

Using the Thai-Human Papilloma Virus Belief Scale to Tailor Messages to Eligible Women: A

Text Message Intervention

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### Abstract

Women ages 18 to 26 have the highest prevalence of human papillomavirus (HPV) disease in the United States as well as worldwide, and in particular, women ages 20 to 24 years (Taylor, Hariri, Sternberg, Dunne & Markowitz, 2011). Ratanasiripong (2012) found that HPV vaccine rates have increased since the introduction of the Gardasil vaccine by Merck in 2006 from between 5 percent in one sample in 2007 to as high as 49 percent of college-aged women receiving at least one dose. The research question for this project was the following: Do women aged 18 to 26 years perceive themselves at risk for HPV disease and do they have the intentions to receive the HPV vaccine series as determined by Thai Human Papillomavirus Vaccine Belief Scale (Thai-HPVBS)? The Thai-HPVBS bases its questions upon the constructs in the Health Belief Model (Rosenstock, 1966) which examines variables which influence health behavior. In their roles as primary care providers nurse practitioners are able to provide the cue to action for women aged 18 to 26 years to consider receiving the HPV vaccine series. Understanding the intentions of women, aged 18 to 26 years guided the nurse practitioner in this project to design a text message educational intervention for the sample population. There were no significant findings.

*Keywords:* human papillomavirus (HPV), Thai Human Papillomavirus Vaccine Belief Scale,

## **Introduction**

### **Identification of the problem and the research question**

The purpose of this research proposal was to examine the use of the Health Belief Model (HBM) (Rosenstock, 1966) constructs regarding women's beliefs and intended behaviors related to intention to receive the human papillomavirus vaccine (HPV) series in a one month time frame (See Appendix A). In particular, the HBM (1966) framed the research and drive the survey questions. The research added to the body of knowledge regarding intention to vaccinate and reasons associated with intentions to vaccinate and use of the HPV vaccine series uptake rates among women. It added to the body of knowledge using the HBM (1966) as a framework for a research proposal. Part one was a survey of the Thai Human Papillomavirus Belief Scale (Thai-HPVBS) among women aged 18 to 26 years of age who were eligible for the HPV vaccine series catch up. Part two was an electronic follow up regarding HPV4 uptake after a one month's timeframe by the nurse practitioner.

### **The trigger for the investigation**

The dates that the HPV vaccines came to market may have missed the current 18 to 26 year old aged female population who may have been anywhere from age 9 in 2006 to 12 in 2009 when the current vaccines were available for patients. A female population aged 18 to 26 years is eligible for the catch up HPV4 vaccine series.

### **Relevance to the role of the nurse practitioner.**

(Nurse the role of primary care providers)and have contact with women aged 18 to 26 years old females in a primary care clinic setting. This contact will allow the nurse practitioner

to discuss the HPV vaccine with the patient, prescribe the vaccine, and perform follow up care such as Papanicolaou smears, and sexually transmitted infection (STI) examinations. At each point of contact, the nurse practitioner will be able to recommend the HPV vaccine to the female 18 to 26 year old patient.

### **Context of the Problem**

Decision making in health care has been studied among various populations and, in particular, the factors that are associated with women's reasons for deciding to receive the HPV vaccine have been studied (Boehner, Howe, Bernstein & Rosenthal, 2008; Gerend & Magloire, 2008). Studies have shown a relationship between the HBM (Rosenstock, 1966) factors and intentions to receive the Human Papillomavirus (HPV) vaccine series and, in particular, that a doctor's recommendation serving as a cue to action is related to vaccination intentions (Boehner et al, 2003; Jones & Cook, 2008). According to the HBM a cue to action can be a provider's recommendation to return to the clinic in one month for the second vaccination or it can be a postcard, email, telephone call, or text message reminder. The studies have linked that females who perceive that the benefits of the HPV vaccine series are greater than the barriers to receiving it are more likely to act or intend to act to receive the HPV vaccine series (DiGuseppe, Abbate, Liguori, Albano & Angelillo, 2008; Giede et al., 2010; Juraskova, Bari, O'Brien & McCaffery, 2011).

Cervical cancer is one of the most common neoplastic diseases affecting women worldwide and is the third most common cancer worldwide (Adegoke, Kulasingam & Virnig, 2012; Franco, Schlecht, & Saslow, 2003). It has been stated that about 20 million Americans between the ages of 15 to 49 are currently infected with HPV with yet another 6 million new infections occur each year (Ratanasiripong, 2013). The risk factors for cervical cancer

associated with HPV infections which can lead to cervical and other cancers include age younger than 25 years, first sexual intercourse at an early age, lack of condom use by the male, multiple sex partners, or a previous history of HPV (Ratanasiripong, 2013).

Over the past thirty five years cervical cancer incidence rates have seen reductions in invasive cervical cancer, but there have been differences among racial groups (Adegoke, Kulasingam & Virnig, 2012). In 2011, global cervical cancer rates were 529,800 and in the United States there were 12,200 new cases of cervical cancer diagnosed in 2010 (Adegoke, Kulasingam & Virnig, 2012). The rates of cervical cancer stated are only one manifestation of the human papillomavirus (HPV) cancers. Cancers associated with HPV have been stated to be cervical, penile, vulvar, oral, and anal. The total disease burden associated with HPV is therefore higher than only cervical alone.

According to the CDC (2007), nearly all cervical cancers are caused by HPV as well as being associated carcinogenic agents in other parts of the body. The HPV is associated with 90% of anal cancers, 65% of vaginal cancers, 50% of vulvar cancers, 35% of penile cancers, and 60% of oropharyngeal cancers (CDC, 2011). The CDC (2011) states that more than 100 HPV strains exist and more than 40 can infect the genital area. Most HPV infections are asymptomatic, unrecognized, subclinical and clear in about two years (CDC, 2011; Hatcher, et al., 2011). The persistent HPV strains are a strong risk factor for the development of pre-cancers and cancers of the genital tract if it does not clear in two years.

There has been considerable effort in the United States as well as the world to increase the uptake of the human papillomavirus vaccine (HPV) in order to decrease the spread of HPV associated diseases and HPV associated cancers (Barr et. al., 2008; Dunne et al., 2007; Frazer, Legatt & Mattarollo, 2011; Heffner & Schust, 2010). The highest prevalence rates for HPV have

been found among women aged 20 to 24 (Dunne et al, 2007; Krawczyk et al, 2012). College aged women are in the age ranges of 20 to 24. The HPV vaccine has been approved for use in the female population ages 9 to 26 years by various agencies (CDC, 2010; ACIP, 2007). Women ages 18 to 26 years of age must evaluate and decide if they will receive the HPV vaccine series, which is a 3 dose series given over 6 months especially due to the fact the HPV vaccine series is relatively new.

The HPV infection has been established as a cause of virtually all cancers of the cervix with cervical cancer the second most common cancer among women worldwide (Patel, et al., 2012; Tota, et al., 2011). The American Cancer Society (ACS) (Saslow et.al., 2007; Smith, Cokkinides, Brooks, Shah & Brawley, 2011) has stated that there is not sufficient evidence for HPV vaccination in the 19 to 26 year old female population, but there are actually a total of 13 strains which are carcinogenic (Tota, Chevarie-Davis, Richardson, DeVries & Franco, 2011). There could be a compelling argument to do the catch up vaccine series among this age group for several reasons with one being transmission of genital warts is associated with HPV strains 6 and 11. Another reason for the need for a catch up vaccine series is that the HPV strains 16 and 18 are considered to be responsible for about 70% of cervical cancers in all continents (Manhart et al., 2011; Tota et al 2011).

### **Description of the clinical system**

An urban primary care clinic located in and around a major university in the Mid-Atlantic United States was the site used. The health center is located in a urban Pennsylvania city and serves and provides primary care to patients of all ages. The clinic employs 4 physicians, 3 medical aides, 3 office staff, 1 office manager and 1 departmental secretary. The patients seek primary care for a variety of health problems.

**Demographics**

The practice was an academic practice for Family and Community Medicine for a major medical school in the Mid-Atlantic United States. The patients ranged in age from birth to the end of life. The patients came from all walks of life and live in the immediate area for the most part. The zip codes covered by most patients are 19140 and 19139. Some patients were employees of the university in this study. Exact data were not available at the time of this paper submission.

**Organizational culture****Key stakeholders**

The key stakeholders in this project were the women and their subsequent sex partners who will benefit from an immunization which provides protection against cancer and a sexually transmitted infection; the health care providers in the health care centers who provided the information about the HPV4 or and administer the vaccine; the females who may answer the survey questions; the males who may have interest in the survey questions, and the parents who may become aware and have questions about the survey. In addition, the future sex partners of the females who participated in the survey were beneficiaries. Finally, the insurance companies who will be paying less for the treatment of cervical cancers and their sequelae were all possible beneficiaries.

**Payor mix**

The women who use the urban Family and Community Clinic must pay cash up front for the HPV4 or Gardasil series injections which is \$131.00 per injection. If the women have insurance coverage, they may file for reimbursement from their respective insurance companies.

After age 18 years, the Vaccine for Children (VFC) Program no longer covers the HPV4 or Gardasil immunizations, so it may be burden for Temple students to pay out-of-pocket. A student may have the intention to receive the immunization, but may not have the money to pay for it. The Affordable Care Act of 2010 (ACA) is expected to cover the cost of the HPV4 or Gardasil series for women, but the implementation of the ACA may miss this group of women. Merck labeling has not indicated that HPV4 or Gardasil will be extended to women over the age of 26 anytime in the near future.

### **Internal and external resources**

The cost of the vaccine may have been a barrier for some women to initiate the vaccine series. There were several external resources for women to obtain the vaccine if cost is an issue. The Affordable Care Act (2010) will be expected to cover preventive services and HPV4 vaccine series is a preventive service. Under the Affordable Care Act (2010) young adults who currently have dependent insurance coverage through a health care policy with a parent or parents will be covered for major medical and preventive services until age 26 years. The issue regarding the vaccination was whether the women will have the intention to receive the HPV4 or Gardasil vaccine if cost is a barrier.

### **Perspectives of the Problem**

#### **Current Practice**

The current practice at the urban Family and Community Medicine clinic sees patients of all ages who are able to see providers in the clinic as allowed by their insurance companies. There are currently 4 physicians, 1 nurse practitioner, 1 office manager, 1 senior administrator, 3 certified medical aides, and 3 front desk clerical workers who are employed in the practice.

#### **Contributing Factors to the Practice**

**Historical Trends**

The services which are provided to the patients are primary care services. The clinic is affiliated with an urban based hospital and is located on the urban campus. The university students, as well as young women who do not attend the university, but live in the neighborhood or attend another university, use the clinic as their primary care provider. There are patients of all ages and all health conditions who visit the clinic.

**National Trends related to the local practice**

According to the current estimates, there are about 18 million students enrolled in colleges and universities in the United States with students in the age range 18 to 24 years group rising 16 percent over the past 10 years (Ratanasiripong, 2012). College women are exposed to situations that may put them at risk for exposure to adverse health outcomes, including unintended exposure to sexually transmitted diseases, such as HPV. The 2010 National College Health Assessment found that 69.9 percent of college women had vaginal intercourse and 24 percent had had 2 or more partners. Although the data for college women for this activity was not available for the urban Family and Community Medicine clinic, women who come to the FCM may be college students at Temple as well as other universities. The national trend conducted after the introduction of HPV4 or Gardasil in 2006 by the use of a survey indicated that only 10 percent of females aged 18 to 26 had initiated the HPV4 or Gardasil vaccine series (Patel, et.al. 2012).

**Impact of maintaining the status quo**

The impact of not meeting the national trend to increase the uptake the HPV4 or Gardasil is to not to increase the uptake among women and also men at some point. This will affect the health, the Papanicolaou smears, and the rates of sexually transmitted diseases among patients, the

fertility of women, and the sexual practices of both women and men. In addition, it increases their susceptibility to all of the cancers mentioned above in the decades of their lives to come. Ratanasiripong (2012) noted that nearly all sexually active people will become infected with the HPV strains, and 74 percent of the HPV infections occur among the 15 to 24 year age group. It was imperative to have college age women between the ages of 18 to 26 years of age understand that the HPV4 or Gardasil vaccine series is an immunization against not only a sexually transmitted disease but also a cancer causing virus.

### **Supporting Site Data**

The HPV4 or Gardasil was available to the women aged 18 to 26 years at the urban Family and Community Medicine Clinic. The numbers of women at the clinic who have received the HPV4 or Gardasil were not available, but among women aged 19 to 26, it has been shown that 17.1 percent have received at least one dose (Center for Disease Control and Prevention, 2009). Taylor, Hariri, Steinberg, Dunne & Markowitz (2011) found that the NHANES Study revealed that only 10.5 percent of women aged 19 to 26 years of age had initiated the HPV vaccine series. Ratanasiripong (2012) found that HPV vaccine rates have increased since the introduction of the vaccine in 2006 from between 5 percent in one sample in 2007 to as high as 49 percent of college aged women receiving at least one dose.

The HPV4 or Gardasil vaccine series has been recommended as a routine vaccination for all girls in the United States ages 11 to 12 years, and the catch up vaccination is for those women aged 13 to 26 years who have not been vaccinated (ACIP, 2009; Laz, Rahman & Berenson, 2012). The HPV4 or Gardasil has been demonstrated to have high efficacy in preventing infections and precancerous lesions among sexually active women who are naïve to the strains covered in the vaccine (ACIP, 2009). The women who missed the routine vaccination at ages 11

to 12 and have been sexually active, and are ages 13 to 26 are still eligible to receive the HPV4 or Gardasil vaccine series (ACIP, 2009).

### **Outcomes of the Thai-HPVBS**

The Thai-HPVBS project provided the following outcomes: demographic data about the women participants; data about the perceived susceptibility to HPV associated diseases; perceived barriers to obtaining the HPV4 or Gardasil vaccine series; perceived threats to HPV associated diseases; likelihood of taking action in a one year's time frame to begin the HPV4 or Gardasil vaccine series; cues to action by the nurse practitioner with a telephone call or a text message to return to the clinic to begin the HPV4 or Gardasil vaccine series; and actual numbers of women who return to the clinic to receive the HPV4 or Gardasil vaccine series. The variables would all be constructs in the HBM and will be tested with the Thai-HPVBS.

The nurse practitioner will call the women aged 18 to 26 years who consent to a text message within a month's time frame from the woman's visit to the clinic. The nurse practitioner will remind the women that it was time to begin or continue the HPV4 or Gardasil vaccine series. The nurse practitioner had the names of the women and was able to track the women who return to the clinic for the vaccine series. Based upon the women's responses to the text message a recommendation to the clinic to incorporate a vaccine reminder system into the clinic protocols will be suggested.

The text message will be made one week after the woman takes the survey. The nurse practitioner will then give the woman a date to return to the clinic for the immunization. Currently, the clinic does not make an appointment for the patient for an immunization, so the woman will be instructed to return to the clinic between the hours of 7:30 A.M. and 4:30 P.M.

The nurse practitioner was not able to track the women who returned for the HPV4 or Gardasil vaccine series.

### **Outcome measures**

The low numbers of HPV4 or Gardasil vaccine uptake indicate that the females who visit the FCM may reflect the national standards of low vaccine uptake rates for women aged 18 to 26 years. It might also indicate a knowledge gap that the HPV4 or Gardasil vaccine series is for the preteen females and not the college aged females. The national data have shown low rates of HPV4 vaccination among the college aged women for various reasons, so the Temple FCM female patients may be trending the same direction as the national statistics. It will be possible to match the incoming patients with HPV4 or Gardasil vaccination rates.

### **Data to demonstrate the existence of the problem**

The urban University Student Health website listed the top three sexually transmitted diseases among the student population as genital warts which are caused by HPV virus strains, chlamydia, and gonorrhea. Perhaps patients who visited the urban FCM did not make the connection between genital warts and increased risk of HPV associated diseases or cancer. It might be expected that the urban FCM patients would be similar to the national trends among women ages 18 to 26 years in the United States.

### **Empiric research, literature, and national database**

The universal coverage of all eligible women with the HPV vaccine series has the potential to reduce cervical cancer by 70 percent and could narrow any gaps which might develop among racial, socioeconomic, and other groups in terms of disparities in cervical cancer incidence and mortality (Brewer et al., 2011; Kahn et al., 2008; Palli, Mehta & Aparasu, 2012). The ability to decrease the burden of cervical cancer associated with HPV and to decrease the

burden associated with other HPV associated diseases will not only save lives, but also decrease healthcare spending in this area.

The American Academy of Pediatrics (AAP, 2013) has recommended that pediatricians recommend that children receive the HPV4 or Gardasil vaccine series before exposure to the virus. This is not possible with the current college aged women. These women may have missed the vaccine for various reasons, newness as the first HPV vaccine came out in 2006, controversy surrounding the vaccine series, political debates about whether the vaccine series should be mandatory or not mandatory, and other personal reasons. The women ages 18 to 26 years of age are the catch up vaccine group. There is no indication for the vaccine to be given after the age of 26. The HPV still does persist in women past the age of 26 and incidences of HPV associated diseases have been found to be bimodal in terms of age in women (Short et.al, 2010).

#### **Establish target benchmarks for project**

The benchmark for the project was a proposal submission to the Capstone Committee Chair by September 30, 2013. The Chair made necessary corrections and suggestions and the second reader was presented with the proposal. The IRB forms were partially completed and submitted to the Capstone Committee Chair by October 7, 2013, for review and final revisions before submission to the IRB electronically. The survey was sent to the urban University Survey Center after IRB submission and approval for any comments or suggestions. The IRB granted consent in January 2014 (See Appendix B). The surveys were to be printed by the end of December, 2013. Advertising the survey was to begin in the first few weeks of the Spring, 2014 Semester in all sites. The nurse practitioner at the urban FCM was to obtain consent, distribute,

administer, collect, and analyze the surveys. The data analysis was to be done as the surveys after the week in February 2014.

### **Statement of the Problem for Change**

The potential problem for practice change is the HPV4 or Gardasil follow up in the clinic. Currently at the clinic, there is no system for vaccination series follow up. Patients are instructed to return to the clinic when necessary for the next series of vaccinations whether the patient is the parent of an infant or an adult over the age of 18. Perhaps, the women between 19 to 26 years of age at the urban University will not have any intentions to receive the vaccine even though their knowledge of HPV is high as revealed by the survey.

### **What is currently being done?**

There was currently no study about HPV4 or Gardasil and intentions to receive the vaccine being done at urban FCM to the researcher's knowledge. There was no vaccine reminder system in place in the clinic at this time. Identifying if patients have the need to know more about the HPV4 or Gardasil and what their intentions are to receive the vaccine would be helpful to the providers in order to direct services and resources appropriately for vaccine clinics. Although there are no mandatory laws in the Commonwealth of Pennsylvania at this time regarding HPV4 or Gardasil, it is possible that it could change with the upcoming changes to the health care system with the *Affordable Care Act of 2010* (Pub L, No. 111-148) and its mandates.

### **Justification of the practice change**

The practice change was based upon the findings of the survey. The survey indicated the specific educational need about the HPV4 or Gardasil. The change was implemented over time with the findings and the steps in Johns Hopkins Nursing Evidence Based Practice Model as

described in and Fineout-Overholt (2011). The survey with the Thai-HPVBS was one of the first steps in the process of the practice change. The second step was to call the patients who take the survey after one month to see who had or had initiated the HPV4 or Gardasil series. Data from this part of the project helped the nurse practitioner design the reminder system for the clinic.

## **Model**

### **Evidence Based Practice Framework**

The evidence based practice framework was the Johns Hopkins Nursing Evidence Model of Evidence Based Practice (JHNEBP) (Melnik & Fineout-Overholt, 2011). This model has been used successfully in clinical, administrative, and educational nursing practice settings as well as state level initiatives to review evidence. There are three stages: practice question; evidence; and translation. The JHNEBP uses internal factors of the culture, environment, equipment and supplies, staffing and standards with the external factors of accreditation, legislation, quality measures, regulation, and standards. The model was able to use research results in the clinical setting.

The survey with the Thai-HPVBS was able to identify if the females aged 18 to 26 years at the urban FCM have knowledge gaps about the HPV4 or Gardasil vaccine. The patient population was women aged 18 to 26 years of age who visit the urban FCM and do have they have the intent after one month to receive the HPV4 or Gardasil vaccine series or the question of interest and does a tailored message to the patient increase uptake of the HPV4 or Gardasil vaccine series. The PICOT format was the formula that allowed the clinical nursing question to be asked in order to begin the search for relevant information for the clinical problem or question of interest. The P stands for patient or patient population; the I stands for intervention or Issue of

interest; the C stands for comparison intervention or group; the O stands for the outcome; and the T stands for the time frame.

### **Health Belief Model (HBM)**

The HBM (Rosenstock, 1966) (See Appendix C) states that a person's perceptions of four variables will predict their behavior. The four major constructs are: perceived susceptibility, perceived seriousness, perceived benefits, and perceived barriers. The original HBM was developed by Rosenstock to focus efforts of public health officials to improve public health by trying to understand why persons failed to adopt a preventative health behavior (Rosenstock, 1966). The model sought to explain and predict a variety of behaviors which were associated with positive outcomes with the following factors: perceived susceptibility, perceived severity, perceived benefits minus perceived barriers, and cues to action (Burak & Meyer, 2013; Carpenter, 2010).

The HBM (Rosenstock, 1966) has been used to frame health care research for several settings. A meta-analysis of the use the HBM (1966) and its variables in predicting behavior was conducted by Carpenter (2010). Carpenter (2010) found among 18 studies published between 1982 and 2007 and found benefits and barriers were the strongest predictors of behavior with benefits  $.09 < p < .45$  and barriers  $.13 < p < .47$ . The variable severity was weakest but in the expected direction ( $-.04 < p < .35$ ).

The Thai HPV Beliefs Scale (T-HPVBS) was the basis of this locally administered survey questionnaire to 18 to 26 year old college students at Temple University in Philadelphia, Pennsylvania in order to assess their beliefs and intentions about obtaining HPV vaccination. The Thai-HPVBS was based upon the tool developed by nurse researchers to assess HPV

vaccination intention (Juntasopeepun et. al., 2011). Depending upon the age of the study participant she may or may not have been vaccinated with either vaccine for HPV.

### **Describe how this framework guides the project**

It has been shown that attitudes have an influence on behavior and are mediated by intentions with the use of various theoretical models in various settings (Ajzen & Fishbein, 1980). Hence, a person's attitudes and or a person's health care provider's attitudes may influence a woman's intention to receive the HPV vaccine. Understanding attitudes and intentions guided the nurse practitioner to develop the appropriate clinical and educational approaches to women aged 18 to 26 years regarding the HPV vaccine series and intent to vaccinate.

### **Critical Appraisal of the Literature**

Decision making in healthcare has been studied among various populations and, in particular, the factors that are associated with women's reasons for deciding to receive the HPV vaccine have been studied (Boehner, Howe, Bernstein & Rosenthal, 2008; Gerend & Magloire, 2008). The studies have shown a relationship between the HBM (Rosenstock, 1966) factors and intentions to receive the HPV vaccine series and in particular, that a doctor's recommendation or cue to action is related to vaccination intentions (Boehner et al, 2003; Jones & Cook, 2008). The studies have linked that females who perceive the benefits of the HPV vaccine series are greater than the barriers to receiving it are more likely to act or intend to act to receive the HPV vaccine series (DiGuseppe, Abbate, Liguori, Albano & Angelillo, 2008; Giede et al., 2010; Juraskova, Bari, O'Brien & McCaffery, 2011).

Cervical cancer is one of the most common neoplastic diseases affecting women worldwide and is the third most common cancer worldwide (Adegoke, Kulasingam & Virnig,

2012; Franco, Schlecht, & Saslow, (2003). Over the past thirty five years cervical cancer incidence rates have seen reductions in invasive cervical cancer, but there have been differences among racial groups (Adegoke, Kulasingam & Virnig, 2012). In 2011 global cervical cancer rates were 529,800 and in the United States there were 12,200 new cases of cervical cancer diagnosed in 2010 (Adegoke, Kulasingam & Virnig, 2012). The rates of cervical cancer stated are only one manifestation of the human papillomavirus (HPV) cancers. Cancers associated with HPV have been stated to be cervical, penile, vulvar, oral, oro-pharyngeal, and anal. The total disease burden associated with HPV is therefore higher.

According to the Centers for Disease Control in 2011 (CDC) nearly all cervical cancers are caused by HPV. The HPV is associated with 90% of anal cancers, 65% of vaginal cancers, 50% of vulvar cancers, 35% of penile cancers, and 60% of oropharyngeal cancers (CDC, 2011). The CDC (2011) states that more than 100 HPV strains exist and more than 40 can infect the genital area. Most HPV infections are asymptomatic, unrecognized, subclinical and clear in about two years (CDC, 2011; Hatcher, et al., 2011). The persistent HPV strains are the strong risk factor for the development of pre-cancers and cancers of the genital tract if they do not clear in two years.

There is considerable effort in the United States, as well as the world, to increase the uptake of the human papillomavirus vaccine (HPV) in order to decrease the spread of HPV associated diseases and HPV associated cancers (Barr & Sings, 2008; Dunne et al., 2007; Frazer, Legatt & Mattarollo, 2011; Heffner & Schust, 2010). The highest prevalence rates for HPV have been found among women aged 20 to 24 (Dunne et al, 2007; Krawczyk et al, 2012). Most college aged women are in the age ranges of 20 to 24. The HPV vaccine has been approved for use in the female population ages 9 to 26 years by various agencies (CDC, 2010; National

Advisory Committee on Immunization (ACIP), 2007). Women in college must evaluate and decide if they will receive the HPV vaccine series which is a 3 dose series given over 6 months especially due to the fact the HPV vaccine series is relatively new.

The HPV infection has been established as a necessary cause of virtually all cancers of the cervix with cervical cancer the second most common cancer among women worldwide (Patel, et al., 2012; Tota, et al., 2011). The ACS (2011) has not recommended the HPV vaccine series for the 19 to 26 year female population even though there are actually a total of 13 strains which are carcinogenic (Tota, Chevarie-Davis, Richardson, DeVries & Franco, 2011). The HPV strains 16 and 18 are considered to be responsible for about 70% of cervical cancers in all continents (Manhart, et al., 2011; Tota, Chevarie-Davis, Richardson, DeVries & Franco, 2011).

The HPV is highly prevalent in the female population aged 18 to 26 years and infection with HPV and subsequent progression to low grade lesions or cervical epithelial lesion 1 (CIN 1) to cervical epithelial lesion high grade lesions (CIN 2, 3) has been firmly documented (Henk, Insinga, Singhal & Darkow, 2009). Henk et al. (2009) estimated nearly 234,603 new cases of CIN 1 and 177,469 new cases of CIN 2, 3 with the United States female population data from 2000. Henk, et al. (2009) found the total cost to manage CIN 1 was \$250 million and \$350 million to manage CIN 2,3. The HPV vaccine series has the potential to impact not only the disease burden, but the economic burden of HPV associated diseases. Henk et al. (2009) only looked at cervical cancer lesions in this study, so the total cost burdens to the economy are much higher than the totals listed here.

The HPV is one of the most commonly sexually transmitted diseases worldwide and also in the United States with an estimated 75% of males or females who engage in sexual activity expected to become infected at some point in their lives (Henk, Insinga, Singhal & Darkow,

2009; Tota et al., 2011). Most HPV infections resolve in one to two years without symptoms, but it is known that some HPV infections in some individuals will progress to cervical cancer or other HPV associated cancers (Chesson, et al., 2012; Henk, Insinga, Singhal & Darkow, 2009; Tota, et al, 2011).

The American Academy of Pediatrics (AAP) has stated that the HPV vaccine should be recommended for males and females at ages 11 to 12 years in routine well child visits. The vaccine administered at these ages will be to children who have not had sexual debut yet. It is also noted by AAP that the vaccine is inactive against HPV strains which have been previously acquired by the recipient. The AAP also noted that antibody responses are highest at ages 9 to 15 years of age (2012). The vaccines which are currently on the market are Merck's Gardasil or HPV4 which arrived in June 2006 and Glaxo Smith Klines's Cervarix or HPV2 which arrived on the market in the United States in 2009. The dates that the HPV vaccines came to market have missed the population of women aged 18 to 26 years who may have been anywhere from ages 9 in 2006 to 12 in 2009 when the current vaccines were available for patients. A female population aged 18 to 26 years will be eligible for the catch up HPV vaccine series.

The reasons that are associated with females and males and their intentions to receive the HPV vaccine series have been examined by several researchers in various populations (Bennett, Buchanan & Adams, 2012; Brewer & Fazekas, 2007; Bynum, Brandt, Annan, Friedman, Tanner & Sharpe, 2011; Krawczyk et al, 2012; Patel et al., 2012). The HBM (Rosenstock, 1966) is a model that has examined the intentions of females and males to begin and or complete the HPV vaccine series (Allen et al, 2009; Bennett, Buchanan & Adams, 2012; Bynum et al., 2011; Brewer & Fazekas, 2007; Hopfer & Clippard, 2010; Kahn, Rosenthal, Hamann & Bernstein, 2003; Liau, Stupiansky, Rosenthal & Zimet, 2012; Manhart et al., 2011; Marlow, Wiler, Evans

& Wardle, 2009; Patel et al., 2012; Wheldon, Buhi & Daley, 2012). Briefly stated, the HBM (1966) states that a person is more likely to engage in a behavior if: she believes she is susceptible; she believes the condition to have serious consequences; she perceives there are greater benefits than barriers; and finally she is exposed to a cue to action or behavior.

The universal coverage of all eligible women with the HPV vaccine series has the potential to reduce cervical cancer by 70 percent and could narrow any gaps which might develop among racial, socioeconomic, and other groups in terms of disparities in cervical cancer incidence and mortality ( Brewer et al., 2011; Kahn et al., 2008; Palli, Mehta & Aparasu, 2012). The ability to decrease the burden of cervical cancer associated with HPV and to decrease the burden associated with other HPV associated diseases will not only save lives but also decrease healthcare spending in this area. The cost of the HPV vaccine series was originally priced at \$120 per injection and 3 were needed for HPV vaccine series completion. Prior to Vaccines for Children (VFC) recommendations to cover the costs for the uninsured; patients with private insurance had spotty coverage through their insurance companies (Haas et al., 2009).

It has been noted that among women aged 19 to 26 years of age that a recommendation from their physician to receive or begin the HPV4 or Gardasil series were more likely to receive the vaccine series (Rosenthal, et.al., 2011). In the Rosenthal et.al. study (2011) it was found that the strength of the provider's recommendation resulted in a 4 fold greater likelihood of HPV4 or Gardasil vaccination. The recommendation in this study mirrors the cue to action in the HBM that is the framework of this practice change.

The recommendation from a health care provider is important as is the ability of the clinic providers to increase vaccine uptake by increasing a return to the clinic for the multi-injection HPV4 or Gardasil series. In one study in 2013 by Laz, et.al., it was found that one of

the main reasons that 18 to 26 year old women did not receive the HPV4 or Gardasil vaccine was that it was not recommended by their physician. Hence, the primary care provider is in the optimal position to increase uptake by a recommendation during a visit.

Increasing rates of immunization uptakes among all groups has been an issue for years. The reminder systems used in some clinics have utilized such systems as post cards, mailings and automated voice mail messages (Ahlers-Schmidt, 2012). The use of email messages has also been used a reminder to return to the clinic for vaccinations (CDC, 2009). The lack of any reminder system in the clinic deters the providers from having all patients in the practice receive all required as well as recommended vaccinations.

### **Problem at Large**

Decision making in healthcare has been studied among various populations and in particular, the factors that are associated with women's reasons for deciding to receive the HPV vaccine have been studied (Boehner, Howe, Bernstein & Rosenthal, 2008; Gerend & Magloire, 2008). The studies have shown a relationship between the HBM (1966) factors and intentions to receive the Human Papillomavirus (HPV) vaccine series and in particular, that a doctor's recommendation or cue to action is related to vaccination intentions (Boehner et al, 2003; Jones & Cook, 2008). The studies have linked that females who perceive the benefits of the HPV vaccine series are greater than the barriers to receiving it are more likely to act or intend to act to receive the HPV vaccine series (DiGuissepe, Abbate, Liguori, Albano & Angelillo, 2008; Giede et al., 2010; Juraskova, Bari, O'Brien & McCaffery, 2011).

Cervical cancer is one of the most common neoplastic diseases affecting women worldwide and is the third most common cancer worldwide (Adegoke, Kulasingam & Virnig, 2012; Franco, Schlecht, & Saslow, 2003). The HPV is a common sexually transmitted virus that

is linked to cervical cancer, genital warts, and head and neck cancers (Dempsey, Cohn, Dalton & Ruffin, 2010). Vaccines to prevent disease are an effective way to offer protection to a large group of people, but a vaccine that is associated with sexual behavior and cancer does not lead to automatic acceptance (Boehner, Howe, Bernstein & Rosenthal, 2003).

Over the past thirty five years cervical cancer incidence rates have seen reductions in invasive cervical cancer, but there have been differences among racial groups (Adegoke, Kulasingam & Virnig, 2012). In 2011 global cervical cancer rates were 529,800 and in the United States there were 12,200 new cases of cervical cancer diagnosed in 2010 (Adegoke, Kulasingam & Virnig, 2012). The rates of cervical cancer stated are only one manifestation of the human papillomavirus (HPV) cancers. Cancers associated with HPV have been stated to be cervical, penile, vulvar, oral, oro-pharyngeal, and anal. The total disease burden associated with HPV is therefore higher.

According to the Centers for Disease Control and Prevention (2011) nearly all cervical cancers as well as cancers in other parts of the body are caused by HPV. The HPV is associated with 90% of anal cancers, 65% of vaginal cancers, 50% of vulvar cancers, 35% of penile cancers, and 60% of oropharyngeal cancers (CDC, 2011). The CDC (2011) states that more than 100 HPV strains exist and more than 40 can infect the genital area. Most HPV infections are asymptomatic, unrecognized, subclinical and clear in about two years (CDC, 2011; Hatcher, et al., 2011). The persistent HPV strains are the strong risk factor for the development of precancers and cancers of the genital tract if it does not clear in two years.

There is considerable effort in the United States as well as the world to increase the uptake of the human papillomavirus vaccine (HPV) in order to decrease the spread of HPV associated diseases and HPV associated cancers (Barr & Sings, 2008; Dunne et al., 2007; Frazer,

Legatt & Mattarollo, 2011; Heffner & Schust, 2010). The highest prevalence rates for HPV have been found among women aged 20 to 24 (Dunne et al, 2007; Krawczyk et al, 2012). College aged women are in the age ranges of 20 to 24. The HPV vaccine has been approved for use in the female population ages 9 to 26 years by various agencies (Centers for Disease Control and Prevention, 2010; ACIP, 2007). Women in college must evaluate and decide if they will receive the HPV vaccine series which is a 3 dose series given over 6 months especially due to the fact the HPV vaccine series is relatively new.

The HPV infection has been established as a necessary cause of virtually all cancers of the cervix with cervical cancer the second most common cancer among women worldwide (Patel, et al., 2012; Tota, et al., 2011). The HPV strains 16 and 18 are considered to be responsible for about 70% of cervical cancers in all continents (Manhart, et al., 2011; Tota, Chevarie-Davis, Richardson, DeVries & Franco, 2011).

The HPV is highly prevalent in the college aged female population and infection with HPV and subsequent progression to low grade lesions or (CIN 1) to high grade lesions (CIN 2, 3) has been firmly documented (Henk, Insinga, Singhal & Darkow, 2009). Henk et al. (2009) estimated nearly 234,603 new cases of CIN 1 and 177,469 new cases of CIN 2, 3 with the United States female population data from 2000. Henk, et al. (2009) found the total cost to manage CIN 1 was \$250 million and \$350 million to manage CIN 2, 3. The HPV vaccine series has the potential to impact not only the disease burden, but the economic burden of HPV associated diseases. Henk et al. (2009) only looked at cervical cancer lesions in this study, so the total cost burdens to the economy are much higher than the totals listed here.

The HPV is one of the most commonly sexually transmitted diseases worldwide and also in the United States with an estimated 75% of males or females who engage in sexual activity

expected to become infected at some point in their lives (Henk, Insinga, Singhal & Darkow, 2009; Tota et al., 2011). Most HPV infections resolve in one to two years without symptoms, but it is known that some HPV infections in some individuals will progress to cervical cancer or other HPV associated cancers (Chesson, et al., 2012; Henk, Insinga, Singhal & Darkow, 2009; Tota, et al, 2011).

The American Academy of Pediatrics (AAP) has stated that the HPV vaccine should be recommended for males and females at ages 11 to 12 years in routine well child visits. The vaccine administered at these ages will be to children who have not had sexual debut yet. It is also noted by AAP that the vaccine is inactive against HPV strains which have been previously acquired by the recipient. The AAP also noted that antibody responses are highest at ages 9 to 15 years of age. The vaccines which are currently on the market are Merck's Gardasil or HPV4 which arrived in June 2006 and Glaxo Smith Klines's Cervarix or HPV2 which arrived on the market in the United States in 2009. The dates that the HPV vaccines came to market have missed current college aged population who may have been anywhere from ages 9 in 2006 to 12 in 2009 when the current vaccines were available for patients. A college aged female population's ages 18 to 26 years will be eligible for the catch up HPV vaccine series.

The reasons that are associated with females and males and their intentions to receive the HPV vaccine series have been examined by several researchers in various populations (Bennett, Buchanan & Adams, 2012; Brewer & Fazekas, 2007; Bynum, Brandt, Annan, Friedman, Tanner & Sharpe, 2011; Krawczyk et al, 2012; Patel et al., 2012). The HBM (1966) is a model that has examined the intentions of females and males to begin and or complete the HPV vaccine series (Allen et al, 2009; Bennett, Buchanan & Adams, 2012; Bynum et al., 2011; Brewer & Fazekas, 2007; Hopfer & Clippard, 2010; Kahn, Rosenthal, Hamann & Bernstein, 2003; Liau, Stupiansky,

Rosenthal & Zimet, 2012; Manhart et al., 2011; Marlow, Wiler, Evans & Wardle, 2009; Patel et al., 2012; Wheldon, Buhi & Daley, 2012). Briefly stated, the HBM states that a person is more likely to engage in a behavior if: she believes she is susceptible; she believes the condition to have serious consequences; she perceives there are greater benefits than barriers; and finally she is exposed to a cue to action or behavior.

The universal coverage of all eligible women with the HPV vaccine series has the potential to reduce cervical cancer by 70 percent and could narrow any gaps which might develop among racial, socioeconomic, and other groups in terms of disparities in cervical cancer incidence and mortality ( Brewer et al., 2011; Kahn et al., 2008; Palli, Mehta & Aparasu, 2012). The ability to decrease the burden of cervical cancer associated with HPV and to decrease the burden associated with other HPV associated diseases will not only save lives but also decrease healthcare spending in this area. The cost of the HPV vaccine series was originally priced at \$120 per injection and 3 were needed for HPV vaccine series completion. Prior to Vaccines for Children (VFC) recommendations to cover the costs for the uninsured; patients with private insurance had spotty coverage through their insurance companies (Haas et al., 2009).

### **Problem at site**

### **EBP model research**

Theories have been used to explain behavior and help to develop health education and health promotion materials (Painter, 2008). The HBM (1966) is one of the oldest models which has used the four main concepts of susceptibility, seriousness, benefits and barriers regarding health. Understanding the intentions of eligible college aged women at the urban University in Philadelphia, Pennsylvania would allow the development of directed health promotion and

education of HPV vaccine for this population. Use of the Thai-HPVBS in this age group is appropriate as it has been used in Thai college aged women.

### **Justification for this project**

Despite the recommendations of the Centers for Disease Prevention and health care providers to young women to receive the HPV vaccine series only 10% of women in the United States have been vaccinated (Laz, Rahman & Berenson, 2013; Zimet, Weiss, Rosenthal, Good, & Vichnin, 2010). The national studies conducted during the years 2007 to 2008 among women showed low vaccine initiation rates of 9% to 12% and low completion rates of 6.2% (Laz, Rahman & Berenson, 2013). The reasons that women aged 18 to 26 have not initiated the HPV vaccine series need to be examined. In particular, this study looked at the intentions women have to receive the HPV vaccine series.

### **Implementation plan**

The overall research design was a quantitative study using the survey which was used by a convenient sample of female patients who are aged 18 to 26 years who were patients at Temple FCM in Philadelphia, Pennsylvania. The female patients were solicited to join the study from their identification by the nurse practitioner. The data was collected over a 4 week time frame in February, 2014, during the regular semester. The data was analyzed from April 1, 2014, to April 15, 2014. The study was conducted via paper and pencil and was anonymous to all parties other than the nurse practitioner. There was monetary remuneration worth \$5.00 Saxby's coffee gift card for the subjects.

The research was conducted over four weeks with data collection done over one regular term semester in February 2014. The telephone numbers of the eligible female patients aged 18 to 26 years of age were solicited to partake in the research. The women completed consent

forms approved by the IRB. There were two pre-qualifying questions to determine HPV exposure which were not used in the analysis.

The research design was a quantitative study of female patients who were aged 18 to 26 years of age who attended the urban FCM, a university based primary care clinic associated with the urban university hospital systems located in the urban Pennsylvania. The sample was a convenient sample of the women who happened to walk into the FCM for a routine visit in the collection weeks in February, 2014. Females were identified not by name, but by the gender, checked on incoming application forms. The approval of the urban university Institutional Review Board was solicited and all rules and regulations dealing with human subjects were followed. Based upon the data from the Thai-HPVBS the researcher designed a standard text mail message from the nurse practitioner as the intervention. The vaccine reminder system was then suggested for the clinic protocol for vaccine recall for all women who are eligible for the HPV4 or Gardasil series.

### **Subjects**

The subjects were women between the ages of 18 to 26 who were patients at the urban FCM in the urban Pennsylvania city who eligible candidates for the HPV vaccine series. The researcher was able to access the population of interest through the daily schedule of patients for the clinic for all the providers. The nurse practitioner approached the patients who were eligible subjects and asked for their voluntary participation. The subjects were not necessarily the urban university students, but the subjects were patients who attended the urban FCM clinic.

The target population was the urban university female patients who were between the ages of 18 to 26. The HPV vaccine has been recommended for this age group for the catch up vaccination. Due to the relative newness of the HPV vaccine, these women were eligible for

catch up. The population was accessed through the urban FCM during the predetermined weeks in February, 2014. The women were either patients or students in any undergraduate or graduate degree seeking program who utilized the urban FCM, or met the age requirement of women who were eligible for the HPV4 vaccine. The requirements for inclusion were female patients who met the project criteria. The requirements for exclusion were the following criteria: age as no subject was to be below 18 or over 26 years of age; receipt of the HPV4 vaccine; or male gender. Information data about the women's sexual experiences were collected but this factor was not an exclusion. The race, socioeconomic status, sexual experience, numbers of sexual partners, history of a pap smear, or history of a gynecological examination were not factors for exclusion.

### **Instrumentation or Tools**

The subjects' consents were obtained by the approved form (See Appendix O). The data to be gathered were demographic data and the survey questions on the Thai-HPVBS. The survey had prequalifying questions to determine if the woman had exposure to HPV vaccine. If a woman was eligible, then she was able to continue with the survey. The demographic data and the Thai-HPVBS tool survey tool were one survey questionnaire (see Appendix A).

The data were collected using a paper and pencil survey that included three sets of measures: demographic data, health characteristics related to HPV associated disease, and Thai HPVBS. The demographic data included age of the woman, undergraduate or graduate status at Temple, major, marital status, and sexually active or never sexually active. The majors question was an open question which the women wrote in their major or undeclared status. The questionnaire was delivered in person to the subjects who entered the urban FCM for an appointment.

The survey consisted of four areas which are consistent with the HBM (1966) variables: demographic and sexually relevant data; awareness and knowledge about HPV; attitudes towards HPV and HPV vaccine series; and intention to obtain the HPV vaccine series. The research in this study utilized a tool that has been previously tested in college aged women who speak English (See Appendix A for tool used).

The Thai--HPVBS is a brief but comprehensive and user friendly tool which has been used with young college aged women in Thailand. The T-HPVBS has construct validity and known group's validity. Construct validity requires according to Polit and Beck (2012) hypothesis testing and factor analysis which was performed with the tool. The use of this tool in the selected population is appropriate as some of the patients who visit the urban FCM were expected to be students, but the overarching criterion to participate was the age range.

The known group validity was done on the T-HPVBS and is a method to assess contrast validity by using the known groups technique to contrast scores of groups hypothesized to differ on an attribute. Juntasopeepun et al. (2011) used the known groups and looked at college aged women ages 18 to 24 who reported having had sexual activity with those women who reported never having had sexual activity. There was a significant relationship noted between perceived susceptibility and history of sexual activity with the group mean of women who had ever had sex being greater than the women who never had sex. Independent t tests were also done to determine differences for each item between the two groups of women. Women who had heard about the HPV vaccine had higher scores on the following items: perceived susceptibility, perceived seriousness, and perceived benefits and lower scores on perceived barriers as compared to women who had never heard of the HPV vaccine.

The researcher in this study decided to use the T-HPVBS due to the positive relationships which were noted in the Juntasopeepun et al. (2011) study. Permission to use the T-HPVBS was granted by Dr. Junatsopeepun via email on August 7, 2013. The T-HPVBS was designed to assess young women and in this particular study, young college aged women's HPV and cervical cancer beliefs. The items were generated using the items in the HBM (1966) as the theoretical framework. The T-HPVBS tool was used in this study to assess Temple FCM female patients aged 18 to 26 years of age and to survey the women's beliefs toward HPV infection, HPV associated cervical cancer, and HPV vaccine series uptake.

The consent of the women was obtained through the IRB approved form (See Appendix D). The researcher was available via email and cell phone for any questions, comments or concerns. The researcher was the only one who saw the data as the study was the Capstone project of the researcher. The nurse practitioner looked at all the providers' schedules during the selected timeframe for the administration of the survey to ascertain which patients met the criteria and might be interested in the survey. All study participants will receive the results and analysis before any publication of the results.

The women's health characteristics or traits were related to ascertaining the women's HPV associated disease. The questions were: ever had vaginal intercourse, number of sexual partners, history of a Pap smear, ever heard of HPV vaccine series, family history of cervical cancer, and intention to begin the HPV vaccine series. The question about vaginal intercourse was asked specifically to try to avoid any misinterpretations of intercourse and to try to avoid any data lost due to misinterpretations.

The survey used was the Thai-HPVBS tool to assess young women's beliefs toward HPV used in Chiang Mai, Thailand, as noted in a study (Juntasopeepun et al., 2011). It was based

upon a comprehensive literature review using the HBM (1966) constructs. The initial version had 12 items in four dimensions: perceived susceptibility to disease (2 items); perceived seriousness of disease (3 items); perceived benefits of HPV vaccine uptake (3 items); and perceived barriers to HPV vaccine uptake (4 items). The items were measured using a Likert scale which was not the method the author of this research article used.

The Thai-HPVBS tool or instrument was originally developed in English and then translated to Thai. The scale's origin therefore was with English as the primary language test subjects. The scale's face and content validity were established by a panel of three Thai and three English speaking members who were fluent in both languages (Juntasopeepun et al., 2011). The experts were given the conceptual and operational definitions for each of the four areas in the T-HPVBS and asked to rate the items. The panel suggested some minor changes and the new revised tool was pilot tested in a group of 30 women who completed the test and then did the retest in two weeks to determine test-retest reliability. Test-retest reliabilities were 0.75 for perceived susceptibility, 0.79 for perceived seriousness, 0.62 for perceived benefits, and 0.76 for perceived barriers. The items were positively correlated, and the higher the coefficient the more stable the relationship between measures.

The test retest method is easy to use, but the approach with the variables of interest in the Thai-HPVBS tool may be modified by the test subject's experiences between testing. The need to continue to use the tool in other study settings is imperative due to this issue. The other issues that may happen to subjects is that the taking of the test may influence their responses on the second testing or the retest. The other issue with test-retest is that the subjects involved may become bored with the retest effort and may not be as careful answering the questions in the retest (Polit & Beck, 2012).

The Thai-HPVBS tool does match the HBM's (1966) constructs so the decision to use it in the population of interest in this study is correct. The tool has the norms and comparisons for the population of interest in this study. The Thai-HPVBS was used in Thai college aged women 18 to 24 years of age. The population in the current study was American women 18 to 26 years of age who were eligible to receive the HPV4 or Gardasil vaccine series. The administration issue with this tool was the lack of privacy issue.

The Thai-HPVBS scale is listed in Appendix A. The first three questions deal with the benefits associated with HPV vaccine uptake; the next set of four questions deals with the seriousness of HPV associated disease; questions 6 through 9 inclusive deal with the barriers to receive HPV vaccine; and the last two questions deal with the susceptibility to HPV disease. The T-HPVBS scale showed positive correlations or Cronbach's alphas above 0.5 which is a measure of internal consistency. The scale may then be stated to have internal consistency and is measuring reliably the items on the instrument or tool (Polit & Beck, 2012).

### **Data Collection**

The subjects' data were collected via convenient sampling. The problem with convenience sampling is that the population may not be representative of the population of women 18 to 26 years old with regards to the variables of interest to the researcher. The use of convenience sampling in nonprobability, non random sampling of the population may not be representative of the group the researcher is interested in studying. The subjects will not be known to the researcher either.

There is no way to study the whole population of women aged 18 to 26 years who visit the urban FCM due to cost and time constraints. The subjects were rewarded for their participation in the study with a monetary gift of five dollars. The money came from the funding

which was sought for the study. The sample size was a nonrandom sample of women ages 18 to 26 who agreed to participate in the survey within a four week time frame in February, 2014.

There was Institutional Review Board (IRB) approval granted through the urban University IRB process. The IRB approval was sought and gained as the questions are dealing with sensitive material and dealing with human beings. The investigator wanted the risks to the subjects to be as minimal as possible; the informed consent of subjects was sought; appropriate means were in place to protect the subjects' privacy and confidentiality; risks of participating in the study were minimal to none while the benefits are positive; and the selection of subjects was equitable. There was no coercion or deception used to recruit subjects. The urban University IRB form was used.

## **SWOT analysis**

### **Strengths**

The strengths of the project were that it was an anonymous survey and an identification of the college aged women's intentions to receive the HPV vaccine series; an assessment of the strength of the recommendations of a friend, teacher, clinician, or significant other to receive the HPV vaccine series; and whether the woman perceives that HPV and its associated disease entities will be a future threat to her.

### **Weaknesses**

The weaknesses of the project were that it was a survey aspect of the HPV questionnaire which may draw a low response rate; it is not anonymous, and so women may have questions about the people who will see their answers and not complete the survey due to confusion; some women may see the survey as invasive and too time consuming; some women may not

understand their individual risk of contracting HPV and its associated diseases; and some women may be too busy to complete any survey of any length.

### **Opportunities**

The opportunities of the survey were an opportunity for identification of the women who do intend to receive the HPV vaccine; an identification of the women with safety concerns about the vaccine; an identification of women with the cost of the vaccine concerns; an identification of the women who do not trust the vaccine; an identification of the women who doubt the vaccine's effectiveness; and an identification of women who do not think that they are at risk for HPV and its associated diseases.

### **Threats**

The threats of the survey were that it was not permitted to be displayed on the student health center website as a link for the women to complete it; possible lack of IRB approval; no site approval; no interest in the project idea; no institution backing for the survey; distrust from the university officials; and no funding for survey respondents.

### **Detailed description of measurement plan**

The subjects were collected via nonrandom convenience sampling. The problem with convenience sampling is that the population may not be representative of the population of women 18 to 26 years old in regards to the variables of interest to the researcher. The use of convenience sampling in nonprobability non random sampling of the population may not be representative of the group the researcher is interested in studying. The subjects will not be known to the researcher either.

There was no way to study the whole population of women aged 18 to 26 years at the urban FCM due to cost and time constraints. The subjects were rewarded for their participation

in the study with a monetary gift from funds awarded to the student. The sample size was a convenient sample size of women ages 18 to 26 who were able to answer the survey within the time frame in February, 2014.

The subjects were approached at the urban FCM the day of their clinic visit to request their participation in a study about the HPV vaccine. There was permission sought to advertise the survey in the public areas of the urban FCM in January 2014 in order to increase interest among potential participants. The subjects were able to contact the researcher via email or cell phone and all questions were to be answered within 48 hours of the researcher reading the email. The researcher checked her email and cell phone messages daily every day of the week during the study.

The researcher wanted the risks to the subjects to be minimal if possible; the informed consent of subjects was sought; appropriate means were in place to protect the subjects' privacy and confidentiality; risks of participating in the study were minimal to none while the benefits were positive; and the selection of subjects was equitable. There was no coercion or deception used to recruit subjects. The urban University IRB form was used.

### **Detailed description of implementation plan**

The implementation plan began with the proposal and its submission to the Capstone committee members. The necessary IRB forms for a pilot study of the Thai-HPVBS among 18 to 26 year old female patients who visit the urban FCM located in the urban Pennsylvania city was obtained. A female participant's consent was the signed consent form.

### **Outcomes**

Outcomes were measured by the women's responses to the questions on the anonymous survey. The desired outcomes were participation by females 18 to 26 years of age active

participation on the Thai-HPVBS pilot study. The questions revealed if the women had the intention to receive the Gardasil or HPV4 vaccine series. The questions also revealed knowledge gaps in the sample population.

### **Timeline**

The timeline was to submit the proposal to the committee in early October for final review. The IRB forms were filed by the middle of October 2013. Prior to submitting the electronic IRB form a faculty member not on the committee was asked to review the IRB proposal for accuracy and completeness. Any and all revisions were completed by the end of January 2014. All required forms and modifications were made (See Appendix E).

### **Budget and financial impact**

There was no budget of money but only the investigator's time to compose the surveys, print out the surveys, transport the surveys to the site, provide a display for elevators and posts around the clinic to advertise the survey, and the compilation of the data. Funding was sought through the urban University Women's Educational Fund and granted. The researcher was granted \$500 and used \$75.00 for Saxby coffee gift cards in \$5.00 amounts. Each participant in the study received a card upon completion of the study.

### **Detailed description of measurement plan**

The female patients were self-recruited into the survey study from the nurse practitioner at the urban FCM clinic. The surveys were advertised after IRB approval on the clinic site. There were no items on the surveys to identify the student participants, but the nurse practitioner was able to identify who the subjects were as she did the text message intervention. It was a convenience sample of self-selected female population of women between the ages of 18 to 26

years of age who were patients at the urban FCM and had not received the HPV4 or Gardasil vaccine series.

Surveys were collected for a four week timeframe in February 2014 at the clinic site. At no time was anyone to have access to the surveys other than the nurse practitioner. The completed surveys were kept in the nurse practitioner's office locker which was locked at all times that the nurse practitioner was not in the office.

### **Data Collection**

The IRB approval was granted in late January 2014. Data collection began on January 30, 2014, at the Family and Community Medicine clinic. Patients who were in the age category of 18 to 26 years were identified in the electronic medical record. Patients were scheduled for routine visits to the clinic. The data were collected from January 30, 2014 to February 28, 2014. All the patients were females aged 18 to 26 years of age who may be potential subjects.

During the identified time frame there were 59 possible eligible subjects identified. The project had a goal of 50 subjects. Over the collection period 32 subjects did not show up for appointments or canceled appointments. The remaining 27 subjects were eligible for the survey. The project ended up with 15 subjects recruited for the intervention.

### **Practice Intervention**

The text messages were sent to all 15 women who consented to be contacted on March 4, 2014. The text message was sent from the student researcher's Iphone. The text message was the following: "Have you started the HPV vaccine? Text Mary Ann Picone yes or no." There were 10 total subjects of the total of 15 who answered the text message during the intervention time period.

The remaining subjects were texted again with the same message on March 7, 2014. One more subject answered the text within 24 hours. The study time parameters had ended as of March 8, 2014, with a total of 10 respondents out of a possible 15. In total the researcher sent out 15 texts the first time and 8 texts the second time. Both text messages occurred within 1 week.

### **Data Analysis**

The outcomes were measured with the SPSS package. The services of a university employed statistician were also used. The data were presented in the best format for ease of readability and interpretation, for example, tables for demographic data. The last question on the survey asked the woman to rank how likely she is to consider receiving an HPV vaccine. The question linked intentions with beliefs about the HPV vaccine and other questions on the survey.

The analysis revealed that all the women participants were African American with a mean age of 22. All the women who participated were unmarried and had had sex. The group was also divided along the low intention and high intention to receive the HPV vaccine (See Tables 1 and 2). The sample size was small due to many factors.

The use of chi square was discussed with the statistician, but due to some cell numbers which would have less than 5 subjects, the statistician recommended the Fisher's Exact Test for each of the 12 questions in the THPVBS. Each of the 12 questions were analyzed for high and low intentions to receive the HPV vaccine. The results were not significant but were found to be what was expected.

For example, for question one there were 5 high intention and 10 low intention people noted. It was found that the women with high intention to receive the HPV vaccine stated 40% said yes, 20% said no and 40% did not know. For the low intention group

70% said yes, 10% said no and 20% did not know. Although the percentages look different between groups, the Fisher's Exact Test is not significant ( $p=0.4406$ ) for question one or any other question. The women who answered do not know may have had lack of knowledge about the HPV vaccine (See Table 3).

Measurement took place at the urban FCM after IRB approval. The paper and pencil surveys were distributed in February, 2014. The survey was administered in person to each woman by the nurse practitioner. The completed surveys were locked in the nurse practitioner's office at the end of each day. The measurements took place over 4 weeks to allow for any closures of health centers due to weather or other conditions. The month of February 2014 in the urban city was very cold and very snowy which led the clinic to have late starts and closures. These weather factors limited the researcher's access to the clinic patients of interest. All the necessary forms and consents were obtained (See Appendix D).

### **Data Analysis**

The data were analyzed with the assistance of the software SPSS and the statistician. The demographic data were analyzed. The Thai-HPVBS questions were analyzed with the assistance of the statistician to see if the beliefs of the women show an intention to receive the Gardasil or HPV4. The statistics used were basic descriptive statistics of the demographic data which was collected. Data was analyzed using the Statistical Package for the Social Sciences (SPSS) and the most current version available at the time. The expertise and consultation of a faculty statistician, Dr. Eugene Komaroff, of the College of Health Professions and Social Work (CHPSW) was also utilized. The demographic data revealed that all the subjects were African Americans (See Table B in Appendices). The average age of the patients was 22 years.

The last question on the survey asked the woman to rank how likely she is to consider receiving an HPV vaccine. The question linked intentions with beliefs about the HPV vaccine and other questions on the survey. The question also identified the low intention and high intention responses by the women.

The analysis revealed that all the women participants were African American with a mean age of 22. All the women who participated were unmarried and had had sex. The group also divided along the low intention and high intention to receive the HPV vaccine (See Appendices F). The clinic served patients in a urban area which might explain that all the women were African Americans. Women who were low intention were found to have low knowledge levels about the HPV vaccine series, and high intention women had high knowledge levels.

There were no statistically significant findings with the THPVBS using the Fisher's Exact Test. The expected outcomes were seen, but the sample size was not large enough to perform any high function statistics. The trends the researcher expected were seen but cannot be described as robust.

The p value from a Fisher's Exact Test answered the following question: If there really is no association between the variable defining the rows and the variable defining the columns in the overall population, what is the chance that random sampling would result in an association as strong (or stronger) as observed in this experiment? The small cell sizes necessitated the use of the Fisher's Exact Test.

The women who answered the text message intervention answered within the timeframe established. The majority of women answered within 24 hours of the text message. The second

text message sent out 6 days later was able to glean 2 more subjects who answered the text message question. The analysis showed an insignificant p value, but the fact that 10 out of 15 women answered the text message questions in the timeframe may necessitate a need for further research in the use of the text message intervention (See Appendix H)..

## **Discussion**

There were many factors which led to a small sample size. The IRB permission was granted late in January which left only 4 to 5 weeks for data collection. The weather in the area in February 2014 was record breaking with many snow storms and ice storms that created other difficulties for both the researcher and the patients who may have participated. The clinic was closed or had late starts during the data collection time.

In addition to the weather issues, there were the clinic issues. During the time frame there were an identified 59 subjects who were eligible for the project. During February 2014 there were 59 identified women. Of those 33 women did not show up for their scheduled appointment which left the researcher with 26 possible subjects. There were 16 women approached and 15 women agreed to participate. Only 1 woman refused to participate. The other 10 women who may have been subjects were late to their appointment and the researcher was not able to stay.

During the project, the researcher was transferred from the FCM clinic to Pre Admission Testing due to the FCM NP position being eliminated in mid-December 2013. The researcher had to adjust the work and personal schedule to be able to visit the FCM clinic and collect the data. The researcher was able to adjust with the assistance of the FCM and PAT management and her Capstone Chair.

The use of email addresses of women at the university might have been able to increase the sample size. Women may have been more receptive to answering an email and not accepting a paper and pencil survey from a person. The anonymous nature of surveys might have been more appealing to more subjects. Being able to email women at the multiple sites at the university may have also gleaned more subjects.

The study looked at the catch up group for women but could also be extended to men ages 18 to 26 in a follow up study. Both men's and women's knowledge and intentions could be tested and their responses to the text messages might be different than just the women's responses in this study. Sexual orientation among men subjects who are eligible for the HPV vaccine series catch up might also be different than the women's responses in this study.

Getting the staff at the FCM clinic to use the text message system as the reminder system for the HPV vaccine series might be the biggest challenge. The current practice is busy and any new procedure is viewed as more work rather than as a better approach to patient care and patient flow through the clinic to receive their needed immunizations. Decreasing HPV diseases and associated cancers might free the provider's time to promote other healthy behaviors.

In concluding, job and time issues can never be predicted, but the need to be flexible and to adjust is part of the research process. The researcher would recommend this study to be replicated with the same age group in a college student health center or a family planning clinic. The study also needs to examine the intentions of 18 to 26 year old males as to their intentions to receive the HPV vaccine series.

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## Appendix A

## Pre-qualifying Survey Questions

Are you a female between the ages of 18 to 26 years of age?

- Yes  No

Have you received the Human Papilloma Virus (HPV) vaccine series?

- Yes  No

For the participant to continue:

- ✓ Answer to question 1 must be yes
- ✓ Answer to question 2 must be no

## Thai-HPV Belief Systems Scale

1. The HPV vaccine will protect people from getting cervical cancer.

- Yes  No  Don't Know

1. The HPV vaccine will be effective in preventing HPV infection.

- Yes  No  Don't Know

2. Getting an HPV infection, it would be disruptive to my health.

- Yes  No  Don't Know

3. If I have cervical cancer, it would threaten the relationship with my boyfriend, husband, or partner.

- Yes  No  Don't Know

4. Cervical cancer is a life-threatening disease.

- Yes  No  Don't Know

5. I think the HPV vaccine is unsafe.

- Yes                       No                       Don't Know
6. I feel embarrassed to get an HPV vaccine because it is for a sexually transmitted disease.
- Yes                       No                       Don't Know
7. It is hard to find a provider or clinic that has the vaccine available.
- Yes                       No                       Don't Know
8. I am concerned that the HPV vaccine costs more than my parents or I can pay.
- Yes                       No                       Don't Know
9. I am at risk for contracting HPV.
- Yes                       No                       Don't Know
10. I am at risk for getting cervical cancer.
- Yes                       No                       Don't Know
11. I have knowledge that my current health insurance plan covers the cost of the HPV series.
- Yes                       No                       Don't Know

#### Demographic Data

1. How old are you?    Month \_\_\_\_    Day \_\_\_\_    Year \_\_\_\_
2. What is your year in college?
- Freshman
- Sophomore
- Junior
- Senior
- Graduate Student

3. Marital Status
  - Unmarried
  - Married
  - Divorced
4. Major\_\_\_\_\_
5. Have you ever had sex?
  - Yes
  - No
6. If yes, on average in one week how many casual sex partners have you had in the past 10 years? \_\_\_\_\_
7. Have you ever had a Pap smear?
  - Yes
  - No
8. Do you have unprotected sex?
  - Yes
  - No
9. Race
  - White
  - Black or African American
  - American Indian or Alaska Native
  - Native Hawaiian or Other Pacific Islander
  - Asian
  - Decline to respond

10. Age of first sexual experience \_\_\_\_\_
11. Have you ever had a nurse practitioner or a physician diagnose you for HPV?
- Yes
  - No
12. Have you ever been pregnant?
- Yes
  - No
13. On a scale of 1 to 10, with 1 being not likely and 10 being very likely, how likely are you to receive the HPV vaccine series in a year? \_\_\_\_\_

**If you plan to receive the HPV vaccine series in the next year and would feel comfortable being contacted after this survey, then please supply your Temple email address.**

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## Appendix B

## IRB Approval

Informed Consent for **Minimal Risk** Social and Behavioral Research

[IRB project 21893 and consent vers. 1]:

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**Title of the research study: A Capstone Project for Urban College Aged Women regarding their Intentions to Obtain Vaccination with Human Papilloma Virus Vaccine: Using the Thai-Human Papillomavirus Vaccine Belief Scale to Tailor Messages: An Intervention**

**Name and Department of investigator: Mary Ann Picone, DNP (c) Dept. of Nursing**

This study involves research. The purpose of the research is **to assess beliefs, intentions, and behaviors among women aged 18 to 26 years regarding the receipt of the Human Papillomavirus Vaccine and to see if a tailored intervention by the nurse practitioner increases vaccine uptake behavior.**

What you should know about a research study:

- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide, it will not be held against you.
- Feel free to ask all the questions you want before and after you decide.
- By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study.

The estimated duration of your study participation is 20 to 30 minutes.

The study procedures consist of answering a survey, agreeing to be contacted via text message or telephone number in 1 month for follow up regarding behavior of vaccine uptake.

The reasonably foreseeable risks or discomforts are none.

The benefit you will obtain from the research is knowing that you have contributed to the understanding of this topic will be participation in research regarding vaccine uptake among the peer group for a vaccine which is a cancer preventing vaccine and a sexually transmitted infection vaccine.

Gift Card: You will be given a gift card worth \$5.00 at Saxby's Coffee. If you are reimbursed for your participation in this study, you may be asked to provide your social security number to a member of the study team via the completion of a IRS Form W-9. It is your responsibility to report any income received that is a result of your participation in this study. In situations where your compensation for this study exceeds \$599.00 or your total compensation for all of the Temple studies in which you participate exceeds \$599.00, you will receive a Form 1099-MISC from Temple which will be reported to the Internal Revenue Service. If you do not provide your social security number, you may still participate in the study but you will not be able to receive any reimbursement for your participation.

Subject Initials: \_\_\_\_\_  
Date: \_\_\_\_\_



Template Revision: November 19, 2013

Informed Consent for **Minimal Risk** Social and Behavioral Research

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The alternative to participating is to not participate.

Please contact the research team with questions, concerns, or complaints about the research and any research-related injuries by calling Mary Ann Picone at 267-279-4015 or e-mailing Mary Ann Picone at tud53749@temple.edu.

This research has been reviewed and approved by the Temple University Institutional Review Board. Please contact them at (215) 707-3390 or e-mail them at: irb@temple.edu for any of the following: questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input.

Confidentiality: Efforts will be made to limit the disclosure of your personal information, including research study records, to people who have a need to review this information. However, the study team cannot promise complete secrecy. For example, although the study team has put in safeguards to protect your information, there is always a potential risk of loss of confidentiality. There are several organizations that may inspect and copy your information to make sure that the study team is following the rules and regulations regarding research and the protection of human subjects. These organizations include the IRB, Temple University, its affiliates and agents, Temple University Health System, Inc., its affiliates and agents, the study sponsor and its agents, and the Office for Human Research Protections.

There will be no use of names or other personal identifying information about study participants used in any papers, presentations, or discussions.



Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Template Revision: November 19, 2013

Informed Consent for **Minimal Risk** Social and Behavioral Research

Page 3 of 4

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research.

**DO NOT SIGN THIS FORM AFTER THIS DATE** →



|   |       |
|---|-------|
| _____   | _____ |
| Signature of subject                              | Date  |
| _____   |       |
| Printed name of subject                           |       |
| _____   | _____ |
| Signature of person obtaining consent             | Date  |
| _____   | _____ |
| Printed name of person obtaining consent          |       |
| _____   | _____ |
| Signature of legally authorized representative    | Date  |
| _____   | _____ |
| Printed name of legally authorized representative |       |
| _____   | _____ |
| Signature of person obtaining consent             | Date  |
| _____   | _____ |
| Printed name of person obtaining consent          |       |

Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Informed Consent for **Minimal Risk** Social and Behavioral Research

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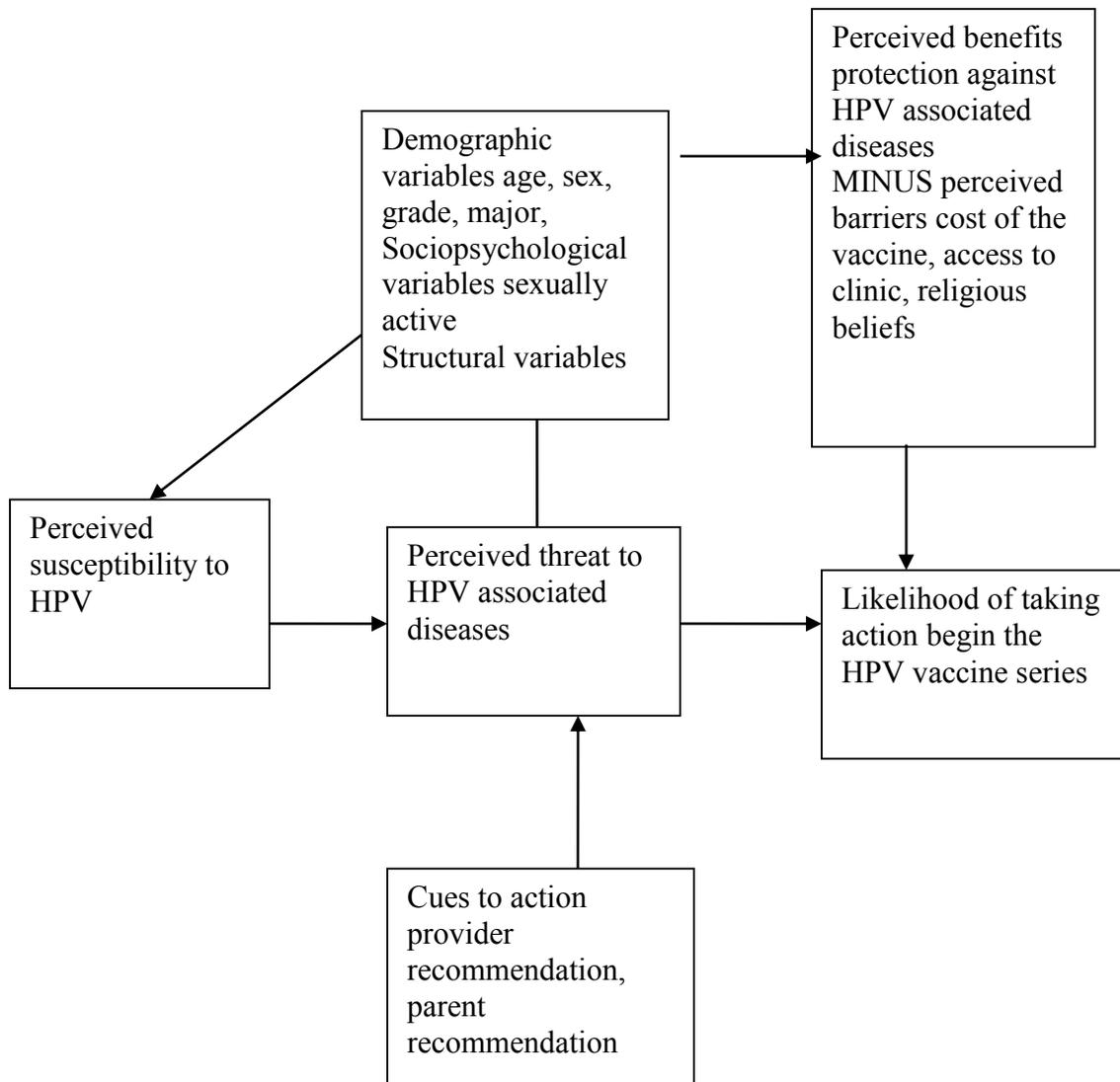


Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Appendix C

Health Belief Model



## Appendix D

## Consent Form

**Authorization to use and disclose personal health information for research at Temple University, Temple University Health System Affiliates, and Temple University Clinical Faculty Practice Plan****Information that will be collected from you and disclosed**

During the course of this research study, which is described by title in the attached consent form and **study-specific document**, certain **personal health information** will be collected and disclosed to **recipients** identified in this document. It is important for you to know that your personal health information may identify you by name, address, telephone number, photograph, social security number, health plan number, and date of birth, dates relating to various tests and procedures, or other personally identifiable information. This information may be obtained from your medical records, physical examinations and procedures: (a) to determine if you are eligible to participate in the research study or (b) created as a result of your participation in the research study.

**How your information will be used and to whom it will be disclosed**

By signing this authorization form, you give Temple University, Temple University Health System affiliates, and Temple University Clinical Faculty Practice Plan, Temple University Institutional Review Board, and the investigator(s) named in the attached study-specific document, permission to use your personal health information and to disclose this information to the following recipients (as applicable): sponsor; sponsor's agents; governmental entities overseeing research in the United States and abroad, which may include in the United States, the Food and Drug Administration and the Department of Health and Human Services. It is important for you to know that the recipients, and their agents or representatives, will take all reasonable efforts to maintain your personal health information in confidence, and to use appropriate safeguards to prevent further use or disclosure by those not authorized to use or disclose your personal health information. However, once your health information is disclosed to the recipients, then your personal health information may no longer be protected by federal privacy laws and regulations and there is a potential for re-disclosure of this information. However, the laws of the Commonwealth of Pennsylvania or your state of residence may provide further privacy protection.

**How you can access your information**

You should know that you have the right to see and receive a copy of your personal health information that was collected from you during the research study for as long as this information is maintained by Temple University and the principal investigator. However, while the research study is in progress, you will not be able to access your personal health information in order to preserve the integrity of the research. You will be able to access this information when the study is completed. There may be associated charges for copying these materials.

**How to revoke your authorization**

You should also know that you can revoke your authorization to disclose your personal health information at any time by sending a written notice to the principal investigator and Temple University at the address listed in the attached study-specific document. Should you decide to revoke your authorization, Temple University and the principal investigator will stop collecting your study-related health information. In addition, Temple University and the principal investigator will stop using and disclosing your personal health information, except to the extent such information was collected prior to your revocation. For instance, Temple University, principal investigator, recipients, and their agents or representatives may use the information obtained before you revoked your authorization in order to preserve the scientific integrity of the research study.

**Important notices**

You will receive a signed copy of this authorization to acknowledge your approval for Temple University and the principal investigator to release your personal health information. If you do not sign this authorization or if you revoke this authorization, the principal investigator and Temple University cannot allow you to participate in or to continue to participate in the research study identified in the attached study-specific document.

**STUDY-SPECIFIC DOCUMENT**

1. **RESEARCH STUDY:** A Capstone Project for Urban College Aged Women regarding their Intentions to Obtain Vaccination with Human Papilloma Virus Vaccine: Using the Thai-Human Papillomavirus Vaccine Belief Scale to Tailor Messages: An Intervention

2. **PRINCIPAL INVESTIGATOR:** Susan Dickey is the Principal Investigator and Mary Ann Picone, DNP (c) is the student researcher.

3. **EXPIRATION DATE:** This Authorization expires June 1, 2014.

**OTHER INFORMATION:** Your telephone number will be obtained in order to make a follow up telephone call or a text message asking if you have received or are about to receive the vaccine.

---

Signature of Subject

Date

---

Printed Name of Subject

---

Signature of Personal Representative of the Subject

Date

---

Printed Name of Personal Representative of the Patient and Relationship to Subject

---

Signature of Person Collecting Authorization

Date

---

Printed Name of Person Collecting Authorization

**Instructions for Completing the Study-Specific Document:**

1. **RESEARCH STUDY:** A Capstone Project for Urban College Aged Women regarding their Intentions to Obtain Vaccination with the Human Papilloma Virus Vaccine: Using the Thai-Human Papillomavirus Vaccine Belief Scale to Tailor Messages: An Intervention
  
2. **PRINCIPAL INVESTIGATOR:** Mary Ann Picone, DNP (c)  
**Temple University**  
**Dept. of Nursing**  
**3400 North Broad Street**  
**Philadelphia, PA. 19140**
  
4. **OTHER INFORMATION:** Your telephone number will be obtained in order to make a follow up telephone call or a text message asking if you have received or are about to receive the vaccine.

Appendix E  
Modifications

Office for Human Subjects Protections

Institutional Review Board

Medical Intervention Committees A1 & A2

Social and Behavioral Committee B

Unanticipated Problems Committee

Student Faculty Conference Center

3340 N Broad Street - Suite 304

Philadelphia, Pennsylvania 19140

Phone: (215) 707-3390

Fax: (215) 707-9100

e-mail: irb@temple.edu

Modifications required to secure approval

Protocol Number: 21893

PI: PICONE, MARY ANN

Review Date: 07-Jan-2014

Committee: A1 - MEDICAL INTERVENTION

School/College: HEALTH PROFESSIONS (0900)

Department: CHP:NURSING (09040)

Sponsor: No External Sponsor

Project Title: A Capstone Project for Urban College Aged Women regarding their Intentions to Obtain Vaccination with Human Papilloma Virus Vaccine: Using the Thai-Human Papillomavirus Vaccine Belief Scale to Tailor Messages: An Intervention

---

The IRB determined that modifications are required to approve the human subjects research. The modifications are as follows:

1. Dr. Dickey is listed as the PI in the eRA study title, but Dr. Picone is listed as the PI on the application. Please clarify the PI by revising the appropriate document.

I agree that Susan Dickey, Ph. D. is the PI and Mary Ann Picone is the student researcher. The changes were made.

2. Please submit Practice Runs training (in CITI) for all research personnel.

The Practice Runs training for Mary Ann Picone was completed and Naomi Starkey should have confirmation.

3. Please submit the poster and consent form that are referenced in section #12 of the protocol.

The poster/flyer to be handed out to interested women has been uploaded.

The consent form has been uploaded.

4. Since you are using or collecting PHI and the PHI may be linked to the subjects via their e-mail addresses, please submit a HPAA authorization form. The form can be found at:

[http://www.temple.edu/research/regaffairs/irb/irb\\_forms.html](http://www.temple.edu/research/regaffairs/irb/irb_forms.html)

The HPAA form has been completed and uploaded.

\* Please submit your response in eRA by entering the protocol and clicking on "Respond" next to Modifications Required to Secure Approval on the submission. Proceed by following the instructions outlined on our website for submitting

Modifications Required to Secure Approval:

<http://www.temple.edu/research/regaffairs/irb/docs/modifications.pdf>

Please submit:

- A letter with a point-by-point response to the above changes indicating whether you agree with each requested change.
- A copy of all revised documents in "Tracked Changes" format or similarly notated to indicate the changes that were made.
- A "clean" copy of all revised and requested additional documents.

If a response is not received by close of business on 90 days from 07-Jan-2014, the IRB will withdraw this offer.

To reiterate, your submission has not yet been approved by the IRB.

Please contact the IRB at (215) 707-3390 if you have any questions.

## Appendix F

## Demographic Data

**Table 1.** Mean age, number of casual sex partners per week, and age of first sexual experience ( $n = 15$ )

|                                    | Mean | Standard Deviation |
|------------------------------------|------|--------------------|
| Age                                | 22.6 | 2.2                |
| Number of Casual Sex Partners/Week | 5.9  | 12.4               |
| Age of First Sexual Experience     | 15.0 | 1.5                |

**Table 2.** Demographic Characteristics ( $n = 15$ )

| Characteristics                           | $n$ | (%)   |
|---|-----|-------|
| Year In College                           |     |       |
| Freshman                                  | 5   | 33.3  |
| Sophomore                                 | 1   | 6.7   |
| Junior                                    | 2   | 13.3  |
| Senior                                    | 0   | 0.0   |
| N/A                                       | 7   | 46.7  |
| Marital Status                            |     |       |
| Unmarried                                 | 15  | 100.0 |
| Married                                   | 0   | 0.0   |
| Divorced                                  | 0   | 0.0   |
| Race                                      |     |       |
| White                                     | 0   | 0.0   |
| Black or African American                 | 15  | 100.0 |
| American Indian or Alaska Native          | 0   | 0.0   |
| Native Hawaiian or Other Pacific Islander | 0   | 0.0   |
| Asian                                     | 0   | 0.0   |
| Decline to Respond                        | 0   | 0.0   |

**Table 3.** Health characteristics related to human papillomavirus (HPV) and cervical cancer ( $n = 15$ )

| Characteristics                   | <i>n</i> | (%)   |
|-----------------------------------|----------|-------|
| Ever Had Sex                      |          |       |
| Yes                               | 15       | 100.0 |
| No                                | 0        | 0.0   |
| Pap Smear                         |          |       |
| Yes                               | 13       | 86.7  |
| No                                | 2        | 13.3  |
| Ever Had Unprotected Sex          |          |       |
| Yes                               | 14       | 93.3  |
| No                                | 1        | 6.7   |
| Ever Diagnosed with HPV           |          |       |
| Yes                               | 0        | 0.0   |
| No                                | 14       | 93.3  |
| No Response                       | 1        | 6.7   |
| Ever Been Pregnant                |          |       |
| Yes                               | 9        | 60.0  |
| No                                | 6        | 40.0  |
| Likelihood of Getting HPV Vaccine |          |       |
| Low (0-4)                         | 7        | 46.7  |
| High (5-10)                       | 5        | 33.3  |
| N/A                               | 2        | 13.3  |
| No Response                       | 1        | 6.7   |

## Appendix G

## Thai Human Papilloma Virus Belief Scale Question Analysis

1. The HPV vaccine will protect people from getting cervical cancer.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 2 (40.00)    | 1 (20.00)   | 2 (40.00)           | p=0.4406            |
| Low       | 7 (70.00)    | 1 (10.00)   | 2 (20.00)           |                     |

2. The HPV Vaccine will be effective in preventing HPV infection.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 4 (80.00)    | 0 (0.00)    | 1 (20.00)           | p=1.0000            |
| Low       | 8 (80.00)    | 1 (10.00)   | 1 (10.00)           |                     |

3. Getting an HPV infection, it would be disruptive to my health.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 2 (40.00)    | 2 (40.00)   | 1 (20.00)           | p=0.1169            |
| Low       | 8 (80.00)    | 0 (0.00)    | 2 (20.00)           |                     |

4. If I have cervical cancer, it would threaten the relationship with my boyfriend, husband, or partner.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 4 (80.00)   | 1 (20.00)           | p=0.6004            |
| Low       | 0 (0.00)     | 6 (60.00)   | 4 (40.00)           |                     |

5. Cervical cancer is a life threatening disease.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 5 (100.00)   | 0 (0.00)    | 0 (0.00)            | p=0.6703            |
| Low       | 7 (70.00)    | 1 (10.00)   | 2 (20.00)           |                     |

6. I think the HPV vaccine is unsafe.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 4 (80.00)   | 1 (20.00)           | p=1.000             |
| Low       | 0 (0.00)     | 7 (70.00)   | 3 (30.00)           |                     |

7. I feel embarrassed to get an HPV vaccine because it is for a sexually transmitted disease.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 5 (100.00)  | 0 (0.00)            | p=1.000             |
| Low       | 0 (0.00)     | 9 (90.00)   | 1 (10.00)           |                     |

8. It is hard to find a provider or clinic that has the vaccine available.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 4 (80.00)   | 1 (20.00)           | p=0.6004            |
| Low       | 0 (0.00)     | 6 (60.00)   | 4 (40.00)           |                     |

9. I am concerned that the HPV vaccine costs more than my parents or I can pay.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 2 (40.00)   | 3 (60.00)           | p=0.2128            |
| Low       | 2 (20.00)    | 7 (70.00)   | 1 (10.00)           |                     |

10. I am at risk for contracting HPV.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 0 (0.00)     | 4 (80.00)   | 1 (20.00)           | p=0.3846            |
| Low       | 3 (30.00)    | 4 (40.00)   | 3 (30.00)           |                     |

11. I am at risk for getting cervical cancer.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 1 (20.00)    | 3 (60.00)   | 1 (20.00)           | p=0.3973            |
| Low       | 5 (50.00)    | 2 (20.00)   | 3 (30.00)           |                     |

12. I have knowledge that my current health insurance plan covers the cost of the HPV series.

| Intention | Response     |             |                     | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) | Don't Know<br>n (%) |                     |
| High      | 3 (60.00)    | 1 (20.00)   | 1 (20.00)           | p=0.5105            |
| Low       | 6 (60.00)    | 0 (0.00)    | 4 (40.00)           |                     |

## Appendix H

## Text Message Intervention

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| Intention | Response     |             | Fisher's Exact Test |
|-----------|--------------|-------------|---------------------|
|           | Yes<br>n (%) | No<br>n (%) |                     |
| High      | 5 (100.00)   | 0 (0.00)    | p=0.2582            |
| Low       | 6 (66.67)    | 3 (33.33)   |                     |

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