in these conversations, it is clear that the relevance of any discussion of sexuality to determine eligibility or appropriateness of vaccination can be a sensitive issue for some male sexual minorities.

#### **Trusted sources of health information**

Overall men in this sample appeared accepting, interested, and engaged in discussions surrounding HPV and HPV vaccination. Many expressed positive intentions to get vaccinated or learn more about the vaccine. While the Internet was listed as the first source of health information, many of the participants expressed doubt in the dependability of the health information provided on many sites. They tended to adopt an information seeking strategy where they looked at a number of sources—usually the first few hits on a basic Google search—and



determined in some way if these sources were in agreement. Other standard sources of trusted health information were healthcare providers and family members who are connected to the healthcare industry in some way.

One interesting source of health information mentioned in several interviews were LGBT-focused centers or groups. These included community-based organizations that offer HIV-testing, HIV case management, and other social services for sexual and gender minorities. Participants recalled health information presented as part of counseling during HIV testing and during social group gatherings in which guest speakers were invited to talk about a variety of health issues. These were described as "welcoming" and "non-judgmental" environments and participants expressed a great deal of trust and respect for them. One participant mentioned that he would prefer to be vaccinated at one of these locations because he was going on a regular basis for HIV testing. In this sense it would be more convenient for him. Subsequent participants were asked about their thoughts/feelings about getting vaccinated at this type of organization (i.e., Community-based LGBT health clinic or HIV testing site). They were overwhelmingly in support of that option. The main reason against this option was that the medical staff would not know their specific medical history and thus would not be able to identify the potential health consequences of getting vaccinated. Overall community-based LGBT organizations were identified as a desirable alternative location for HPV vaccination.

#### Phase 2 Results: Quantitative Survey

## Sample characteristics

See Table 2 for complete demographic characteristics of the study sample. Participants were on average 22 years old (SD = 2.43). They were primarily white (63%) college students



(58%) with health insurance (83%) who had a place they usually go to for "routine medical care" (74%). The majority identified as gay (75%), but a significant proportion identified as bisexual (22%). The number of lifetime male sexual partners was widely varied. Fifty-three (9%) respondents reported no male partners. The median number of male sexual partners was 6 (Interquartile range = 13).

Most were HIV-negative (67%); however, over a quarter reported never being tested (27%). Among those who have received an HIV test, 50% were not tested within the previous year. Nearly 15% reported ever being diagnosed with Gonorrhea, Chlamydia, Syphilis, herpes, or Trichomoniasis. Four percent reported a previous diagnosis of genital or anal warts.

Overall awareness of the HPV vaccine was limited. After being provided with the following information, a minority of participants (39%) indicated that they had previously heard of the HPV vaccine.

A vaccine to prevent HPV (human papillomavirus) infection is available and is referred to by several names, such as: the HPV shot, cervical cancer vaccine, GARDASIL®, or CERVARIX®. The HPV vaccine is approved for males Currently, the HPV vaccine requires 3 shots given over 6 months. The HPV vaccine is proven safe and effective at preventing genital warts and cancers caused by HPV (e.g., Anal Cancer). The HPV vaccine is recommended by the Centers for Disease Control and Prevention (the CDC) for men who have sex with men who are 26 years of age or younger.

Most participants (63%) also indicated that they did not personally know someone who has received the vaccine. And only 8% indicated that a doctor or health care provider recommended that they get the HPV vaccine (note that this study excluded men who had already initiated HPV vaccination).



## Descriptive and bivariate statistics of HPV-related beliefs

## Behavioral beliefs

The 10 behavioral beliefs elicited from Phase 1 are presented in Table 5 along with the means for beliefs strength  $(b_1)$ , outcome evaluations  $(e_1)$ , and the product of the belief strength and outcome evaluation  $(b_1e_1)$ . The means associated with perceived physical and psychological advantages were all greater than the neutral mid-point of the scale (>3) indicating an overall positive perception of HPV vaccination. The disadvantages of vaccination were generally perceived as unlikely to occur. Outcome evaluations were only assessed for side effects. On average, participants indicated little concern regarding vaccine side effects. All of behavioral beliefs had significant correlations in the expected direct with the direct measure of attitude—that is perceived advantages positively correlated with a positive attitude toward vaccination and perceived disadvantages negatively correlated with a positive attitude toward vaccination.

An expectancy-value index of belief strength and evaluation was calculated ( $\Sigma b_i e_i$ ) reflecting the salient physical and psychological advantages that underlie attitudes toward HPV vaccination among this population. There was a strong positive correlation between this index and the direct measure of attitude suggesting that the more participants endorsed this set of behavioral beliefs, the more positive their attitude toward HPV vaccination.

# Normative beliefs

Table 6 contains the normative referents assessed with regard to obtaining HPV vaccination within the next 12 months. All of the referents were perceived as being supportive of a decision to get vaccinated; however, the value of their influence with regard to this decision was low (see values for  $m_i$ ). The degree of social influence is indicating by the expectancy-value indicators  $(n_1m_1)$  with anything greater than 9 (the midpoint) indicated some degree of positive



influence to get vaccinated. The most frequently mentioned referent group was gay male friends who did have a degree of social influence over decisions regarding HPV vaccination. The least influential individuals, just at the midpoint of the index, were fathers. All normative referents contributed positively to perceived norms as indicated by moderate positive correlations. Similarly, the expectancy-value index of normative referents ( $\Sigma n_i m_i$ ) was positively correlated with the direct measure of perceived norms.

## Control beliefs

Table 7 contains the influence of control beliefs on perceived behavioral control associated with getting the HPV vaccine within the next 12 months. These beliefs are looking at facilitators of vaccination. In particular, having health insurance over the next 12 months was strongly endorsed by participants as a key factor influencing their ability to get vaccinated. An examination of the expectancy-value indicators  $(c_1p_1)$  shows that health insurance is the strongest facilitator of vaccination followed by making vaccine available at HIV testing locations. All of the control beliefs exhibit small to moderate correlations with perceived behavioral control. Participants expressed a moderate degree of self-efficacy in getting vaccinated if they had to discuss their sexual orientation with a healthcare provider. Self-efficacy was also positively associated with perceived behavioral control.

# Descriptive and bivariate statistics of model variables

Scale means, standard deviations, coefficient alphas, and zero-order correlations for all scales are presented in Table 8. All scales exhibited at least acceptable internal consistency ( $\alpha$  >.65), which is sufficient for the purpose of this research. The mean for the main outcome variable, HPV vaccine intentions, was greater than but close to the scale midpoint (midpoint = 3), suggesting positive vaccine intentions with widespread indecision.



Behavioral beliefs	Belief strenoth		Outcome		bıeı		Correlation
	(b <sub>i</sub> )		(e <sub>i</sub> )				attitude
	Μ	SD	Μ	SD	Μ	SD	
Physical advantages							
It would make me healthier	3.29	1.02	4.34	0.70	14.48	5.54	0.42*
It would prevent me from getting genital and anal warts	3.86	1.00	4.31	0.86	16.84	5.86	0.40*
It would prevent me from getting anal cancer	3.66	1.04	4.40	0.86	16.31	5.97	0.39*
Psychological advantages							
Feel protected from HPV	4.11	0.85	3.73	1.00	15.64	5.88	0.51*
Feel like there is one less thing to worry about	3.89	1.06	3.98	1.00	15.90	6.56	0.47*
Less likely to spread HPV to future sex partner(s)	4.22	0.86	4.11	0.94	17.64	5.90	0.39*
Expectancy-value index for physical/psychological advantages of					96.76	29.34	0.53*
HPV vaccination (Σb <sub>i</sub> e <sub>i</sub> )							
Disadvantages							
I will contract HPV from the vaccine <sup>a</sup>	1.98	1.11	1	1	ł	ł	-0.17*
Not completely protected from future HPV infections <sup>a</sup>	2.80	1.06	1	1	ł	ł	-0.22*
The vaccine may not work for me <sup>a</sup>	2.54	0.99	1	ł	ł	ł	-0.26*
I would have side effects	2.69	1.00	2.79	0.92	7.83	4.34	-0.25*

Table 5: Behavioral beliefs associated with HPV vaccination and correlations with attitudes

b<sub>l</sub>e<sub>l</sub> ranges from 1 to 25 with higher values indicating likely and important beliefs <sup>a</sup> Outcome belief was not assessed. Correlation coefficient represents correlation with belief strength and attitude

\**p*<.05

$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Normative beliefs	n	Belief		Motivation		$\mathbf{n}_{1}\mathbf{m}_{1}$		Correlation
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			strength		to comply				n <sub>1</sub> m <sub>1</sub> with
$\begin{array}{cccccccccccccccccccccccccccccccccccc$			(n <sub>i</sub> )						norm
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$			Μ	SD	Μ	SD	Μ	SD	
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Mother	513	3.91	1.32	3.19	1.66	13.29	8.72	0.40*
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Father	445	3.48	1.39	2.57	1.59	9.83	8.10	0.33*
531     3.86     1.14     2.95     1.44     12.00     7.55       2 index for normative referents (Σn <sub>i</sub> m <sub>i</sub> )     48.65     22.96	Gay male friends	521	4.19	0.99	3.57	1.43	15.35	7.58	0.39*
48.65 22.96	Straight friends	531	3.86	1.14	2.95	1.44	12.00	7.55	0.35*
	Expectancy-value index for normative referents $(\Sigma n_i m_i)$						48.65	22.96	0.45*

Table 6: Normative beliefs associated with HPV vaccination and correlations with perceived norms

Table 7: Control beliefs associated with HPV vaccination and correlations with perceived behavioral control

Belief strength		Perceived power (p <sub>i</sub> )		c <sub>1</sub> p <sub>1</sub>		Correlation c <sub>1</sub> p <sub>1</sub> with
(c <sub>i</sub> )		,				PBC
Μ	SD	Μ	SD	Μ	SD	
3.85	1.01	4.09	1.07	15.79	6.10	0.37*
4.20	1.02	4.02	1.21	18.97	6.45	0.44*
3.13	1.10	4.44	1.02	12.44	5.90	0.22*
3.87	1.13	4.04	1.23	16.21	7.24	0.18*
				63.15	0.85	0.42*
						0.42*
	Belief strength (c;) M 3.85 4.20 3.13 3.87		SD 1.01 1.02 1.10 1.13	SD 1.01 1.02 1.10 1.13	Perceived power (pi)           SD         M         SD           1.01         4.09         1.07           1.02         4.02         1.21           1.10         4.44         1.02           1.13         4.04         1.23	Perceived power (p;)           SD         M         SD           1.01         4.09         1.07           1.02         4.02         1.21           1.10         4.44         1.02           1.13         4.04         1.23

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	1	2	ω	4	J	6	7	8	9	10	11	12	13	14	15	16
1. Intention	1															
2. Attitude	.47*	1														
3. PHY Advantages	.47*	.46*	1													
4. PSY Advantages	.54*	.50*	.68*	1												
5. Low efficacy	19*	27*	19*	21*	1											
6. Contract HPV	.00	17*	.03	.01	.51*	1										
7. Side effects	06	25*	02	01	.45*	.51*	1									
8. Norms	.43*	.39*	.49*	.54*	14*	01	01	1								
9. Normative beliefs	.26*	.18*	.31*	.38*	12*	.06	04	.45*	1							
10. PBC	.27*	.16*	.14*	.20*	16*	14*	16*	.17*	.13*	1						
<ol> <li>Control beliefs</li> </ol>	.35*	.30*	.33*	.38*	16*	10*	03*	.30*	.32*	.42*	1					
<ol> <li>Self-efficacy</li> </ol>	.14*	.11*	.22*	.17*	09*	02	03*	.16*	.20*	.24*	.23*	ł				
13. Threat	.28*	.27*	.33*	.35*	08	.07	.08	.27*	.24*	.07*	.18*	.04	ł			
14. Information-O	.26*	.12*	.26*	.32*	.09*	05	.06	.23*	.21*	.18*	.35*	.23*	*80.	ł		
15. LGBT-SUS	02	.00	.02	.02	.06	.16*	.13*	01	<del>-</del> .10*	13*	10*	51*	.01	16*	1	
16. Concealment	04	.04	04	00	01	12*	01	12*	02	04	.01	23*	.03	03		1
Mean	3.26	4.23	47.57	49.19	2.67	1.97	7.84	3.75	48.66	3.76	63.15	3.42	9.51	4.24		45.66
Standard Deviation	1.07	.80	15.20	16.82	.90	1.11	4.34	.79	22.96	.85	18.06	1.26	4.99	.69	.86	26.08
Cronbach's alpha	.90	.86	.85	.91	.71	1	1	.70	.76	.70	.66	.90	.96	.80		.71

Table 8: Scale means, standard deviations, coefficient alphas and zero-order correlations for scales

Nebraska Uutness Scale-Concealment Subscale \*p < .05

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Overall participants expressed positive attitudes toward vaccination, supportive norms, and perceived control over their decision to get vaccinated. The mean perceived threat score was below the scale midpoint (midpoint = 12.5) indicating low levels of concern among this sample.

Zero-order correlations provided initial support for the proposed relationships. As expected, attitudes, norms, and perceived control/efficacy exhibited statistically significant correlations with behavioral intention. In turn, each of these main determinants of intention were significantly correlated with their respective belief measures (i.e., attitudes with behavioral beliefs, norms with normative beliefs, and perceived behavioral control with control and efficacy beliefs). Notable relationships among background factors include: (1) positive correlations between perceived threat and behavioral beliefs; (2) positive correlations between information orientation and behavioral beliefs; (3) negative correlation between Outness-concealment and self-efficacy; (4) negative correlation between LGBT-SUS and self-efficacy; and (5) positive correlation between LGBT-SUS and Outness-concealment.

## Test of an integrative model of HPV vaccine decision-making

Structural equation modeling was used to test a comprehensive model of HPV vaccine decision-making. In addition to the propositions examined above, the following relationships were also modeled because of the theoretical importance identified in Phase 1 qualitative interviews (See Figure 4): (1) HIV-positive men will exhibit higher levels of perceived threat than HIV-negative men; (2) men in monogamous relationships will exhibit lower levels of perceived threat compared to men not in monogamous relationships; (3) men with a history of anogenital warts will exhibit higher levels of perceived threat compared to other men; (4) knowing someone who received the HPV vaccine will be positively associated with normative beliefs; (5) bisexually identified men will score higher on outness-concealment than other MSM;



(6) bisexually identified men will score higher on the LGBT-SUS scale; (7) outness-concealment will be positively associated with LGBT-SUS.

## Measurement model

Confirmatory factor analysis of the measurement model found poor absolute fit of the data to the latent factors,  $\chi^2(df) = 4.28.76$  (254), p<.001; however, the chi-square test is highly sensitive to sample size so additional fit indices were examined. All three fit indices suggested the measurement model fit the data well (RMSEA = .04 [90% CI: .03, .04], CFI = .97, SRMR = .04). Item-to-factor correlations are presented in Table 9. All items significantly loaded on their respective factor. No modifications to the measurement model were warranted.

# Structural model

The initial structural model tested 28 propositions or structural relationships. This model had poor fit among all but one of the indices examine:  $\chi^2(df) = 1808.28$  (640), p<.001; RMSEA = 0.06 [90% CI:.05, .06]; CFI = .85; SRMR = .10. The following relationships were not statistically significant (p > .05): Low efficacy  $\rightarrow$  Attitudes (B = -.04; 95% CI = -.11, .04); Contract HPV  $\rightarrow$  Attitudes (B = -.04; 95% CI = -.10, .02); Perceived Threat  $\rightarrow$  Contract HPV (B =.02; 95% CI = .00, .04); Communication-orientation  $\rightarrow$  Contract HPV (B = -.09; 95% CI = -.24, .06); Perceived Threat  $\rightarrow$  Side effects (B = .08; 95% CI = -.00, .16); Communicationorientation  $\rightarrow$  Side effects (B = .33; 95% CI = -.34, .93); Knew someone who got vaccinated  $\rightarrow$  Normative beliefs (B = -3.73; 95% CI = -7.16, .10); and having a medical home  $\rightarrow$  Control Beliefs (B = 3.11; 95% CI = .46, 5.91). These paths were removed from the model one at a time starting with the weakest relationships (indicated by lower  $\beta$  values). A total of eight paths were removed. The revised model (model 2) approximated acceptable fit: :  $\chi^2(df)$ = 1132.22 (503), p<.001; RMSEA = 0.05 [90% CI:.04, .05]; CFI = .91; SRMR = .10. Mplus



modification indices were examined to determine if any theoretically relevant paths could be added to the model in order to increase fit. Based on this information three additional paths were added: (1) a direct path from Physical/Psychological benefits to intention; (2) a direct path from perceived threat to normative beliefs; and (3) a direct path from communication-orientation to normative beliefs. In addition, control beliefs were allowed to covary with Physical/Psychological benefits and normative beliefs. This model exhibited adequate fit and is of theoretical importance:  $\chi^2 (df) = 1265.48 (507)$ , p<.001; RMSEA = 0.05 [90% CI:.05, .06]; CFI = .91; SRMR = .09.

Determinants of intention. Standardized parameter estimates for the final model (model 3) are depicted in Figure 5. As is shown, the largest direct effects on HPV vaccine intentions are from Physical/Psychological benefits ( $\beta = .32$ , B = .01; 95% CI = .01, .01) and attitudes ( $\beta = .27$ , B = .25; 95% CI = .17, .34). This is a slight deviation from the original model where the effect of Physical/Psychological benefits is completely mediated by attitudes. Perceived norms had a small association with intention ( $\beta = .12$ , B = .12; 95% CI = .02, .20). Perceived behavioral control had a moderately strong association with intentions ( $\beta = .23$ , B = .31; 95% CI = .20, .44).

*Structure of beliefs*. There were five key characteristics of HPV-related beliefs that underscore the main determinants of intention. This included beliefs regarding the physical/psychological benefits of vaccination, which was strongly correlated with positive attitudes ( $\beta = .55$ , B = .02; 95% CI = .01, .02). Concern about potential side effects was negatively associated with attitudes ( $\beta = -.25$ , B = -.05; 95% CI = .06, -.03). As was expected, normative, control, and efficacy beliefs were each positively associated with their respective determinant; however, the relative association of self-efficacy with perceived behavioral control was low compared to the others.



Antecedents of beliefs. The strongest antecedents of HPV-related beliefs were perceived threat, suspicions of LGBT cultural competence, and information orientation. The larger perceptions of threat the higher the perceived benefits of vaccination ( $\beta = .34$ , B = 2.27; 95% CI = 1.82, 2.75). In addition, the perceived benefits of vaccination were higher among those with higher levels of health information orientation ( $\beta = .31$ , B = 12.79; 95% CI = 8.90, 16.36). There was also a strong negative association between those expressing suspicion of LGBT cultural competence and self-efficacy ( $\beta = .56$ , B = -1.63; 95% CI = -2.05, -1.32).

Socio-demographic targets. HIV positive men had higher levels of perceived threat ( $\beta$  = .13, B = 2.34; 95% CI = .74, 3.83). Inversely, men in monogamous relationships reported lower levels of threat ( $\beta$  = -.18, B = -1.67; 95% CI = -2.25, -1.04). Bisexual identification was positively associated with both outness-concealment ( $\beta$  = .10, B = 5.91; 95% CI = 1.46, 10.37) and suspicions of LGBT cultural competence ( $\beta$  = .21, B = .23; 95% CI = .14, .31).

*Indirect effects.* Indirect effects are displayed in Table 10. In general, the indirect effects were relatively small. The most theoretically meaningful indirect effects are from the salient belief measures to intentions, mediated by the main determinants of behavior (i.e., attitudes, norms, perceived control/efficacy). All of these indirect paths were statistically significant and among the largest indirect paths identified in the model.

# Phase 3 Results: Open-Ended Survey

The purpose of the open-ended survey was to further identify salient beliefs, information needs, and trusted information sources, as well as underlying background factors that influence HPV vaccine decisions among young MSM. This was accomplished through the use of a vignette that provided context for thinking about vaccination and subsequent open-ended questions.



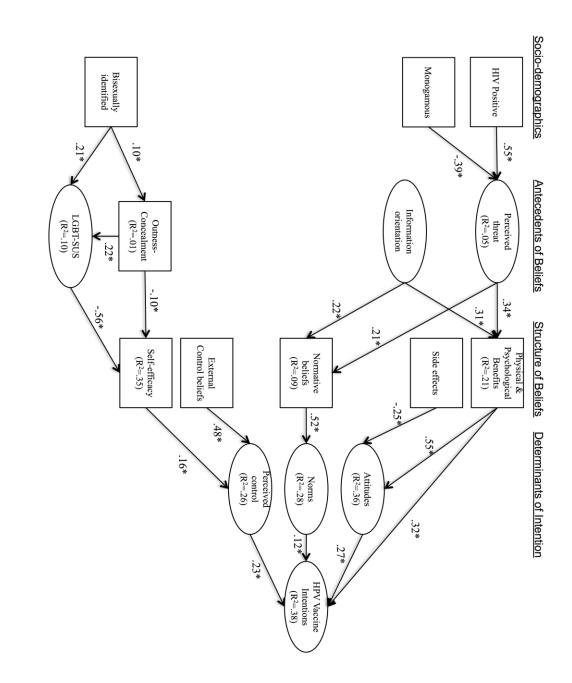
Latent factor title in bold	$\beta$ (SE)
Vaccine Intentions	
Find out more information about the HPV vaccine within the next 12 months	.72 (.03)
Make an appointment to talk to a doctor about the HPV vaccine within the next 12 months	.93 (.02)
Get your first HPV shot within the next 12 months	.94 (.01)
Direct Attitude	
Not worth it - Worthwhile	.81 (.03)
Harmful - Beneficial	.77 (.03)
A bad thing for me – A good thing for me	.80 (.03)
Unimportant – Important	.80 (.03)
Ineffective - Effective	.72 (.03)
Direct Normative influence	
People who are important to me would encourage me to get the HPV vaccine	.75 (.04)
I can think of at least one person in my life who would like for me to get the HPV vaccine	.74 (.04)
Most of my gay/bisexual male friends would get the HPV vaccine if it was offered to them free of	.52 (.04)
charge	
Direct Perceived Behavioral Control	
There are factors beyond my control that would prevent me from getting the HPV vaccine	.49 (.04)
I am confident that I can get the HPV vaccine in the next 12 months	.84 (.04)
Getting the HPV vaccine sometime in the next 12 months would be: Impossible for me—Possible	.67 (.04)
for me	
Perceived Threat	
Threat of HPV infection	.82 (.03)
Threat of Anal Warts	.93 (.02)
Threat of Genital Warts	.94 (.01)
Threat of Anal Cancer	.82 (.03)
<b>Information Orientation</b> When I take medicine, I try to get as much information as possible about its benefits and side effects	.80 (.04)
Before making a decision about my health, I find out everything I can about the issue	.83 (.03)
It's important to me to be informed about health issues affecting gay and bisexual men	.63 (.05)
Suspicion of LGBT Cultural Competence	
I have received lower quality healthcare services as a result of my sexual orientation	.41 (.05)
I prefer that my doctor or healthcare provider does not know that I am gay/bisexual	
	.80 (.04)
I feel uncomfortable talking about my sexual orientation or sexual behaviors with a doctor or HCP	.67 (.04)
There is no reason why a doctor or health care provider would need to know that I have sex with	.61 (.04)

#### N = 569

All factor loadings are statistically significant (p < .05)



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N = 568; Parameter estimates are standardized regression ( $\beta$ ) weights. Model Fit Statistics:  $\chi^2$  (df) = 1265.48 (507), p<.001; RMSEA = .05 (90% CI: .04-.05); CFI = .91; SRMR = .09



Indirect paths	β	(SE)	р
Benefits—Attitudes—Intention	.15	(.03)	*
Side effects—Attitudes—Intention	07	(.02)	*
Normative beliefs—Norms—Intentions	.06	(.03)	*
External control beliefs—PBC—Intentions	.11	(.03)	*
Self-efficacy—PBC—Intentions	.04	(.01)	*
Outness—Self-efficacy—PBC—Intentions	00	(.00)	ns
Outness—LGBT-SUS—Self-efficacy—PBC—Intention	01	(.01)	*
LGBT-SUS—Self-efficacy—PBC—Intentions	02	(.01)	*
Bisexual—LGBT-SUS—Self-efficacy—PBC—Intentions	00	(.00)	ns
Bisexual—Outness—Self-efficacy—PBC—Intentions	.00	(.00)	ns
Threat—Benefits—Attitudes Intentions	.05	(.01)	*
Information-O-Benefits-Attitudes-Intentions	.05	(.01)	*
HIV-Positive—Threat—Benefits—Attitudes—Intentions	.02	(.01)	*
Monogamous—Threat—Benefits—Attitudes—Intentions	02	(01)	*

Table 10: Indirect effects on HPV vaccine intention

N = 568; Benefits = Physical and psychological benefits; PBC = Perceived behavioral control;

Information-O = Information orientation; LGBT-SUS = Suspicion of LGBT cultural

competence Scale; Concealment = Nebraska Outness Scale-Concealment Subscale

\*p<.05

As such Phase 3 serves as a confirmatory check on the findings from the Phase 1 semi-structured interviews. The goal of this analysis was to identify new information that was not uncovered in the interviews and to shed more light on the decision-making process undergone by MSM when thinking about HPV vaccination.

The results for this phase are presented along with the vignette that was used to elicit responses. This helps to put the findings in context and highlights the key elements involved in the decisions surrounding HPV vaccination. The first part of the vignette focused on general HPV information as is shown below.

One respondent commented that "Most information I have heard about it was straight female centric" (P25, 24, White), which was a belief supported by other men who made explicit mention of cervical cancer. One participant commented that, "The statistic took me aback because it's quite personal- it affects me on a personal level because I am gay and have anal sex quite often" (P26, 21, Latino).



# **Vignette Part 1: HPV information**

Please read Brandon's story and respond to the questions. There are 3 short sections to his story and each has a set of questions and areas for you to provide your thoughts. This story is based on the experiences of real people who previously participated in this study.



Figure 6a: Part 1 of the vignette

What is HPV?	Why you should care?
<ul> <li>HPV is a sexually transmitted virus that you can get from skin-to-skin contact during all types of sexual activites</li> <li>Most people will become infected with HPV in their lifetime</li> <li>Most of the time HPV has no symptoms so people don't know they have it</li> </ul>	<ul> <li>For most people, HPV goes away on its own but if it doesn't it can cause genital and anal warts and some types of cancers including anal cancer</li> <li>Men who have sex with men are 17 times more likely to develop anal cancer than other men</li> </ul>
How to pr	event HPV?
<ul> <li>Gardasil—the HPV vaccine— cancers caused by HPV</li> </ul>	-protects against genital warts and
-	d for men 26 years old and younger.

Figure 6b: Part 1 of the vignette



Others reiterated this thought mentioning, "For something so prevalent among MSM it isn't often talked about" (P27, 18, White). It was mentioned by one respondent, "cancer is a serious disease which I didn't know men were vulnerable to based on their sexual habits" (P28, 26, White).

Of the 102 participants who commented on the information, 32% mentioned that the asymptomatic nature of HPV infection was particularly "alarming." There was concern that "people can be spreading this around without realizing it" (P29, 23, White) or that they "could pass something that doesn't outright affect you but might the next person" (P30, 21, White). This was also noteworthy to some men who expressed a belief that most sexually transmitted infections result in clinical symptoms.

Anogenital warts were mentioned much less than cancer, suggesting that warts are the most common characteristic associated with HPV among this population. In fact some respondents explicitly mentioned that they "already knew this" or disclosed that they previously had anogenital warts. With that said, 16% mentioned the fact that HPV can result in anogenital warts as impactful.

Interestingly, approximately 16% of respondents commented on the age recommendation as noteworthy. In most of these cases they were surprised of the upper age limit and inquired as to why the vaccine isn't recommended for men of all ages. This finding is highlighted in the following remark: "The age recommendation also stood out to me - surely men over 26 are still sexually active, so why are they not recommended to get it as well" (P31, 22, White)? This suggests that even among those who are aware that the HPV vaccine is licensed for use in males, they are unaware of the specific vaccine recommendations for MSM and the reasons behind this recommendation.



# **Vignette Part 2: Decision uncertainty**



After reading this information about HPV, Brandon was a little worried. He thought HPV was only something women could get. And while he almost always uses protection when he hooks up, he couldn't help but wonder if he has HPV. But Brandon wasn't going to let it bother him. He got his drink and went back to his friends.

The next day Brandon googled HPV vaccine and read more about it. He read that GARDASIL is given as 3 injections over 6 months and that the ideal time to get vaccinated is before becoming infected with HPV.



Brandon isn't sure if he can be vaccinated. He is already 18. He's not what his friends would consider "slutty" but he certainly isn't a virgin either. He wonders how he would know if he's been exposed to HPV.

Figure 7: Part 2 of the vignette

# Making a decision: what to do and why?

Out of the 102 responses regarding what Brandon should do, 47 (46%) suggested that Brandon should consult with a doctor or primary care provider. Some specified a "trusted" or "reliable" provider with whom Brandon would feel comfortable discussing his sexual history in order to make a good decision about vaccination. For example, one participant stated: "He should talk to his doctor and get advice on what to do and to see if Gardasil is the right choice for him after being very honest about his sexual behavior" (P32, 24, White). Collectively the primary care provider served as the main referent or source of informational support regarding HPV vaccination.



About 29% recommended that Brandon get tested for HPV in order to determine if he should get vaccinated. There was a common misperception that HPV testing is routinely done during STI screening for males. The thinking behind this recommendation is expressed in the following quote: "The first step should be for him to determine his risk, getting tested for the virus and based on those results, proceed with vaccination/treatment" (P23, 22, Black). Inherent in this example, and in similar responses, is the notion that one can know his HPV "status" and make appropriate health decisions based on that information. There was also a sense of responsibility in knowing one's status:

It's important to know your health status when having sex with others (moral and public health issue). If he finds out his status he can make more informed opinions about preventing the spread of HPV or preventing infection from HPV. (P33, 23, White) These comments evince a limited understanding of HPV infection, available testing procedures, as well as recommendations on vaccination.

It should be noted that the majority of comments were in favor of Brandon getting vaccinated even if they suggested he should consult a health care provider first. However, there was one participant who stated that Brandon "doesn't need it" because "He's 25 and the shot is recommended if you're under 26 so he's close to not needing it" (P34, 25, White). This was not a view shared by anyone else but represents an interesting perspective—and perhaps an unintended consequence of the age-based vaccine recommendation. For other men the upper age limit elicited a sense of urgency since they perceived themselves as coming close to "aging out."



Vignette Part 3: The threat of anal warts

A few weeks passed and Brandon mostly forgot about HPV until one afternoon the topic came up while he was hanging out with his friend Jeremy. Jeremy and Brandon are best friends, and they share everything. It turns out Jeremy just found out he has anal warts!

# PICTURE OF ANAL WARTS GOES HERE

He told Brandon he was having some "issues down there" so he went to get it checked out. He spared Brandon the details but told him that "they aren't pretty." Luckily the warts were all on the outside around his anus so the doctor was able to freeze them off so he didn't need surgery. Jeremy was worried that the warts might come back since there is no cure. Brandon was supportive as usual and reassured his friend. But deep down he was freaking out.



After hearing about Jeremy's experience Brandon decided that he wanted to get the HPV vaccine. He didn't EVER want to get anal warts. He didn't care if he had already been exposed to HPV. If there was any chance that the HPV vaccine would prevent warts or cancer he thought it was worth it.

# Figure 8: Part 3 of the vignette

# Deciding to get vaccinated: Good or bad?

In the vignette, Brandon made an explicit decision to get vaccinated. Out of the 102

participants who responded, 80% said they would have done the same thing (i.e., decided to get

the HPV vaccine). These men described Brandon's decision as "reasonable," "wise," and

"smart." The fact that someone Brandon knew had anal warts influenced their thinking of the

issue as is noted in the following comment:



I think it's a good decision. The shots are definitely a no brainer over getting HPV and anal warts. Finding out somebody you know has it makes it hit more close to home than a poster. (P35, 22, White)

Many of their comments regarding Brandon's decision described behavioral beliefs endorsing the physical and psychological advantages to HPV vaccination. The same participant described the value of vaccination:

If it's as prevalent as the poster says, then why not take the extra step to prevent against it. Sure getting 3 shots over 6 months is a little inconvenient, but so are anal warts and cancer. If Gardasil is effective, why not get the shots and have one less thing to worry about? A small price to pay for peace of mind. (P24, 22, White)

Other comments referred to protecting partners and contributing "to stopping the spread of HPV." Overall there was a large focus on the importance of prevention and being "better safe than sorry." There were minimal concerns about risks associated with vaccination. While no participant noted any specific concerns, some made statements that "you shouldn't blindly put something in your body, the more knowledge the better," (P36, 21, White) and that they would do their own research to determine if the "peace of mind outweighs the inconvenience and whatever side effect may exist" (P37, 26, White).

Despite their own stated beliefs in the advantages to getting vaccinated, some men who indicated they would get vaccinated explained that this was something they would approach with little urgency. One man said he would:

Ask my doctor at my next appointment if he or she thinks I should get the HPV vaccine (or test to see if I already have it). I don't know if I would necessarily make a new



appointment specifically for that question, because it doesn't seem like an immediate concern. (P33, 23, White)

Another man described his low motivation to get vaccinated:

I think that I should get the vaccine but probably not get it just because it doesn't seem like an impending danger. Out of sight out of mind. (P38, 21, White) Both of these men described their perceived susceptibility to HPV infection as "average" and indicted that they were "slightly" or "somewhat" concerned about becoming infected with HPV. These participants are in contrast to those who described themselves as "Moderately" or "Extremely" concerned about HPV infection and who subsequently advocated for Brandon to take more immediate action (e.g., "get the shots ASAP").

These findings represent the importance of perceived threat in the justifications explaining vaccine decisions. Those who perceived their risk as low referred to what they believed as limited exposure: "Unlike Brandon I don't hook-up and have had sex with only a few people in my life so my chances of already contracting it would be low" (P39, 25, White). Similarly, being in a "monogamous" relationship was used to justify a limited concern regarding HPV infection and vaccination. Other respondents countered these claims stating, "all you need is one exposure" (P40, 23, White) or "regardless of how much or as little he is having, it is still possible that he will get HPV" (P41, 22, White). For some, learning that penetration isn't necessary for HPV transmission elicited threat. One man wrote: "…anal penetration isn't even necessary; you can get it through skin contact. Scary" (P42, 24, Asian).

There was some ambivalence about Brandon's decision with 15% stating they were "Not sure" if they would have decided to get vaccinated and 5% said they would not have been vaccinated. These men described Brandon's decision as "reactive" and "emotional." They



expressed a strong need for more information and a desire to seek medical advice prior to making any decisions. The men selecting "Not sure" (N = 15) questioned the efficacy of getting vaccinated in the event that they have already been exposed. This group also tended to focus on the importance of getting tested before making a decision. Many of these comments are represented by the following statement:

There are many factors to consider. Getting tested to see if I do not have HPV/HIV, then looking to see where I can get the Vaccine, cost, travels, measures, actions. Although I would have researched more on HPV then talked about it to a GP or headed to a health clinic to find further information. Aside from this I had so many vaccines in my life that I later found out are for other things as well, so I would need to look at my full medical history to see if I am applicable for the vaccine, as well as other factors like allergies etc. that may cause problems. However this would all be discussed with my doctor. (P43, 23, Asian)

The men who indicated they would not get vaccinated described three distinct rationales: (1) they already made a decision not to get vaccinated; (2) they do not need the vaccine because they are not at risk; and (3) they have already been exposed to HPV so the vaccine would not confer any benefit. One of the participants commented that "one experience isn't enough to change my mind" (P34, 25, White) suggesting that Brandon is reacting to a unique situation. Others mentioned that they are "not very promiscuous" or not sexually active as reasons not to get vaccinated.



## **Vignette Part 4: Trusted sources**

## Preferred places to get vaccinated

The final passage of the vignette was used to determine where the participants would prefer to go to get vaccinated as well as any issues they perceive discussing sexuality and/or sexual behavior with their providers. The passage of the vignette read:

Brandon wanted to get the HPV vaccine but he didn't know where to go to get it. He doesn't really like going to the doctor and feels a little awkward asking a healthcare provider about the HPV vaccine since it's an STD. He knows it's unprofessional but sometimes thinks that doctors judge him for his sexual behaviors.

Participants were asked "Where would you go to get the HPV vaccine if you were in Brandon's situation?" Seven categories of locations were described and are numbered in order of the frequency in which they were mentioned: (1) Primary care doctor, (2) University/College health center, (3) Walk-in or Community Clinic, (4) Planned Parenthood of STI clinic, (5) LGBT-focused/friendly clinic or provider, and (6) Pharmacy. A number of participants indicated that they were unsure about where to go to get vaccinated.

Next, participants responded to a structured question asked about the likelihood (unlikely-likely) of them getting vaccinated at the four hypothetical locations: (1) HIV testing site, (2) Pharmacy with a walk-in clinic, (3) Primary care provider's office, and (4) a communitybased health clinic servicing LGBT people. Participants were provided with a description of each location (see appendix 3). All of the locations were acceptable by a majority of respondents (see Table 3).



Participants were then prompted to explain what they liked about the locations where they were likely to get vaccinated and what they did not like about the other locations. Responses were coded and added to Table 11 for comparison.

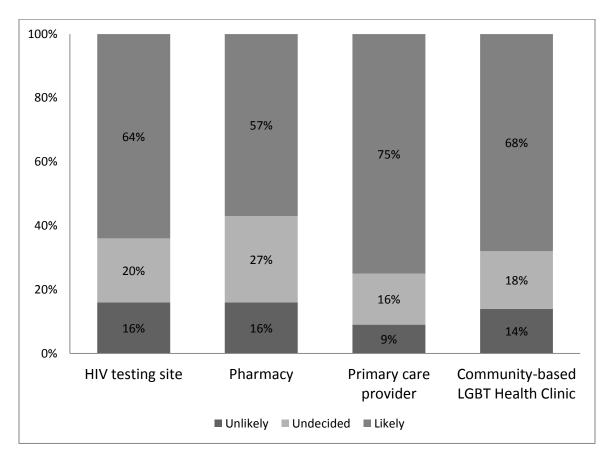


Figure 9: Acceptability of locations for HPV vaccination

Similar responses (e.g., LGBT friendly and accepting environment) were combined into one category. A characteristic was considered present for a location if more than one participant mentioned it (see Table 11).

The perceived benefits associated with HIV-testing sites included convenience, which was often described as not needing an appointment and going to a location that they already



utilize for HIV testing. These locations were described as discrete where they did not have established relationships with any one provider. Participants also believed that HIV-testing sites would be LGBT friendly and have staff that is more knowledgeable about LGBT health issues. Common concerns included the lack of availability of such locations in more rural areas, that some participants were unfamiliar with them, and that they seemed less private than a primary care provider's office. There was also some concern that going to a location associated with HIV could be stigmatizing.

Categories	HIV testing sites	Pharmacy	Primary care provider	LGBT Clinic
Benefits				
Convenient	Х	Х		
Widely Available		Х		
Discrete	Х			Х
Multiple medical services	Х		Х	
Familiar			Х	
LGBT Friendly	Х			Х
Focus on LGBT health	Х			Х
Know medical history			Х	
Privacy			Х	
Concerns				
Lacks privacy	Х	Х		Х
Not available	Х		Х	Х
Stigmatizing	Х			
Unfamiliar	Х	Х		Х
Customer-focus		Х		
Judgmental		Х	Х	
Lacks knowledge of LGBT health			Х	
Lacks medical professionalism		Х		Х

Table 11: Perceived benefits and concerns of hypothetical locations to receive HPV vaccinations

The primary benefits ascribed to pharmacies were their convenience and widespread availability-although one participant noted that no pharmacies in his small town offered medical services. The concerns over being vaccinated at a pharmacy included lack of privacy and being unfamiliar with receiving these types of services at these locations. Participants also



noted the customer-focus vs. patient-focus of pharmacies as well as a fear of judgmental or unprofessional staff as concerns.

The primary care provider was the most likely source of HPV vaccination mentioned by participants. Many of them said that they prefer this location for vaccination because their providers were familiar to them and knew their medical history. The ability to ask for the vaccine while receiving other medical services was also stated as a benefit. However, participants without a primary care provider noted the lack of availability. There was some concern that primary care providers—some of which were family doctors—would lack knowledge specific to LGBT health issues. And although some noted the patient-provider relationship as increasing their sense of privacy, others explicitly mentioned a concern that their provider might disclose personal information to family members. There was also the fear that a provider might be judgmental and some participants preferred to seek sexual health services like HPV vaccination at other locations.

The perceived benefits of seeking vaccination at community-based LGBT health clinics are their specific knowledge of important sexual health issues experienced by LGBT individuals as well as their friendly and non-judgmental staff. Participants liked that these clinics are discrete and they can go for very specialized services. Others perceived these types of clinics as lacking privacy. Community health clinics focusing on LGBT populations are less commonly available and many of the participants said they were unfamiliar with such clinics. There was also a concern that the staff at these types of clinics would lack the necessary medical professionalism as would be found at a primary care provider office.



# Sources of health information

## Confidence in healthcare providers

The data thus far have demonstrated the key role of the primary healthcare provider in providing information about HPV vaccination and the prevention of HPV-related diseases. Participants were asked if they think their own healthcare providers are knowledge about health issues affecting gay and bisexual men and to explain why or why not. A total of 86 responses were recorded. Approximately 44% indicated they believed their providers were knowledgeable, 31% thought they were not knowledgeable, and 22% said they were unsure.

Confidence in their provider's knowledge of gay/bisexual men's health issues resulted from previous interactions when the provider asked or answered specific questions about sexual health. Evidence of specialized training (e.g., safe zone training) also promoted this confidence. Others relied on assumptions. Providers in urban areas with large gay populations were assumed to be more knowledge because of frequent interactions with gay/bisexual patients. In many cases it was stated that in general doctors are knowledgeable about gay/bisexual men's health issues because they are professionals and there is an expectation that they would be well informed. But even the trust and confidence in the competency of their doctors had its limits. Older doctors, as well as those from "certain communities," were described with suspicion, which was related to an "old school" mentality, lack of up-to-date training, or judgmental attitudes.

Some of these sentiments were also described by the men who expressed a lack of confidence in the knowledge of their provider. A general bias toward sexual minorities was described. Some of this was based in previous experiences in which doctors were perceived as dismissing concerns due to their ignorance of an issue or having witnessed negative treatment of other LGBT patients. There was also some reliance on expectations that doctors don't want to



think about gay/bisexual men's health issues, avoid talking about it, or don't take them seriously. Living in small towns or areas without a large visible gay population was frequently noted as a reason for these biases. And while some of the responses described explicit bias, many participants wrote about a lack of up-to-date training and a focus on their specific patient population that doesn't include many openly gay/bisexual men.

## Emotions surrounding disclosure

Experiences disclosing one's sexual minority status (i.e., identity or behavior) to a health care provider were explored through a series of questions asking about history of disclosure and emotions surrounding disclosure experiences. Out of the 102 responses, 55% had previously disclosed to a healthcare provider, 40% had not, and 6% could not remember. There were three sets of comments that described the relevance of disclosing to a HCP. The more common opinion was that it is important for a HCP to know about one's sexual minority status because "being gay" or engaging in certain "risks" is of medical relevance. Others thought it was relevant but only in certain situations (these situations were not described). The minority opinion was that sexual orientation is not relevant. One participant's comments were particularly informative about this issue:

It's awkward enough discussing my sex life with friends, so unless I had reason to believe I was exposed to an STD, I don't think I'd make it my doctor's business. Even then, I would probably leave it to "I think I was exposed, I need a test," and leave the details up to my doctor's imagination. I can't think of a good-enough reason that my doctor would NEED to know I'm gay. (P31, 22, White)



It is interesting to note that no participants who explicitly questioned the relevancy of their sexual behaviors or identity to their medical care had previously disclosed to a HCP.

Reasons for feeling *comfortable* disclosing included a strong sense that HCPs are professionals and are ultimately motivated to help people. Also they "see all kinds of people" including those who share similar sexual activities and risks. Other reasons were based on specific experiences with HCPs that were "welcoming," who built rapport with their patients by asking questions and showing non-judgmental interest/concern. It was also assumed that female HCPs and those practicing in urban areas or at universities would be accepting.

In contrast, descriptions of disclosing as *uncomfortable* were based on previous experiences where the HCP provider was perceived as reacting negatively. One participant described his perspective as follows:

It can be very frightening and off-putting to reveal sexual behaviors because doctors do judge. You see it on their face, body language, tone of voice, and quality of treatment, and the length of time that they spend with you. It's not a comfortable, supporting, or healing environment to be in and one should find all of those qualities in a doctor and at the facility because their job is to heal, cure, and prevent illnesses. (P45, 25, Black)

Others reiterated these feelings talking about the way in which their providers "react much differently when you say I was with my boyfriend" (P46, 24, White) or seemed "surprised" by information about one's sexuality.

Participants managed perceptions and expectations of judgment in four distinct ways: (1) they avoided bringing up sexual health concerns or lying about sexual behaviors if asked directly; (2) sought out non-judgmental providers using the characteristic outlined previously; (3)



went to a separate clinic (e.g., planned parenthood) for sexual health services; or (4) accepted the fact that people judge but they are not going to let it bother them.



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# **CHAPTER 5: DISCUSSION**

The primary purpose of this study was to provide information that aids in our understanding of the factors important to young MSM when making decisions about HPV vaccination. Young MSM represent a distinct group with regard to HPV prevention for multiple reasons including their disproportional risk of HPV-related anal cancers, the limited herd immunity conferred to them through the vaccination of females, their current low vaccine uptake, and their public health relevance as a socially marginalized population. A comprehensive study of HPV-related attitudes, beliefs, and perceptions was undertaken and described in this manuscript. The following discussion of these findings is presented in three sections. In section one, I provide a summary of the major findings by addressing the three specific aims. In section two, I outline the limitations and strengths of each phase and the overall study. And in section three the public health implications and directions for future research are discussed.

# **Section I: Summary of Major Findings**

## Specific Aim 1a: Describe salient outcome, normative, and control beliefs

Specific aim 1a was to describe salient behavioral, normative, and control beliefs related to HPV vaccination among young MSM. This aim was addressed using qualitative data from Phases 1 and 3.

# Behavioral beliefs

There were three salient categories of behavioral beliefs that included physical and psychological advantages, as well as risks or concerns, associated with HPV vaccination.



Participants did not describe any of one specific advantage or risk as being critical in determining their attitudes toward vaccination. Instead they described the physical and psychological benefits in somewhat generic terms unless they had a personal experience with HPV—primarily in the form of anogenital warts. In these cases individuals were able to draw on their own experiences, which were used to express their thoughts and feelings about vaccination. But most of the men in the interviews and open-ended surveys lacked a specific context, or point of reference, in which to evaluate and express their thinking about HPV vaccination.

Up until their participation in this study, most of the men had little knowledge of HPV outside of a general understanding and a perception that HPV was a women's health issue. Limited HPV knowledge—particularly as it relates to the health consequences of HPV infection in men—is widely established in the extant literature (Nadarzynski et al., 2014); however, participants in this study—when asked in an open-ended format—were unable to describe even basic facts about HPV. And while many did correctly identify the link between HPV infection and anogenital warts, few understood HPV vaccination as a strategy for men to prevent this disease. Once informed, they adopted a positive attitude toward vaccination. This was consistent with an implicit—and sometimes explicit—value regarding health: "It's better to be safe than sorry."

Similar to beliefs regarding the advantages of vaccination, those expressing a concern over potential limits or risks of HPV vaccination were often generic and without specific details. As a result, these beliefs did not appear to exert a strong influence over their ultimate attitude towards HPV vaccination. In this sense, beliefs regarding the advantages and risks of HPV vaccination appear to be largely fluid and amenable to change in this population.



# Normative beliefs

Normative beliefs—both descriptive and injunctive—were not salient factors in the way in which participants described their beliefs regarding HPV vaccination. In fact the general sentiment was that HPV vaccination would not be something they would openly discuss with friends or family. The limited role of norms in deciding HPV vaccine decisions was also found in the quantitative preliminary (Wheldon et al., 2011) and has been noted in focus group interviews with MSM (Gutierrez et al., 2013). As sexual minorities, they appeared cognizant of the need to conceal or manage information about their sexual behaviors from specific people in their lives—most notably parents and heterosexual friends. This was motivated in part by a fear of judgment. With that said, older gay friends who take on a mentor-type role were considered influential and respected referents in some cases. Overall, the decision regarding HPV vaccination would be a private decision made primarily in consultation with a healthcare provider. In fact, privacy regarding this decision is important as young MSM who receive health insurance benefits through their parents or who see a family practitioner may avoid vaccination for fear of disclosure.

# Control beliefs

External control factors identified in this study were similar to those found in previous quantitative studies (Nadarzynski et al., 2014). These included a focus on cost, availability, and convenience. Cost is by far the most important factor related to HPV vaccination (Nadarzynski et al., 2014). The data from these interviews overwhelming identify cost as a "make or break" proposition. While most participants indicated a willingness to pay a small copay, none would accept the full out-of-pocket cost.



Limited research is available that explores the acceptability of alterative vaccination settings. Brewer and colleagues (Brewer, Chung, Baker, Rothholz, & Smith, 2014) identified pharmacies as a promising setting for HPV vaccination, yet the acceptability of these locations among MSM has not been investigated. The acceptability of alternative vaccination settings was explored in the qualitative phases. Four distinct preferences for HPV vaccine setting were identified.

There was a subset of men who would only be vaccinated at their primary care provider's office. This desire was motived by a need for their doctor to determine if the vaccine would be safe for them given their medical histories. An established patient-provider relationship was important for these men. Other men would likely be vaccinated at a variety of locations including pharmacies and community-base organization offering health services. The key factor for this group was convenience. They do not want to wait, make an appointment, or put much effort into finding out where HPV vaccination was available. This group of men seem comfortable getting vaccinated almost as an afterthought—for example, if vaccinations were offered during their regular HIV testing.

Another group of men prioritized their privacy above most other considerations. This group was more uncomfortable with disclosing aspects of their sexuality and managed their patient-provider relationships carefully. For these men pharmacies were too public and did not provide a suitable environment for something like HPV vaccination. If they had a good relationship with a primary care provider, one in which they felt comfortable, they would likely ask for the vaccine in that setting. If they did not have a comfortable and established relationship with a primary care provider, this group may be more amenable to vaccination at a clinic that caters to LGBT populations. For college students there was a general acceptance of being



vaccinated at campus-based health clinics. These locations were perceived as being safe places that were accepting and capable of addressing health concerns of male sexual minorities.

# Specific Aim 1b: Determine factors that underlie these beliefs

The existing behavioral research on HPV vaccination focused specifically on MSM consists primarily of quantitative studies and relies on standard theoretical constructs to explain HPV vaccine intention (Nadarzynski et al., 2014; Newman, Logie, Doukas, & Asakura, 2013). This limits models of decision-making to the most proximate determinates of intention, acceptability, or willingness. Tailoring health education interventions for this population requires the identification of modifiable belief structures salient to MSM when making decisions about HPV vaccination. This is what was described as the salient beliefs. These are *what* need to be changed in interventions. Insights into *how* to change them come from the identification of their antecedents. In this next section, I will synthesize findings from Phases 1 and 3 (i.e., the qualitative investigations) in order to develop general observations regarding key background factors that inform decision-making about HPV vaccination among male sexual minorities. *The HIV lens and HPV threat* 

The key to understanding the way in which young MSM think about *HPV* prevention is to consider the larger sociocultural impact of the *HIV* epidemic. This population is acutely aware of HIV risks (Wagenaar, Sullivan, & Stephenson, 2012) and they encounter HIV messages frequently in popular culture, as targets of research, and through pharmaceutical advertisements (Salyer, 2001). Their decision-making process regarding HPV vaccination appears to be heavily influenced by these sociocultural factors. Subjective risk of HPV infection (i.e., perceived threat) was often discordant with objective facts about HPV infectivity and their sexual histories. Risk perceptions regarding HPV infection were managed by a dedication to "safe sex," which was



generalized to mean condom use, infrequent anal penetration, and minimizing the exchange of semen and blood. Thus the same set of risk factors for HIV transmission was equally applied to perceptions of HPV transmission. When learning of the nature of HPV transmission (i.e., skin-to-skin sexual contact) many participants expressed concern as if their individual "models" of risk were challenged by this new information.

Two other key observations support the claim that HPV—and subsequent decisions regarding vaccination—is viewed through the "lens" of the HIV epidemic. There was a focus on "knowing your status" and "stopping the spread of HPV." These are powerful and prevalent HIV messages targeted toward the gay community (CDC, Act Against AIDS Campaign). Knowing their status before making health decisions about vaccination was commonly mentioned by participants yet belies an understanding of HPV infection, available testing procedures, and vaccine recommendations. In the absence of knowledge of these facts, male sexual minorities rely on heuristics informed by HIV knowledge and the wider practices in the gay community (Meadowbrooke, Veinot, Loveluck, Hickok, & Bauermeister, 2014). These messages also appeal to a sense of community responsibility, which was reiterated by men in this study in the form of protecting future sex partners from HPV through testing, safe sex, and, for some, vaccination.

#### Specific Aim 2: Identify information needs and trusted sources of information

#### *Information needs*

Men in this study had significant deficits in their basic understanding of HPV and HPVrelated diseases. This lack of knowledge did not impact their enthusiasm for vaccination suggesting that a minimal amount of information is needed in order for them to form vaccine intentions. The higher-risk of anal cancer associated with HPV infection was often cited as new information and had significant implications for the way in which participants understood the



benefits of vaccination. Similarly, anogenital warts and HPV infection, even in the absence of clinical disease, elicited a strong negative reaction underlying their sense of threat. Health messages can capitalize on these emotional reactions to increase awareness of the benefits of HPV vaccination and improve attitudes towards vaccination. Risk messages in the presence of an effective prevention strategy can significantly influence behavior (Witte & Allen, 2000). *Patient-provider communication* 

# Healthcare providers are perceived as the primary source of reliable information regarding HPV vaccination. The importance of healthcare providers in HPV vaccine decisionmaking is well documented (Newman et al., 2013). In this study we call attention to issues of sexuality and the patient-provider relationship that may serve as barriers to HPV vaccination. Disclosure—or "coming out to a healthcare provider"—is of central importance to HPV vaccination among adult MSM since there are different recommendations for vaccination of this population compared to the general male population. MSM who are "out" to their healthcare providers have more opportunity to receive recommended health services like HPV vaccination. Meites and colleagues (2013) found that a large percent of male sexual minorities in their national sample did not disclose to their healthcare providers, resulting in missed opportunities for preventive services (Meites et al., 2013). In this study we identified a number of factors related to disclosure including fear of judgment and mistreatment. Men were found to use a variety of strategies to manage their patient-provider relations in order to avoid disclosure or to seek out situations in which disclosure becomes more tenable. These data suggest that there is a segment of young MSM for whom avoidance of disclosure may serve as a barrier to HPV vaccination.

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#### Specific Aim 3: Test a structural equation model

The integrative model of behavioral prediction described in this study provided a good framework from which to understand HPV vaccine decision-making among young MSM. The overall model explained approximately 38% of HPV vaccine intentions. This model identified key determinants of behavioral intention to get vaccinated, the structure of beliefs that influence the key determinants, as well as the antecedents of those beliefs. The model goes one step further to identify specific populations of MSM that may require specially tailored health messages or other interventions. The findings from this model are summarized below.

The strongest determinant of behavioral intention was attitude. According to this model, increasing positive attitudes toward HPV vaccination is the best strategy to affect intention and subsequent behavior. Attitudes can be changed by increasing beliefs in physical and psychological benefits of vaccination and decreasing concerns about side effects. Perceived threat and information orientation serve as the key motivational factors related to perceived advantages of vaccination. The antecedent role of perceived threat in HPV vaccine decisionmaking was identified in a previous study of young MSM (Wheldon et al., 2013). This relationship implies that the motivation to process information pertaining to a health threat like HPV infection (e.g., information about the advantages of vaccination) varies as a function of perceived threat (Chen & Chaiken, 1999; Wheldon et al., 2013). As such, this theoretical model predicts that messages regarding the advantages of HPV vaccination—and those that minimize negative outcomes—are more likely to be systematically processed if a threat stimulus is present (Das, de Wit, & Stroebe, 2003). Similarly, information orientation is a motivational quality that primes an individual to process relevant information related to a health risk (Dutta-Bergman, 2009). Individuals high on health information orientation will likely require little stimulus to



motivate information seeking and processing (Dutta-Bergman, 2009). Individuals who are low on information orientation can best be reached through passive communication channels (Dutta-Bergman, 2009). For this population, that may include mobile phone sexual networking applications (Holloway et al., 2014).

Perceived behavioral control was also a moderate predictor of vaccine intentions. As predicted by the IM, perceived behavioral control is a function of external control beliefs and, in this model, self-efficacy pertaining to disclosure of sexual orientation. Self-efficacy inversely related to both the general tendency to conceal aspects of one's sexual orientation and a suspicion of healthcare providers. Both of these relationships have important implications for patient-provider interactions. If the perceived LGBT cultural competency of providers were increased, that would increase confidence in disclosing one's sexual orientation and provide more opportunities for healthcare providers to recommend HPV vaccination to this population of men. The qualitative findings provide specific behaviors that providers can adopt in order to build rapport with male sexual minorities. At the most basic level, these findings stress the importance of asking about sexual behaviors in a way that does not confer judgment and focuses on the relevance of this information for optimal medical care.

The exogenous variables in the model identified three subpopulations of MSM who may benefit from targeted health education intervention. HIV-infected individuals exhibited higher perceived threat of HPV, and ultimately higher vaccine intentions. When this relationship is understood within the context provided by the qualitative findings, it is clear that HIV-infected individuals have different experiences with the healthcare system and are motivated to process information about HPV in significantly different ways given their increased risk of cancer. HIV



status has consistently been shown to positively correlate with vaccine intentions (Newman et al., 2013).

Typically bisexual identity has been unrelated to HPV vaccine intuitions or acceptability (Wheldon et al., 2011) or vaccination status (Reiter et al., 2015). In this study, bisexual identity was positively correlated with concealment of sexual orientation and suspicion of healthcare providers. While not directly associated with vaccine intention, bisexually identified men may not be reached through health education interventions targeting gay men. Rates of nondisclosure of sexual minority status to healthcare providers have shown to be higher among bisexually identified men (Durso & Meyer, 2013). Limitations of patient-provider interactions experienced by these men can result in fewer opportunities for vaccination.

Finally, men in monogamous relationships exhibited lower levels of perceived threat. This relationship supports the finding in the qualitative interviews where men expressed low levels of perceived threat as a result of being in a monogamous, or semi-monogamous, relationship. Lower perceived threat among men in relationships ultimately resulted in lower levels of vaccine intention. Further research is needed to identify the specific targets of behavioral intervention for this unique subpopulation.

#### Section II: Limitations and Strengths

#### Strengths

This study makes a unique contribution to the behavioral HPV vaccination literature in several ways. (1) It is the first systematic study of HPV vaccine decision-making among MSM or males in general that uses the IM as a theoretical framework. While several studies have explored similar psychosocial constructs (Nadarzynski et al., 2014) as they relate to HPV vaccination, no published research utilized a mixed methods approach to elicit salient beliefs



directly from the priority population and then tested a structural model of those beliefs. In addition, the IM was uniquely expanded to incorporate antecedent factors important for the targeting and tailoring of health education interventions. (2) The sequential mixed methods study design allowed for a comprehensive exploration of HPV vaccine decision-making. Decisionmaking processes surrounding vaccinations among adults are complex and driven by multiple factors. The qualitative phases allowed for in-depth exploration of salient beliefs and perceptions, while the quantitative survey provided the data needed to validate the theoretical propositions. (3) The application of an open-ended survey using a vignette to provide context in which to evaluate specific steps in the decision-making process was an innovative approach and provided a rich source of data. (4) The use of structural equation modeling, which allows for a complex representation of the theoretical constructs through the use of multivariate modeling techniques, provided information about the direct and indirect relationship of theoretical constructs. Mapping out the structural relationships between theoretical constructs is useful for the subsequent application of program planning models. (5) Finally, the use of a ethno-racially diverse community-based sample of young MSM in combination with geographically diverse samples obtained through Internet-based research recruitment helps to increase the external validity of findings and subsequent implications for health education interventions.

#### Limitations

The current study has four major limitations including the use of (1) non-probability sampling techniques, (2) cross-sectional data, (3) proxy indicators for vaccine uptake (i.e., modeling vaccine intentions), and (4) mode effects of in-person, telephone, and web-based data collection. Probability sampling techniques ensure that every individual or element within the priority population from which the research seeks to generalize has a known non-zero probability



of being sampled (Fowler, 1993). This is accomplished from operationalizing the conceptual population into a sampling frame from which elements are randomly selected. External validity is most rigorously established when a sample is randomly generated from a sampling frame that closely approximates the conceptual population. This ensures that the sample is representative of the population and that findings generated from the sample can be generalized to the population within a specified range of confidence.

There are a number of issues inherent to sampling members of sexual minority populations. The target population for this research included men who have ever engaged in sexual contact with another male or who identify as gay or bisexual. This conceptual population included both gay identified and non-gay identified MSM in order to be inclusive of all those who engage, or may engage at some point, in similar behaviors that increase the risk of anal HPV infection. This population is based on stigmatized sexual identities and sexual behaviors, which are often concealed or "hidden." Therefore, constructing sampling frames that closely approximate these types of conceptual populations is inherently flawed, which results in biased and unrepresentative samples.

In addition to the limitations inherent to the use of non-probability sampling techniques, the use of cross-sectional data and proxy measures for behavioral performance (e.g., vaccine uptake) limits the degree to which the IM would be directly tested. The IM posits that, in the absence of environmental constraints, a given health behavior is determined by an individual's intention to perform that behavior. This proposition could not be tested using cross sectional data since no temporal relationship can be established between behavioral intention and behavioral performance. Furthermore, the full IM could not be tested since vaccine intention and not vaccine behavior (i.e., getting vaccinated or not getting vaccinated) was the final outcome.



Internet-based self-administered surveys have some significant limitations that bear consideration. Unequal access to the Internet was a primary concern associated with this survey method; however, the most recent data from the Pew Internet and American Life Project estimates that approximately 95% of Americans between the ages of 18 and 29 use the Internet. In contrast, only 56% of 18 to 30 year olds have a landline telephone in their household. The ubiquitous use of the Internet and mobile technologies provides strong rationale for Internet-based survey research targeting younger cohorts. Internet surveys have been shown to have low response and completion rates relative to other survey methods (Cook, Heath, & Thompson, 2000). These limitations to Internet-based survey research can present a challenge to the validity of results utilizing this method.

Three modes were used to collect qualitative data used in this study: in-person face-toface interviews, telephone interviews, and web-based self-administered open-ended survey items. It is unclear to what degree these data collection techniques influenced data quality. There is a perception in qualitative research that face-to-face interviews result in the richest data, providing more context and opportunity to build rapport, interpret non-verbal cues, and ask probing questions (Novick, 2008). And there is some empirical support for these claims (Irvine, 2011) and also in support of the quality of data resulting from telephone interviews (Sturges & Hanrahan, 2004).

#### Section III: Implications

#### **Implications for research**

Longitudinal studies are needed in order to establish temporal relationships between the key theoretical variables identified in this investigation and to determine how well they predict HPV vaccine initiation as the main outcome. Future research should also replicate the findings of



the current study with diverse samples of MSM including those with lower socioeconomic status and MSM who do not identify as gay or bisexual. HIV infected MSM are also a unique subpopulation that was not fully represented by this research. While the current investigation provides needed and useful information, the next steps for vaccine promotion research among this population should include community-based needs assessments to identify environmental barriers or factors that may facilitate vaccination of MSM in specific community locales. This research could benefit by building on the theoretical framework utilized in the current study and expanding it using program planning models like the social marketing framework (Kotier & Zaltman, 1996) or an intervention mapping approach (Bartholomew, 2011).

Promoting HPV vaccination among sexual minorities can be viewed within the larger framework of healthcare disparities experienced by this population (Institue of Medicine, 2011). Barriers to care center on issues of discrimination and stigma and are rooted in a long history of mistreatment of sexual minorities by healthcare systems and personnel. The charge of public health research is to identify ways to minimize or eliminate these barriers. In the current investigation—which focused on the individual as the unit of analysis—we identified suspicion of healthcare providers as a potential barrier to HPV vaccination among young MSM. This finding requires further investigation to develop valid and reliable measures of this phenomenon, to examine how widespread these perceptions are among subpopulations of MSM, and to further describe antecedents that facilitate these beliefs. Research in this area can benefit from and expand upon the work done on medical mistrust among other minority populations (Benkert, Hollie, Nordstrom, Wickson, & Bins-Emerick, 2009; Buseh, Kelber, Millon-Underwood, Stevens, & Townsend, 2014; Guadagnolo et al., 2009).



#### **Implications for policy**

This study identifies key points for structural interventions. Policies that allow for and promote alternative vaccine settings can help facilitate uptake among young MSM. While pharmacies were identified as acceptable locations for a subset of MSM, others would prefer to get vaccinated at community-based clinics that offer HIV testing and that are perceived to be LGBT-friendly. A model of LGBT care has been developed and put into practice by places like Fenway Community Health in Boston and in other urban centers with established LGBT communities (Mayer et al., 2001). The challenge is expanding this model to smaller cities. This is an area where community-based participatory research could offer unique insights.

The age- and sex-based recommendations for HPV vaccination appear to be a source of considerable confusion among men in this study and have created a perception that HPV is a female problem. These perceptions appear to be enduring even after changes in vaccine policy. And while targeted vaccine promotion campaigns can seek to modify these beliefs, simplifying HPV vaccine policy would be the most wide reaching and impactful intervention. Given the decreasing cost of HPV vaccine, the promise of alternative dosing schedules, the increasing burden of HPV-related diseases, and the lack of standardized secondary screening guidelines for men, a universal, gender neutral policy recommendation is warranted (Bonanni et al., 2014).

#### **Implications for practice**

The findings from this study have several implications for public health practice. First among these are the implications for health education interventions to promote HPV vaccine uptake among MSM. The final IM supported by the findings identified key modifiable psychosocial factors including specific beliefs and perceptions that either directly or indirectly affect behavioral intention. Risk messages can be designed to influence these beliefs and can be



targeted to the specific subpopulations of MSM identified in the model. Promoting beliefs about the physical and psychological benefits of vaccination can be accomplished through paring information and risk messages. More research is needed to test specific messages, but this study has implications for the content of these messages. Rather than framing HPV vaccination as a cancer vaccine, which previous research has suggested (McRee, Reiter, Chantala, & Brewer, 2010), the findings from this study indicate that framing HPV vaccination as a way to prevent a sexually transmitted infection may be particularly effect for MSM. Building on existing HIV prevention messaging (e.g., "Stop the spread," "protect you partners") may also be effective.

The findings also suggest limited efficacy of interpersonal-based approach to vaccine promotion aside from interventions targeting healthcare providers. This research underscores the importance of LGBT cultural competency training. Currently there are no specific evidencebased clinical practices to increase competency, but there are some guidelines that can be implemented to begin to address these issues (McNair & Hegarty, 2010).



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**APPENDICES** 



## **Appendix A: Phase 1 Interview Guide**

Date: / / (mm/dd/yy)

Participant ID#

Time: \_\_\_\_\_(AM / PM)

Men4Men Health Study

IRB# Pro00012092

## **Interview Guide**

## **INTRODUCTION**

Thank you for taking the time to meet with me for this interview. I recognize that your time is valuable and I appreciate your participation. Before I start, let me take some time to introduce myself and explain why I am here to speak with you.

My name is Chris Wheldon from the University of South Florida. I am conducting a research study to learn more about your views, beliefs, and attitudes toward health topics that affect sexually active men. This interview is one of many interviews that will take place over the next three months. I want to know what are your thoughts, opinions and experiences when it comes to health in your community. There are no right or wrong answers. I am interested in finding out what you think.

The information I gather will be summarized and shared in order to find better ways to serve the health needs of guys like you.

The interview should not last more than 45 minutes.



## SECTION 1: BACKGROUND/ATTRIBUTE LISTING

*INTERVIEWER SAY:* In order to get to know you please introduce yourself and list 10 things about yourself [Have him write them down]

*Probe:* I am a brother, son, student etc.

*Probe*: Age | Sexual Orientation | Residence | Health Insurance | Healthcare place Race/Ethnicity | Student | Education

## SECTION 2: Health & Information

*INTERVIEWER SAY:* I want to talk a little about health.

- 1) What does it mean for you to be healthy?
- 2) What sort of things do you do to be healthy?
- 3) What do you think are some major health concerns that affect guys your age

(Probe: A lot of times we talk about "women's health" but what comes to mind when I say "men's health"?

(Probe: What about specific health concerns for gay/bisexual men? How do these differ from other men?)

- 4) How do you find health information? (Probe: What sources do you trust?)
- 5) Tell me about the last time you went to a doctor or health care provider.

(Probe: What did you see him/her for? Have you ever been tested for HIV/STIs? Where and when was the last time?)

6) Have you ever discussed being gay/bisexual with a health care provider. Tell me about that experience (Probe: When did this happen? Who initiated the discussion?).



## **SECTION 3:** HPV

#### Knowledge

- 1) Have you every heard of human papillomavirus (or HPV)?
- 2) What do you know about HPV (Human Papillomavirus)?
- 3) How did you first hear about HPV? What sources would you trust?
- 4) Have you ever heard of a vaccine to prevent HPV? (If yes, what have you heard?)
- 5) Where did you hear about the HPV vaccine? (Probe: Which of these sources [repeat/display response to previous question] would you trust the [most/least] to provide information about HPV?

[Show HPV Brochure] What stands out or surprises you? What else would you like to know?

- a. Based on what you know now about HPV, what do you think your risk is of [having been/becoming] infected with HPV? Or developing an HPV related disease? What about in 3-5 years from now? [0-10 scale]
- b. When you try to calculate your risk, what first comes to mind?

## **Outcome beliefs**

6) What do you believe are the [advantages "good things" / disadvantages "bad things"] of receiving the HPV vaccine? How would you benefit from the HPV vaccine?

## Normative beliefs

- 7) What individuals or groups would [approve/disapprove] if you decided to get the HPV vaccine? Why or why not? (Probe: Friends? Family? Doctor?)
- 8) What do you think about people who receive the HPV vaccine?

## **Efficacy/Control Beliefs**

9) What factors or circumstances would [help you/make it difficult or impossible] for you to get the HPV vaccine?



- a. Where would you get it? [Probe: What about from a primary care provider? Would it prevent you from receiving it if you had to discuss your sexuality?
- b. How would you pay for it?



## **Appendix B: Phase 2 Survey Instrument**

ETH Which of the following best describes your race or ethnicity (check all that apply)?

- 1. White/Caucasian (1)
- 2. African American (2)
- 3. African (9)
- 4. Hispanic/Latino (3)
- 5. Asian (4)
- 6. Native American (5)
- 7. Pacific Islander (6)
- 8. Other (7) \_\_\_\_\_

SEX What sex were you assigned at birth, on your original birth certificate?

- Male (1)
- Female (2)
- Other (Please explain) (4) \_\_\_\_\_\_

GENDER Which of the following describes your gender identity, how you think about yourself?

- Man (1)
- Woman (2)
- Genderqueer (3)
- Transgender (4)
- A gender identity not listed here (please explain) (5) \_\_\_\_\_\_

SEXOR How would you describe your sexual orientation?

- Gay (1)
- Bisexual (2)
- Straight / heterosexual (3)
- Not sure (4)
- Other (5) \_\_\_\_\_

STUDENT Are you currently a student?

- Yes (1)
- No (2)



EDU What is the highest level of education you have completed?

- Less than High School (1)
- High School / GED (2)
- Some College (3)
- 2-year College Degree (4)
- 4-year College Degree (5)
- Graduate/Professional Degree (6)

INSURANCE Do you have medical insurance coverage?

- Yes (1)
- No (2)
- I don't know (3)

MEDPLACE Is there a place that you usually go to when you need routine medical care (e.g., a family doctor, a specific clinic, etc)?

- Yes (1)
- No (2)
- I don't know (3)

HIVTEST In the past 12 months, how many times have you been tested for HIV, including times you did not get your results? \*Including blood or saliva tests specific for HIV. Do not count tests you may have had as part of a blood donation.

- 0 I have not been tested for HIV in the last 12 months (1)
- 1 (2)
- 2 (3)
- 3 (4)
- 4 (5)
- 5 or more times (6)

HIV What is your HIV status?

- HIV Negative (1)
- HIV Positive (2)
- Never been tested for HIV (3)



STI Have you ever been told by a health care provider that you had either Gonorrhea ("the clap"), Chlamydia, Syphilis, herpes, or Trichomoniasis ("trich")?

- Yes (1)
- No (2)
- I don't know (3)

OUT\_CON How often do you avoid talking about topics related to or otherwise indicating your sexual orientation when interacting with members of these groups (e.g., not talking about your significant other, changing your mannerisms)?

- \_\_\_\_\_ Members of your immediate family (e.g., parents and siblings) (1)
- \_\_\_\_\_ Members of your extended family (e.g., aunts, uncles, grandparents, cousins) (2)
- \_\_\_\_\_ People you socialize with (e.g., friends and acquaintances) (3)
- \_\_\_\_\_ People at your work/school (e.g., coworkers, supervisors, instructors, students) (4)
- \_\_\_\_\_ Strangers (e.g., someone you have a casual conversation with in line at the store) (5)

HPV101\_I Ever heard of HPV? A lot of guys don't know much about it. Read the info below and then go to the next page.

HPV\_HAD Has a health care provider ever told you that you had human papillomavirus or HPV?

- Yes (1)
- No (2)
- I don't know (3)

HPV\_WARTS Has a health care provider ever told you that you had genital or anal warts?

- Yes (1)
- No (2)
- I don't know (3)

KNOW\_WARTS To the best of your knowledge, do you personally know someone who has had genital or anal warts (other than yourself)?

- Yes (1)
- No (2)
- I don't know (3)



KNOW\_HPV To the best of your knowledge, do you personally know someone who has had HPV (other than yourself)?

- Yes (1)
- No (2)
- I don't know (3)

VAC\_AWARE Before today, have you ever heard of the HPV vaccine?

- No (1)
- Yes (2)
- I don't know (3)

HPV VACC Have you ever received the HPV shot?

- Yes (1)
- No (2)
- I don't know (3)

If Yes Is Selected, Then Skip To End of Block

KNOW\_VAC Do you personally know someone who has gotten the HPV vaccine?

- Yes (1)
- No (2)
- I don't know (3)

VAC\_DRREC Has a doctor or health care provider ever recommended that you get the HPV vaccine?

- Yes (1)
- No (2)
- I don't know (3)

VAC\_INT\_D1 Do you intend to get vaccinated against HPV within the next year?

- Yes (1)
- No (2)
- I don't know (3)

VAC\_I2 Now that you know a little about the HPV vaccine I would like to know if you will get the HPV vaccine. Respond to the following statements based on what you know right now about the HPV vaccine. How likely are you to do the following:



INTENTION1 Find out more information about the HPV vaccine within the next 12 months

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

INTENTION2 Make an appointment to talk to a doctor about the HPV vaccine within the next 12 months

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

INTENTION3 Get your first HPV shot within the next 12 months

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

INTENTION4 How likely are you to get the HPV vaccine if the CDC recommendation was changed to include men older than 26?

- Very Unlikely (6)
- Unlikely (7)
- Undecided (8)
- Likely (9)
- Very Likely (10)

DOSE\_I Each dose can cost up to about \$170, so all three shots may cost about \$500. Many health insurance companies may pay for the HPV vaccines. There are also programs that allow some people without insurance to get a vaccine for low or no cost. Think about what you might do in the next year. Would you...



INTENTION5 Get the HPV vaccine if it were offered to you free of charge?

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

INTENTION6 Get the HPV vaccine if it was covered by your health insurance or discounted to approximately \$30 per dose?

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

## ATT Overall, I think that getting the HPV vaccine is...

	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)
Not worth it:Worthwhile (1)	•	•	•	•	•
Harmful:Beneficial (2)	•	•	•	•	•
A bad thing for me:A good thing for me (3)	•	•	•	•	•
Unimportant:Important (4)	•	•	•	•	•
Ineffective:Effective (5)	•	•	•	•	•

BB\_I2 If you got vaccinated for HPV within the next year, how likely are the following things:

BB1 It would make me healthier

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)



BB2 It would prevent me from getting genital and anal warts

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB3 It would prevent me from getting anal cancer

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB\_I3 You just told me how you think you might benefit (or not) from the HPV vaccine. Now I'd like to know how important each of those outcomes are to you at this point in time.

EB1 Being healthy is...

- Not at all Important to me at this time (1)
- Very Unimportant to me at this time (2)
- Neither Important nor Unimportant to me at this time (3)
- Very Important to me at this time (4)
- Extremely Important to me at this time (5)

EB2 Preventing genital and anal warts is...

- Not at all Important to me at this time (1)
- Very Unimportant to me at this time (2)
- Neither Important nor Unimportant to me at this time (3)
- Very Important to me at this time (4)
- Extremely Important to me at this time (5)

EB4 Preventing anal cancer is...

- Not at all Important to me at this time (1)
- Very Unimportant to me at this time (2)
- Neither Important nor Unimportant to me at this time (3)
- Very Important to me at this time (4)
- Extremely Important to me at this time (5)



BB\_i4 If you got vaccinated for HPV within the next year, how true are the following things likely to happen for you? Would you...?

BB4 Feel protected from HPV

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB5 Feel like there is one less thing to worry about

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB6 Be less likely to spread HPV to your future sex partner(s)

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)
- •

BB\_I5 How important are these things to you currently or over the next 12 months?

EB4 Feeling protected from HPV

- Not at all Important (1)
- Very Unimportant (2)
- Neither Important nor Unimportant (3)
- Very Important (4)
- Extremely Important (5)



EB5 Not having to worry about getting HPV from my sex partner(s)

- Not at all Important (1)
- Very Unimportant (2)
- Neither Important nor Unimportant (3)
- Very Important (4)
- Extremely Important (5)

EB6 Protecting my sex partner(s) from HPV

- Not at all Important (1)
- Very Unimportant (2)
- Neither Important nor Unimportant (3)
- Very Important (4)
- Extremely Important (5)

BB\_I6 We've talked to some guys who expressed some concerns about the HPV vaccine. How likely do you think the following things are to happen to you if you got vaccinated? If I got vaccinated for HPV within the next year...

BB7 I will contract HPV from the vaccine itself

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB8 I would not be completely protected from future HPV infection

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

BB9 The vaccine may not work for me

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)



BB10 I would have side effects from the HPV vaccine

- Very Unlikely (1)
- Unlikely (2)
- Undecided (3)
- Likely (4)
- Very Likely (5)

EB10 If you did experience side effects from the HPV vaccine, how serious do you think that would be?

- Not serious at all (1)
- Not serious (2)
- I'm not sure (3)
- Serious (4)
- Very serious (5)

NORM\_I If you considered getting the HPV vaccine in the next year, there might be people (e.g., your family) or groups (e.g., health care providers) who would think you should or should not do so. I would like to ask you some questions about this.

NORM1 In general, people who are important to me would encourage me to receive the HPV vaccine.

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

NORM2 I can think of at least one person in my life who would like for me to get the HPV vaccine.

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



NORM3 If I decided to get the HPV vaccine within the next year, I would seek advice from my friends or family prior to getting vaccinated.

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

NORM4 Most of my gay/bisexual male friends would get the HPV vaccine if it was offered to them free of charge.

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

NB Listed below are some people in your life who may approve or disapprove of you getting the HPV vaccine. What do you think their opinions would be? If you don't have a relationship with the specific person just choose "not applicable." 1 = Very Disapproving2 3 = Neither Approving/Disapproving 4 5 = Very Approving

- \_\_\_\_\_ Your Mother (24)
- \_\_\_\_\_ Your Father (25)
- \_\_\_\_\_ Most of your gay male friends (26)
- \_\_\_\_\_ Your straight friends (28)
- \_\_\_\_\_ Your health care provider (29)

MC When deciding whether or not to get the HPV vaccine, would you seriously consider the advice/opinion of...1 = Very Unlikely23 = Undecided45 = Very Likely

- \_\_\_\_\_ Your mother (24)
- \_\_\_\_\_ Your father (25)
- \_\_\_\_\_ Your gay male friends (26)
- \_\_\_\_\_ Your straight friends (28)
- \_\_\_\_\_ Your healthcare provider (29)

Q73 You're swell. Hang in there! Let's assume that you decide to get the HPV vaccine in the next 12 months (i.e., by this time next year). Select your responses to the following statements accordingly.



PBC1 There are factors beyond my control that would prevent me from getting the HPV vaccine in the next 12 months

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

PBC2 I am confident that I can get the HPV vaccine in the next 12 months

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

Q168 Getting the HPV vaccine sometime in the next 12 months would be

- Impossible for me (6)
- (7)
- (8)
- (9)
- Possible for me (10)

PC What would make it easier for you to get the HPV Vaccine? Tell me below. It would make it \_\_\_\_\_\_\_ to get the HPV vaccine in the next 12 months...1 = more difficult for me2345 = much easier for me

- \_\_\_\_\_ If I could quickly find out where to go to get vaccinated (1)
- \_\_\_\_\_ If my health insurance covered the vaccine (4)
- \_\_\_\_\_ If I could get it without having to make an appointment (i.e., walk-in) (3)
- \_\_\_\_\_ If I could get it when I get tested for HIV (6)

CB\_I Tell me how much you agree or disagree with the following statements

CB1 I can find out where to go to get vaccinated

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



CB2 I will have health insurance during the next year

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

CB3 I can find a place to get vaccinated where I don't need to make an appointment (i.e., walk-in)

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

CB4 I will get tested for HIV in the next 12 months

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

SE\_I Assuming you decided to get the HPV vaccine.

SE\_GAY1 How confident are you in your ability to get the HPV vaccine if you had to talk to your doctor or healthcare provider about your sexual orientation (e.g., that you are gay or bisexual)?

- Not at all confident (1)
- Somewhat confident (2)
- Rather confident (3)
- Very confident (4)
- Extremely confident (5)



SE\_BEH1 How confident are you in your ability to get the HPV vaccine if you had to talk to your doctor or healthcare provider about your sexual behaviors (e.g., your sexual history)?

- Not at all confident (1)
- Somewhat confident (2)
- Rather confident (3)
- Very confident (4)
- Extremely confident (5)

SUS Without getting the HPV vaccine, what do you think the chances are that you will... 1 = Very Unlikely 2 = Undecided 4 = Very Likely

- \_\_\_\_\_ Get HPV (1)
- \_\_\_\_\_ Get warts on your penis or scrotum (2)
- \_\_\_\_\_ Get anal warts (3)
- \_\_\_\_\_ Get anal cancer (4)

SEV Please indicate on a scale of 1 to 5 how serious you feel the following events would be for you.

- \_\_\_\_\_ If you became infected with HPV (1)
- \_\_\_\_\_ If you developed warts on or inside your anus (2)
- \_\_\_\_\_ If you developed warts on your penis or scrotum (3)
- \_\_\_\_\_ If you developed anal cancer (4)

Q173 Ok! That's enough about HPV!!! I just have a few more questions. Remember to enter your email at the end of the survey to enter the drawing for Amazon.com Gift Cards.

COMM\_I The next few statements focus on health information. Indicate below how much you agree or disagree with each statement.

COMM\_M1 When I take medicine, I try to get as much information as possible about its benefits and side effects

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



COMM\_M2 Before making a decision about my health, I find out everything I can about the issue

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

COMM\_M3 It's important to me to be informed about health issues affecting gay and bisexual men

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

15 I would like to ask you about your health care experiences. When I ask about a "health care provider" I am referring to a medical doctor or nurse who is licensed to practice medicine. Sometimes we call them family or primary care physicians.

DISLOSE Have you ever told any health care provider that you are gay or bisexual or that you have sex with men?

- Yes (1)
- No (2)
- I don't know (3)

I6 Please tell me how much you agree or disagree with the following statements.

HLTCARE1 I have received lower quality healthcare services as a result of my sexual orientation

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



HLTCARE2 I prefer that my doctor or healthcare provider does not know that I am gay/bisexual

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

HLTCARE3 I feel uncomfortable talking about my sexual orientation or sexual behaviors with a doctor or healthcare provider

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

HLTCARE4 There is no reason why my doctor or healthcare provider would need to know that I have sex with men

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

SEX\_BEH\_I Now I would like to ask you some questions about your sexual activities and experiences. This information is very important to this study. Each person has different sexual experiences, so some questions may not apply to you. Remember: Your answers are anonymous!

SEX\_#M In your lifetime, with how many males have you had sex?

REL Are you currently in a monogamous relationship?

- Yes, with a man (1)
- Yes, with a woman (2)
- No (3)

Answer If Are you currently in a monogamous relationship? Yes, with a man Is Selected Or Are you currently in a monogamous relationship? Yes, with a woman Is Selected REL\_LENGTH How long have you been in this relationship?



VAC\_INT\_D2 Last Question!!! And this is a repeat but I'm curious if you've changed your mind. Do you intend to get vaccinated against HPV within the next year?

- Yes (1)
- No (2)
- I don't know (3)

OPEN Thank you for taking the survey. On the next page you can submit your responses and move on to enter to win a gift card. If you have any thoughts you'd like to share with me you can do so below.

CLOSING\_I You're fabulous! Thank you for taking the time to complete this survey. If you have any questions about the study or about HPV don't hesitate to contact me at cwheldon@health.usf.edu. If you are curious about the findings from this study I can update you when I am finished. Just send me an email and let me know you are interested. On the next page you can enter to win a gift card for your participation. If you are one of the winners the gift card will be emailed to you. This email will not be linked to your survey responses in any way.



# **Appendix C: Phase 3 Survey Instrument**

D2 What sex were you assigned at birth, on your original birth certificate?

- Male (1)
- Female (2)
- Other (Please explain) (4) \_\_\_\_\_\_

Q61 Which of the following describes your gender identity, how you think about yourself?

- Boy/man (1)
- Girl/woman (2)
- Genderqueer (3)
- Transgender (4)
- A gender identity not listed here (please explain) (5) \_\_\_\_\_\_\_

D3 How would you describe your sexual orientation?

- Gay (1)
- Bisexual (2)
- Straight / heterosexual (3)
- Not sure (4)
- Other (5) \_\_\_\_\_

D4 Which of the following best describes your race or ethnicity (check all that apply)?

- 9. White/Caucasian (1)
- 10. African American (2)
- 11. African (9)
- 12. Hispanic/Latino (3)
- 13. Asian (4)
- 14. Native American (5)
- 15. Pacific Islander (6)
- 16. Other (7) \_\_\_\_\_

## D5 Are you currently a student?

- Yes (1)
- No (2)



D6 What is the highest level of education you have completed?

- Less than High School (1)
- High School / GED (2)
- Some College (3)
- 2-year College Degree (4)
- 4-year College Degree (5)
- Graduate/Professional Degree (6)

HLT1 Do you have medical insurance coverage?

- Yes, through my employer (1)
- Yes, through my school (4)
- Yes, through my parents (5)
- Yes, through an individual policy (6)
- Yes, through medicaid or state based program (7)
- Yes, through another source (8)
- No, I do not currently have medical insurance (2)
- I'm not sure (3)

HLT2 Is there a place that you usually go to when you need routine medical care (e.g., a family doctor, a specific clinic, etc)?

- Yes (1)
- No (2)

HLT3 If you needed to see a doctor for a non-emergency issue, where would you go?

- My primary care provider (1)
- Clinic at my school (2)
- A local walk-in clinic (3)
- County public health clinic (4)
- Planned Parenthood clinic (5)
- Emergency room (6)
- Other (please explain) (7) \_\_\_\_\_\_



HIV2 In the past 12 months, how many times have you been tested for HIV, including times you did not get your results? \*Including blood or saliva tests specific for HIV. Do not count tests you may have had as part of a blood donation.

- 0 I have not been tested for HIV in the last 12 months (1)
- 1 (2)
- 2 (3)
- 3 (4)
- 4 (5)
- 5 or more times (6)

HIV3 Where do you usually go to get tested for HIV?

HIV What is your HIV status?

- HIV Negative (1)
- HIV Positive (2)
- Never been tested for HIV (3)

HPV1 Has a doctor or other health care provider ever told you that you had human papillomavirus or HPV?

- Yes (1)
- No (2)
- I'm not sure (3)

HPV2 Has a doctor or other health care provider ever told you that you had genital warts?

- Yes (1)
- No (2)
- I'm not sure (3)

HPV3 A vaccine to prevent HPV infection is available and is referred to by several names, such as: the HPV shot, cervical cancer vaccine, GARDASIL®, or CERVARIX®. Have you ever received the HPV shot or cervical cancer vaccine?

- Yes (1)
- No (2)
- I'm not sure (3)

Bran1 Please read Brandon's story and respond to the questions. There are 3 short sections to his story and each has a set of questions and areas for you to provide your thoughts. This story is based on the experiences of real people who previously



participated in this study. Brandon is a young guy in his 20s. He isn't overly concerned about health issues but he tries to eat healthy and stay active. He doesn't go to the doctor often but he does try to get tested for HIV on a regular basis. He's currently single and enjoys hanging out with his friends and meeting new guys. On a recent Friday night he was spending an evening out with a group of friends at his favorite hangout. While waiting in line to order, he casually scanned the fliers posted on the wall next to him. Most of them featured hard bodied men advertising for fundraisers or party events. But one flier caught his eye. It read "Cover your BUTT with GARDASIL. HPV affects guys, too." And under the large text it said...

## Bran2 PLEASE READ THESE HPV FACTS

Bran3 What is HPV? Why you should care? HPV is a sexually transmitted virus that you can get from skin-to-skin contact during all types of sexual activites. Most people will become infected with HPV in their lifetime. Most of the time HPV has no symptoms so people don't know they have it. For most people, HPV goes away on its own but if it doesn't it can cause genital and anal warts and some types of cancers including anal cancer. Men who have sex with men are 17 times more likely to develop anal cancer than other men. How to prevent HPV? Gardasil—the HPV vaccine—protects against genital warts and cancers caused by HPV. HPV vaccine is recommended for men 26 years old and younger.

StandOut What about this information stands out to you? Why does it stand out to you? Please explain in detail.

Learn What did you learn about HPV that you didn't already know?

Prisk Without the HPV vaccine, what do you think the chance is that you will be infected with HPV at some point in your life?

- No chance (0%) (1)
- Very unlikely (2)
- Unlikely (3)
- Average chance (50%) (4)
- Likely (5)
- Very likely (6)
- Certain to happen (100%) (7)



Concern How concerned are you about getting infected with HPV?

- Not at all concerned (1)
- Slightly concerned (2)
- Somewhat concerned (3)
- Moderately concerned (4)
- Extremely concerned (5)

Bran4 After reading this information about HPV, Brandon was a little worried. He thought HPV was only something women could get. And while he almost always uses protection when he hooks up, he couldn't help but wonder if he has HPV. But Brandon wasn't going to let it bother him. He got his drink and went back to his friends. The next day Brandon googled HPV vaccine and read more about it. He read that GARDASIL is given as 3 injections over 6 months and that the ideal time to get vaccinated is before becoming infected with HPV. Brandon isn't sure if he can be vaccinated. He's not what his friends would consider "slutty" but he certainly isn't a virgin either. He wonders how he would know if he's been exposed to HPV.

Decision1 What do you think Brandon should do? I think Brandon should...(explain in detail)

Q67 Why should he do that? I think Brandon should do that because...(explain in detail)

Decision2 What would you do if you were in Brandon's situation? Please explain why. If I were in Brandon's situation, I would...

BranThreat A few weeks passed and Brandon mostly forgot about HPV until one afternoon the topic came up while he was hanging out with his friend Jeremy. Jeremy and Brandon are best friends, and they share everything. It turns out Jeremy just found out he has anal warts! He told Brandon he was having some "issues down there" so he went to get it checked out. He spared Brandon the details but told him that, "they aren't pretty." Luckily the warts were all on the outside around his anus so the doctor was able to freeze them off so he didn't need surgery. Jeremy was worried that the warts might come back since there is no cure. Brandon was supportive as usual and reassured his friend. But deep down he was freaking out. After hearing about Jeremy's experience Brandon decided that he wanted to get the HPV vaccine. He didn't EVER want to get anal warts. He didn't care if he had already been exposed to HPV. If there was any chance that the HPV vaccine would prevent warts or cancer he thought it was worth it.

Threat1 What do you think about Brandon's decision? I think that Brandon's decision...



Threat 1b Would you have decided to do the same thing (i.e., decide to get the HPV vaccine)?

- Yes (1)
- No (2)
- I'm not sure (3)

Answer If Would you have decided to do the same thing (i.e., decide to get the HPV vaccine)? No Is Selected

Threat2\_N Why would you decide NOT to get vaccinated?

Answer If Would you have decided to do the same thing (i.e., decide to get the HPV vaccine)? Yes Is Selected

Threat2\_Y Why would you decide to get vaccinated?

Answer If Would you have decided to do the same thing (i.e., decide to get the HPV vaccine)? I'm not sure Is Selected

Threat2\_U What are you unsure about?

Answer If Do you have medical insurance coverage? No, I do not currently have medical insurance Is Not Selected And Do you have medical insurance coverage? I'm not sure Is Not Selected And Is there a place that you usually go to when you need routine medical care (e.g., a family doctor... No Is Selected

BranGet1 Brandon wanted to get the HPV vaccine but he didn't know where to go to get it. He had health insurance but didn't have a regular doctor or a place he usually goes to for care. He doesn't like going to the doctor and feels a little awkward asking a health care provider about the HPV vaccine since it's an STD. He knows it's unprofessional but sometimes thinks that doctors judge him for his sexual behaviors.

Disclose Have you ever told any health care provider that you are \${q://QID9/ChoiceGroup/SelectedChoices} or that you have sex with men?

- Yes (1)
- No (2)
- I don't remember (3)

Answer If Brandon wants to get the HPV vaccine but he doesn't know where to go to get it. He has health insurance but doesn't have a regular doctor or a place he usually goes to for care. He doesn't... Is Displayed

Get1 Where would you go to get the HPV vaccine if you were in Brandon's situation?



Answer If Brandon wants to get the HPV vaccine but he doesn't know where to go to get it. He has health insurance but doesn't have a regular doctor or a place he usually goes to for care... Is Displayed

Disclose1 How do you feel about talking to your health care provider about your sexual behavior (example: telling him or her you've had male partners)? Do you feel like they judge you? Why or why not?

Answer If Brandon wants to get the HPV vaccine but he doesn't know where to go to get it. He has health insurance but doesn't have a regular doctor or a place he usually goes to for care. He doesn't... Is Displayed

Trust1 Do you think that your doctor or health care providers are knowledgeable about the health issues that gay and bisexual men have to deal with? Why or why not?

BranGet2 Brandon wants to get the HPV vaccine but he doesn't know where to go to get it. He has health insurance and a regular doctor he sees, but he feels a little awkward asking his doctor for the HPV vaccine. He knows it's unprofessional but sometimes he thinks that his doctor judges him for his sexual behaviors.

Get2 Where would you go to get the HPV vaccine if you were in Brandon's situation?

Disclose2 How do you feel about talking to your health care provider about your sexual behavior (example: telling him or her you've had male partners)? Do you feel like they judge you? Why or why not?

Trust2 Do you think that your doctor or health care providers are knowledgeable about the health issues that gay and bisexual men have to deal with? Why or why not?

BranGet3 Brandon wants to get the HPV vaccine but he doesn't know where to go to get it. He does not have health insurance and is worried that the vaccine is too expensive. He read that out of pocket the vaccine could cost almost \$500 for all 3 shots.

Recom3 What would you recommend that Brandon do?

Decide3 What would you do if you were in Brandon's situation?

Get3 Where would you go to get the the HPV vaccine if you wanted it?

Bran5 Even if he could find some way to get the HPV vaccine Brandon doesn't like going to the doctor and feels a little awkward asking a health care provider about the HPV vaccine since it's an STD. He knows its unprofessional but sometimes thinks that doctors judge him for his sexual behaviors.



Decide5 How do you feel about talking to your health care provider about your sexual behavior (example: telling him or her you've had male partners)? Do you feel like they judge you? Why or why not?

Trust5 Do you think that your doctor or health care providers are knowledgeable about the health issues that gay and bisexual men have to deal with? Why or why not?

Context Brandon ended up getting vaccinated for HPV and felt good about his decision. He felt that he did something that will help to protect his health as well as the health of his partners. He found several different locations in his area where he could get the HPV vaccine at an affordable price. These included: A HIV-testing site or clinic that offers vaccination in addition to HIV testing. No appointment is usually needed. Many of these clinics offer medication and case management for people infected with HIV. Some of these organizations now offer HPV vaccination as part of there services for gay and bisexual men. A pharmacy with a walk-in clinic (e.g., CVS, Walgreens, Target, Walmart, Arlington, and others). These walk-in clinics provide basic health care services including vaccinations. A primary care providers office where you can receive routine medical care. This may be a "family doctor" or an in-network doctor affiliated with a health insurance organization. Community-based organization that "promotes a healthy environment for all regardless of race, ethnicity, religion, sexual orientation, gender identity, age or economic status." They offer a number of health and social services and even a weekly social group for young lesbian, gay, bisexual, transgender and queer youth.

	Unlikely (1)	Undecided (2)	Likely (4)
HIV testing site (5)	•	•	•
Pharmacy with a walk-in clinic (8)	•	•	•
Primary care provider office (9)	•	•	•
Community-based organization serving LGBT people (10)	•	•	•

PlacesC Assuming you wanted to get the HPV vaccine, indicate below if you would be likely or unlikely to get the HPV vaccination at any of these locations.

PlacesO Are there any other locations that you would prefer to get the HPV vaccine? Please explain below.

Thank you very much for taking the time to complete this survey. Two last important questions.



Intention Based on what you know right now about HPV and the HPV vaccine, how likely is it that you will receive your first HPV shot by this time next year?

- Very Unlikely (1)
- Unlikely (2)
- Somewhat Unlikely (3)
- Undecided (4)
- Somewhat Likely (5)
- Likely (6)
- Very Likely (7)

IntentionO You said that you are "\${q://QID82/ChoiceGroup/SelectedChoices}" to get your first HPV shot by this time next year. Why did you select this response? Is there anything you would like to know about the vaccine before making your decision?

OPEN Thank you for taking the survey. On the next page you can submit your responses and move on to enter to win a gift card. If you have any thoughts you'd like to share with me you can do so below.



## **Appendix D: IRB Approval**



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 18, 2013

Christopher Wheldon Community and Family Health 13201 Bruce B. Downs Blvd., MDC 56 Tampa, FL 33612

RE:	Expedited Approval for Initial Review
IRB#:	Pro00012092
Title:	Men4Men Health Study

#### Study Approval Period: 3/18/2013 to 3/18/2014

Dear Mr. Wheldon:

On 3/18/2013, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

### Approved Item(s):

Protocol Document(s): Diss IRB Protocol (APA 6).docx

### Consent/Assent Document(s)\*:

Name	Version
Phase 1A In person IC	0.01
Phase 1A online IC	0.01
Phase 1B and 2 Online IC	0.01
All consent forms granted a Waiver of Informed Consent Documentation	

All consent forms granted a Waiver of Informed Consent Documentation

\*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.

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,

inka Ph.D.

John Schinka, Ph.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

3/24/2014

Christopher Wheldon Community and Family Health 13201 Bruce B. Downs Blvd., MDC 56 Tampa, FL 33612

RE: Expedited Approval for Continuing Review

IRB#: CR1\_Pro00012092

Title: Men4Men Health Study

Study Approval Period: 3/20/2014 to 3/20/2015

Dear Mr. Wheldon:

On 3/20/2014, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

### Approved Item(s):

Protocol Document(s): Diss IRB Protocol (APA 6).docx

**Please submit an amendment to the IRB within 30 days** to update the recruitment flyer to reflect the following changes: include the word "research" on the flyer and provide disclosure of the collection of demographic information. Please update the study protocol to indicate the gift card compensation amount of \$25.

The waiver of informed consent documentation has been renewed.

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):



(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.

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,

Imka. Ph.D.

John Schinka, Ph.D., Chairperson USF Institutional Review Board

