

EDUCATION AND REMINDER INITIATIVE TO DECREASE SEXUALLY
TRANSMITTED INFECTIONS AND INCREASE HPV VACCINATIONS IN
PRIMARY CARE

A Doctor of Nursing Practice Project Report

by

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This Doctor of Nursing Practice Project Report meets the standards for scope and quality of Texas A&M University-Corpus Christi College of Nursing and Health Sciences and is hereby approved.

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ABSTRACT

Sexually transmitted infections (STIs) continue to rise within the United States and within local communities. The adolescent and young adult population accounts for nearly half of the new STI prevalence. All STIs are preventable however only 2 have an available vaccine. Since 2006, HPV vaccinations have been available to prevent the incidence of HPV infections and yet the vaccination rates remain low within the United States. An initial chart review of 50 electronic medical records (EMRs) from patients within that age group revealed these patients had no updated HPV vaccination information on their profiles and were not up to date with the completed HPV vaccination series. A quality improvement project was initiated to improve the STD education and HPV prevalence by providing reminders and administering HPV vaccines and educating patients on each visit about STDs at a local clinic within South Texas. A total of 85 patients between the ages of 13-24 years met the criteria to participate in the project, however 33 were excluded due to decline to participant and/or unable to contact for telephone follow up visit, leaving a total of 52 participants (n=52). The study showed an increase of STI education by approximately 87% after implementing verbal and written education during routine visits in primary care. A total of 47 referrals were discussed with the patients in regards to contacting the health department when opens to receive and completion of the HPV vaccination series. Due to the COVID-19 pandemic, patients were also given the health department's information in efforts for them to contact and follow up with their HPV vaccination administration and completion of series. The number of vaccinations administered and the completed vaccination series among the participants were unable to be obtained due to the inability of administration from COVID-19

Education and Reminder Initiative to Decrease Sexually Transmitted Infections and Increase HPV Vaccinations in Primary Care

Introduction

More than 1 million preventable sexually transmitted diseases (STDs) and sexually transmitted infections (STIs), including human papilloma virus occurs each day within the United States (World Health Organization [WHO], 2018). Sexually transmitted diseases and STI rates continue to rise within the United States and within local communities. In 2018, STDs were at a record high for the fourth year in a row in the U.S. (Ducharme, 2018). Untreated, other common STI's such as chlamydia, gonorrhea, syphilis, and trichomoniasis can lead to pelvic inflammatory disease (PID), infertility, damage to internal organs and even death (CDC, 2018).

Genital human papilloma virus (HPV) is the most common STI in the United States, estimating approximately 14 million newly infected individuals each year which results in an estimated 1.7 billion in direct medical costs (CDC, 2017a). Majority of HPV infections cause no symptoms and are self-limited, however persistent HPV infections can cause cervical cancer in women along with other anal-genital cancers, oropharyngeal cancer, and genital warts in men and women (CDC, 2017a). More than 200 HPV types have been identified with 40 % directly infecting the genital mucosa (CDC, 2017a). Persistent and high-risk HPV infections are recognized as the primary causative factor for the development of cervical cancer, 500,000 new cases annually have been identified with 265,000 attributable deaths in 2012 (CDC, 2017a).

All STI's are preventable through use of condoms and abstinence; however only two, have an available vaccine, hepatitis B and HPV. A three dose HPV vaccination became available globally in 2006 which was approved and recommended by the World Health Organization (WHO) and the CDC for girls aged 9-26 years old and extended to boys in 2016 (Walling, et. al., 2016). The vaccination uptake at a rate of 80% or greater, has the capability to prevent an

estimated two-thirds of new cervical cancer cases worldwide (Walling, et. al., 2016). Despite the safety and efficiency record of the vaccination over the past 10 years, the adherence rates within the United States remain low, averaging 60% in females who initiate vaccination however only 39.7% receive all the of the three-dose series (Walling, et. al., 2016). In males, approximately 41.6% initiate the vaccination and only 21.6% complete the three-dose series (Walling, et. al., 2016). Healthcare provider efforts to decrease adolescent and young adult STI incidence and prevalence must occur in the primary care setting, should focus on providing STI prevention education and scheduling reminders to parents, children, and young adults on recommendations, the availability, and importance of the HPV vaccinations.

Background

Review of the Literature

Health care providers caring for the adolescents and young adults can significantly impact the preventable morbidity of STDs within this population. The American Medical Association's Guidelines for Adolescent Preventive Services (GAPS) recommend all healthcare providers screen adolescents for STD/HIV risk behaviors, educate all patients on the STD/HIV transmission, and consult with patients about reducing risks for contracting STDs and HIV (Millstein, Igra, & Gans, 2016). According to Luk et al. (2017), sexually active adolescent females are more likely than their male counterparts to receive advice about sexual behavior risk and advice for avoiding STDs from their physician. A qualitative study focusing on in-depth, one on one interviews with adolescents revealed adolescents' perceptions towards their provider's communication style about STD prevention resulted in adolescents having a more positive and increased STI testing and treatment (Hoopes, et al. 2017).

Since 2006, HPV vaccinations have been available to prevent the incidence of HPV infections. However, the vaccination rates among the population of 13-25 years of age remain

low (CDC, 2017b). Niccolai and Henson (2016) conducted a qualitative study to understand why parents may accept or refuse the HPV vaccine. Parents recognized the preventative consequences of the HPV infection with vaccination in early adolescence however many believed the vaccine should be given at the onset of sexual activity, a perception that has led to a delay in the administration of the vaccine among the adolescent population (Niccolai & Henson, 2016). In addition, the study found that implementing HPV vaccinations in a health care setting with reminders and recall strategies within a community-based location significantly impacted the rates of HPV vaccines (Niccolai & Hansen, 2016). Healthcare providers can impact HPV rates within the community by implementing HPV vaccination administration and reminding HPV vaccination schedules by sending out text message reminders.

Problem description in the setting

STDs have become a growing concern over the past several years with a significant increase of the prevalence and rates within the United States, the State of Texas, and within the Nueces County. According to the CDC (2018a), adolescents and young adults, 15-24 years of age acquired half of all the new STDs, reporting that one in four sexually active adolescent females will have an STD of chlamydia or HPV. In 2015, Texas was ranked 13th among the 50 states in chlamydia infections, ranked 16th in primary and secondary syphilis cases, and ranked 11th in gonorrheal infections (CDC 2015). In 2019, there was a reportedly amount of 520.4 per 100,000 population cases of chlamydia within Nueces County (County Health Rankings, 2019). Providers providing informal education with verbal and written communication methods to this population group about preventable STDs are all essential in efforts to decrease the number of occurrences within the adolescent and young adult population.

The location of this quality improvement project was a primary care clinic, Primary Diagnostic Medical Center (PDMC) in Corpus Christi, Texas, Nueces County. The PDMC is

located very a local rural high school, possibly accounting for the high percentage of adolescents and younger adults in its patient population (30% aged 15-24 years) that seek care at the clinic. PDMC is privately owned and is managed by one health care provider, a Nurse Practitioner; in which is the project director for this quality improvement project.

The 2017 Texas STD surveillance report indicated Nueces County was one in the top 15 counties in Texas with the highest number of STD cases among a total of 254 counties in Texas (Texas Department of State Health Services, 2017). In 2017, the Texas Department of Health Services (TDHS) reported 2,360 cases of chlamydia, 525 cases of gonorrhea, and 54 cases of syphilis in the city of Corpus Christi (Texas Department of Health Services, 2017).

An initial chart review of 50 electronic medical records (EMRs) from patients within that age group revealed these patients had no current HPV vaccination information or vaccination administration/series states on their profiles. This quality improvement initiative will bring awareness and knowledge of STIs to parents, adolescences, and young adults the importance of HPV vaccinations. Thus, need for education implementation and HPV vaccination awareness was essential for this population at this medical office.

Project Purpose and Aims

The purpose of this project was to increase general STI patient knowledge and more specific, HPV prevention knowledge and improve the uptake and adherence to the HPV vaccination rates for patients aged 13 to 25 years of age at a PDMC, a local primary care clinic in Nueces County. The clinical question guiding this project was: P: the adolescent and young adult populations ages 13-25 years; I: implementing informal education with written handouts on initial visits, repetitive verbal education, and HPV vaccine reminder text messages on dose series; C: no education and no vaccinations reminders; O: increase patient knowledge/education of STDs by 70% within the population group of 15-24 years of age, improving the adherence to

the HPV vaccinations by 70% with providing written and verbal educational information at routine visits and referring the HPV vaccine with providing reminder text messages for the completion of their HPV vaccination series within the population group of 13-25 years of age.

The projects specific goals included:

Aim #1: Increase Improve patient's education knowledge regarding transmission, symptoms, complications, prevention and treatment of STDs with focus on HPV, by providing verbal education, and written educational handouts to patients and their parents during routine primary care visits. The STI Knowledge Survey was used to measure patient knowledge at the first visit prior to the first educational session and at the end of three months, following the 3rd educational session. The goal was to improve patients' mean knowledge scores by at least 70% by the end of the 3-month period, when compared to the mean initial score.

Aim#2: Increase HPV vaccinations in patients 13-25 years of age by providing verbal educational sessions and written educational handouts on the need for and the advantages of the vaccine as well as by using text messaging to remind patients to obtain the vaccine. The number of vaccines provided by the Nueces County Health Department to these patients will be recorded by the PD over the three-month project period. The specific goal was to improve the HPV vaccination rates within the primary care clinic by 70% within a 3-month period, when compared to the number of vaccines provided to patients in the same time period last year.

The American Association of College of Nursing (AACN) DNP Essentials associated with this project were Essential VI: Inter professional collaboration for improving patient and population health outcomes and Essential VII: Clinical prevention and population health for improving the nation's health. Inter professional collaboration with medical assistants and the Nueces County health department for treatment, HPV vaccines, and reporting of findings was necessary to conduct this QI project. In addition, necessary referral to a specialist such as

Obstetrical & Gynecological providers for other medical complications associated with STDs that may coincide was necessary for management and treatment. Clinical preventative measures were provided during each visit conducted that consisted of continuous education, efficient treatment, and vaccinations for improving the overall health and wellbeing within the population group 13-25 years of age.

Methods

Conceptual and Theoretical Frameworks

Conceptual and theoretical frameworks guided this quality improvement initiative. Pender's Health Promotion Model (PHPM) was developed in 1982, with a revision in 1996 (McCutcheon et al., 2016). With the foundation of Albert Bandura's Social Learning Theory and Fishbein's Theory of Reasoned Action, the PHPM believes the individuals attitudes, social standards, and cognitive affects one's behavioral change (McCutcheon et al., 2016). Pender's health model was developed collectively from personal observations of healthcare professional's initial intervention after the development of an illness as opposed to the prevention phase (McCutcheon et al., 2016). Thus, health is a broadly defined as a positive, dynamic state as opposed to an absence of illness that emphasizes on positive motivational methods within the PHPM (McCutcheon et al., 2016). Pender's model is a nursing-based theory that correlates a metaparadigm into the theoretical framework of the concepts of person, environment, health, and nursing (McCutcheon et al., 2016).

The nursing aspect of the Pender's model is the concept reflects the promotion of awareness, healthy behaviors, self- efficiency, and behavioral changes (McCutcheon et al., 2016). The model's foundation proposes individuals' past behaviors will define their health beliefs and help determine their participation to health promoting behaviors (McCutcheon et al., 2016). The individual's cultivation and influences lead to the ability or inability of their own

health outcomes. Barriers that factor towards these actions are one's attitudes towards expenses, inconvenience, the difficulty, unavailability, or delay of a specific action will affect their intentions to change the past behavior (McCutcheon et al., 2016). The health promoting behaviors associated with the PHPM can improve health, exchange the functional ability, and improve the quality of life at all stages of development (McCutcheon et al., 2016). Figure 1 displays the breakdown of the model further examining the individual's characteristics with the behavior-specific cognitions and affects with the behavior outcome. As related to this project, the sexual individual characteristics with their sexual experiences related to the social factors were examined from the individual's electronic medical records (EMRs). Then, the patient's actions towards educational pamphlets and providing education regarding the transmission and treatment of STDs were implemented at each routine visit by the provider. The outcomes assessed were geared towards increasing the knowledge from test scores in reference towards STI/STDs, improving the HPV vaccination rates with referring patients to have HPV vaccinations, and sending out reminder text messages for completion of series within the primary care clinic by 70% within the population of 15-24 years of age.

Lewin's Change Theory of Nursing has positive effects on implementing change to increase the likelihood of success (Mitchell, 2012). The change theory (Figure 2) has three major components: driving forces, restraining forces, and equilibrium (Nursing Theory, 2016). Driving forces influences the direction that causes a change; this change shifts the equilibrium towards change (Nursing Theory, 2016). The restraining forces are those that counter the driving forces in which hinder the change by pushing the patient in the opposite direction (Nursing Theory, 2016). The change model was used to change the population's knowledge on STI/STD and change the rates of HPV vaccines by unfreezing the misconception associated with lack of knowledge on STI/STDs.

Ethics Considerations

This project has been reviewed by the Texas A&M University- Corpus Christi Institutional Review Board (IRB) for project classification, and received a determination of “Not Human Subjects Research” and permission to proceed as a Quality Improvement project. Refer to the Letter of Determination from the TAMU-CC IRB in Appendix A. Personal health information (PHI) was collected for the purposes of this project only following the guidelines of the (HIPAA) Confidentiality Agreement from the facility (Appendix B). A letter of support was completed and signed by the Chief Executive Officer of the clinic agreeing to fully support this project and acknowledgement of the collection from PHI for purposes only related to the project (See Appendix C).

Project Design

This quality improvement (QI) initiative used a before and after design to improve STI and HPV knowledge as well as HPV vaccination rates by providing patients aged 15-24 years old with educational sessions and written materials and text message reminders to obtain the HPV vaccine. A convenience sample of patients that met inclusion criteria was recruited from routine visits at the clinic during the first month of the project. The sampling design of convenience sampling was used for the easy contact of individuals from being seen at the clinic and the inability to be randomly selected at the clinic due to the specific age group of 13-25 years of age (Melnyk & Fineout-Overholt, p.669). Patients were asked face to face if they are willing to participate in a DNP project on STDs and HPV vaccinations, in which consents were obtained for participation (appendix D). Participants were included if they meet the following criteria: (1) within the ages of 13-25; (2) are sexually active; (3) have or are at high risk of conducting an STD due to sexually activity and multiple partners; (4) are not up to date with their HPV vaccination schedule; (5) are willing to participant. Approximately 150 patients were seen at the

clinic meeting these criteria over the past 3 months, therefore sample size of 75 participants was expected.

Potential barriers affecting the goals and completion accomplishment of this project included: confidentiality concerns, unwillingness to share personal sexual health information, and inability to follow up with clinic visits due to the patient's work/school schedule (Appendix E). According to the CDC (2017a), the prevalence of STDs within this population group contributes to the multiple barriers of inability to pay or lack of transportation for treatment, long clinic waiting times, conflict between clinic hours and work/school schedules, embarrassment seeking STD services, methods of specimen collection, and confidentiality concerns. Approximately 12.7 % of adolescents and young will not seek sexual or reproductive health services because they are on their parent's health care insurance and afraid of their parents finding out (Leichliter, Copen, & Dittis, 2017). Developing a good rapport with patients by engaging in conversations and answering any questions, educating on confidentiality and patient rights based on the HIPAA regulations, and providing frequent reminders on upcoming appointments was essential to decrease risk factors towards a successful project.

Intervention

All clinic staff and the healthcare provider were notified of this project and in-serviced on project interventions and goals. The project director (PD) provided training to the MAs and medical staff on STI/STD education, HPV vaccination education, and projects process in which is necessary to be implemented at the medical clinic. The PD provided the educational handouts and surveys that will be used for patients.

During the initial patient visit, MAs distributed patient educational handouts that consisted of CDC guidelines on prevention, testing, complications, and early treatment methods of STDs (See Appendix F, G). Patients were asked to read the handouts and ask questions. The

MA then read the handout content out loud to the patient, asked the patient if they had questions, answered questions if applicable and then confirmation of content understanding by the patient. After confirming patient understanding and agreement paper-pencil surveys STD education and true and false (Appendix N, O) were administered to the patient, then calculated with a test score and recorded by the PD. These test scores were reassessed at the end of the 3-month period and evaluated by a post score on the follow up visit. The EMR was reviewed and updated during each visit in the clinic on the participant's vaccination records to monitor the compliance and administration of the HPV vaccine schedule. Additional educational handouts regarding HPV and HPV vaccinations (See Appendix H, I) from the Immunization Action Coalition (IAC) were given to the patients and verbal education read by the medical assistance at the initial visit to provide rationale for cooperation and importance towards HPV prevention and completion of the HPV vaccination series. This was measured by the number of patients that completed their vaccination series within the 3-month period. The use of Nola Pender's (1996) PHPM during this phase was necessary to assess the individual's sexual health and the affects from the behavior outcome (See Appendix J). The Lewin's change theory conceptual model assisted the PD with initiating change within the clinic organization related to STD screening and HPV vaccination adherence on all visits within the population 15-24 years of age; and preventable change within the population towards STDs and acceptance of the HPV vaccination (See Appendix K). Refer to Appendix M for visualization of the project's detailed timeline.

Data Collection

Qualitative data was collected at the initial visits then at the follow up visits that were scheduled in 2 weeks, 6 weeks, and 12-week time frames. Questionnaires adopted from Planned Parenthood Federation of Canada (2001) and Kids Health (2017), previously used for education purposes for this age group, were conducted on the initial visits with patient's providing their

vaccination record through verbal or written documentation (Appendix N, O). The medical assistants discussed and provided written educational handouts, followed by the two questionnaires that assessed the patient's baseline knowledge towards STD/STIs. The PD then calculated scores from the questionnaires and reported the findings on the Data Collection Form (See Appendix L). Follow up visit of 2 weeks were conducted on those individuals that were previously tested and received treatment. During this visit, treatment completion was addressed and assessed patient's symptoms occurring. Lab results were also discussed and reviewed with the patients. A 6 week follow up visit conducted for the evaluation of the vaccination records for those individuals referred for their HPV vaccine and to further assess their sexual health through verbal communication with asking individuals any changes to their sexual activity, partners, and if contraception was being used. Patients then returned for their final visit to assess their educational status by a written post-test survey with provided materials of writing utensils and clipboard. Refer to Appendix M for visualization of the project's detailed timeline from collection to dissemination of events. Text message reminders by the receptionist were made the day before their appointments to remind of the upcoming appointment time and date. Phone calls by the MAs were made for those individuals that do not make their follow up appointments.

Measurement Tools

The outcomes were measured using two questionnaires during initial visit and at the follow up visits to test the individual's knowledge regarding STDs (Appendix N, O). The STD quiz (Appendix N) is an effective and easy way to understand and comprehend, as it was designed specifically towards the young adult and adolescent population (KidsHealth, 2017). A second survey regarding sexual transmitted infections (STIs) was adapted from the Planned Parenthood organization from a source book on sexual and reproductive health education (Planned Parenthood Federation of Canada, 2001) (Appendix O). Both surveys were to be valid

and reliable from reliable sources. These surveys were carefully chosen based on the specificity towards this age group of 13-25 years and has been previous used for sexual health educational classes. Written information was gathered by conducting pre-educational survey about sexual health and medical information from the EMR in reference to their social and sexual history as well as their vaccination history; obtain and gather on STD testing and results; conducting post questionnaires after treatment and their visits. The same surveys were conducted and scored at the end of the 3-month period in efforts to compare to the individual's initial test score. Pre surveys were labeled as "A" and post surveys as "B". Patients that were unable to attend or failed to follow up after the 3-month period, phone calls were made to complete the questionnaire. If no contact and no follow up were made by the patient, the patient was excluded from the project.

Analysis

Aims for this project were to improve patient knowledge by 70% on patients within the ages of 13-25 on STDs and improve the uptake and adherence to HPV vaccinations by 70% within a 3-month period. Pre and post test scores were graded, calculated in a test score of maximum 100% grade, and the average of the test scores were compared. Patients that have been consistent and had completed their vaccination series were compared to the number of patients that attend the clinic within the ages of 13-24 that have not completed any HPV vaccination series. Methods used for analyzation of the collected data included statistical information of paired t-tests. Analysis of ANOVA was used to determine the statistical differences from the collective data collected. See Appendix P for analyses plan of outcomes.

Results

Outcomes

Verbal and written education were provided at routine visits initiated by the medical assistants and implemented by the PD on STDs; and implementation of better delivery of testing

and treatment per the CDC guidelines on prevention, testing, and early treatment methods of STDs. Written educational handouts were provided from the CDC and Immunization Action Coalition (IAC). Medical staff initiated written educational handouts at the initial visit with verbal education provided from the practitioner on STD/STI and HPV vaccinations then continued throughout the follow ups scheduled at 2 weeks and 8 weeks. Primary outcomes included increasing the awareness by 70% of sexually transmitted disease (STD) rates within the local community by educating patients within the ages 13-24 years of age at routine visits and improve the uptake and adherence to the HPV vaccination rates by 70% at a local primary care clinic in Nueces County. Implementation and outcome measures focused on improving education on STD within the population of ages 13-24 years of age in the urban clinic of Nueces County with the use of survey tools that were calculated at the initial and final visit for comparison of the test scores, monitoring timeframe of testing and treatment, monitoring HPV vaccination series, and monitoring follow up visits.

The medical assistants provided written educational handouts adopted from the CDC and IAC at routine visits for individuals 13-24 years of age, followed by a survey at the time of the initial visits that was adopted from Planned Parenthood Federation of Canada and Kids Health. These instrumental handouts have been used previously in sexual education classes within the target population of 13-24 years of age. The surveys were then graded as a test score that was used as the participants' baseline knowledge of STDs. These scores were then compared to the post-test questionnaires that were initiated at the 2-month follow up. Medical records were evaluated followed by the medical staff inquiring about the individual's HPV vaccination. Documentation of receiving the vaccination was made in the EMR for the NP to review during the visit with the patients.

With the pandemic of COVID-19, referrals to the health department was impossible with

the closure of the county. After 3 weeks, the health department re-opened however is currently not doing vaccinations at this time due this COVID-19 pandemic. During the study, patients that were in need of referrals to the health department were notified to contact the health department when start performing immunizations. Phone numbers to the health department were given to the necessary individuals.

Discussion

Summary

A total of 85 patients between the ages of 13-24 years met the criteria to participate in the project. Thirty-three patients were excluded due to decline to participate and/or unable to contact for telephone follow up visit, leaving a total of 52 participants. Among the participants (n=52), 36 were female and 15 males. The results showed an increase of STI education by approximately 87% after implementing verbal and written education during routine visits in primary care. A total of 47 referrals were discussed with the patients in regards to contacting the health department when opens to receive and completion of the HPV vaccination series.

Limitations

Due to the COVID-19 pandemic, many participants were not able to attend their scheduled office visits in regards to their follow up care. Telephone follow up visits were then conducted and performed post STI post-tests verbally. Patients were also given the health department's information in efforts for them to contact and follow up with their HPV vaccination administration and completion of series. The number of vaccinations administered and the completed vaccination series among the participants were unable to be obtained due to the inability of administration from COVID-19. Therefore, the number of potential referrals and information provided to the participants were obtained and collected as data.

Interpretation

The participants ranged within the ages of 10-25, majority at the age of 24 years and female. Ethnicity of the participants were at 54% Hispanic/other and 46% white. When asked if sexually active, 67.3% indicated no and 33% indicated yes. When assessing HPV vaccination received and completed, 33% indicated they have initiated the vaccine and received however only 9.6% have actually completed the HPV vaccination series, see appendix R for data collection details. Standard deviation for the STI pre/post tests were evaluated, see appendix S. Post-testing standard deviations were all lower than the pre-testing scores with a 95% confidence interval difference.

Conclusion

The project success can provide new insights for STI/STD prevention and management within the adolescent and young adult population. The clinical significance of projects interventions has the ability to impact the individual's lives and change their health behaviors and well-being. The project has shown educational awareness improved the patient's knowledge on STIs and has potential to improve current health improvements with preventable outcomes and quick treatment.

For future implications of practice, the clinic should purchase and provide the HPV vaccine for the patients rather than referring patients to the health department, which causes more time out of the patients' day to seek the vaccine. The future outcomes for the patients should be successful with the ability of discrete, rapid cost-effective STD testing that will also improve their experience at the clinic that allows patients to be more compliant and willing to follow up on their medical care. Patients will then become more intuitive towards their medical care that can then improve the clinic revenues from increased number of patients and visits conducted. Developing a public health and primary care partnership can also influence a

comprehensive and effective immunization program at a public and private sector setting that will assess the vaccinations effectiveness and safety, monitors vaccination coverage, and ensures evidence-based practices (Association of State of Territorial Health Officials {ASTHO}, n.d.). A strong partnership is essential towards achieving immunization coverage targets and low incidence of vaccine-preventable diseases (ASTHO, n.d.).

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Appendix A



TEXAS A&M UNIVERSITY
CORPUS CHRISTI

OFFICE OF RESEARCH COMPLIANCE
Division of Research and Innovation
6300 OCEAN DRIVE, UNIT 5844
CORPUS CHRISTI, TEXAS 78413
O 361.825.2497

Human Subjects Protection Program

Institutional Review Board

DATE: January 28, 2020
TO: Christina Murphey, College of Nursing and Health Sciences
CC: Stacey Pompa, Student
FROM: Office of Research Compliance
SUBJECT: Not Human Subjects Determination

Activities meeting the DHHS definition of research or the FDA definition of clinical investigation and involves human subjects are subject to IRB review and approval.

On January 28, 2020, the Texas A&M University-Corpus Christi Institutional Review Board reviewed the following submission:

Type of Review:	Not Human Subjects Determination
Title:	Educating and Reminder Initiative to Increase HPV Vaccinations in Adolescents and Young Adults.
Project Lead:	Christina Murphey
IRB ID:	TAMU-CC-IRB-NHS- 2020-01-009
Funding Source:	None
Documents Reviewed:	Pompa S. NHSR-IRB PompaS. QI Project Template-IRB

Texas A&M University-Corpus Christi Office of Research Compliance determined that the proposed activity does not meet the DHHS definition of research or the FDA definition of a clinical investigation.

Therefore, **this project does not require IRB approval.** You may proceed with this project.

This determination applies only to the activities described in the documents reviewed. **Any planned changes require submission to the IRB to ensure that the research continues to meet criteria for a non-human subject research determination.**

Please do not hesitate to contact me with any questions at irb@tamucc.edu or 361-825-2497.

Respectfully,

Matthew R. Gaynor, J.D.
Digitally signed by Matthew R. Gaynor, J.D.
Date: 2020.01.28 16:07:28 -06'00'

Office of Research Compliance

Appendix B



Mario A. Martinez, M.D. & Medical Associates
3829 Saratoga Blvd.
Corpus Christi, TX 78415
Phone (361) 906-2121
Fax (361) 906-2264

NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBE HOW MEDICAL/PROTECTED HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

SUMMARY:

By law, we are required to provide you with our Notice of Privacy Practice (NPP). This Notice describes how your medical information may be used and disclosed by us. It tells you how you can obtain access to this information.

As a patient, you have the following rights:

1. The right to inspect and copy your information;
2. The right to request corrections to your information;
3. The right to request that your information be restricted;
4. The right to request confidential communications;
5. The right to a report of disclosures of your information; and
6. The right to a paper copy of this Notice.

We want to insure you that your medical/protected health information is secure with us. This Notice contains information about how we will insure that your information remains private.

If you have any questions about this Notice, the name and phone number of our contact person is listed on this page.

Acknowledgement of Notice of Privacy Practices

"I hereby acknowledge that I have received a copy of this practice's **NOTICE OF PRIVACY PRACTICES**. I understand that if I have questions or complaints regarding my privacy right that I may contact Mario A Martinez, M.D. & Medical Associates at (361) 906-2121. I further understand that the practice will offer me updates to this **NOTICE OF PRIVACY PRACTICES** should it be amended, modified, or changed in any way."

Sancy Rompa
Patient or Representative Name (PLEASE PRINT)

Sancy Rompa
Patient or Representative Signature

10/4/19
Date

☐ Patient refused to sign

The terms of this Notice of Privacy Practices are effective January 4, 2010

Appendix C

October 4, 2019

Dr. Sara Baldwin
Associate Dean for Academic Programs
College of Nursing and Health Sciences
Texas A&M University – Corpus Christi
6300 Ocean Drive
Corpus Christi, TX 78412

Dear Dr. Baldwin,

The purpose of this letter is to provide Stacey C. Pompa, a Doctor of Nursing Practice student at Texas A&M University College of Nursing and Health Sciences, support in conducting a quality improvement project at *Primary Diagnostics and Medical Center of Texas of Texas*. The project Sexual transmitted diseases (STDs) among adolescences and young adults in Nueces County, entails providing education to patients among the population of 13-24 years of age of STD transmission, prevention, symptoms, and treatment on routine visits; and educating importance of HPV vaccinations, referring for HPV vaccine administration, and sending reminders for completion for the HPV administration schedule as recommended by the CDC guidelines.

The purpose of this project is to decrease the STD prevalence and improve HPV vaccination rates within the target population of patients ages 13-24 in Nueces County among the patients seen at the clinic. Primary Diagnostics and Medical Center of Texas was selected for this project because of the significant rise in STD rates within Nueces County and the low rate of this population receiving HPV vaccinations. Stacey C. Pompa is employed at this institution, *does have* an interest in improving care at this facility.

I, Dr. Mario A. Martinez, Chief Executive Officer/Administrator at *Primary Diagnostics and Medical Center of Texas*, Staples, do hereby fully support Stacey C. Pompa in the conduct of this quality improvement project, Sexual transmitted diseases (STDs) among adolescences and young adults in Nueces County at Primary Diagnostics and Medical Center of Texas, Staples.

I also approve Stacey C. Pompa to access protected health information (PHI) for purposes of conducting this quality improvement project. She has signed a HIPAA release form.

Sincerely,

[Dr. Mario A. Martinez, Chief Executive Officer/Administrator]

Appendix D

Patient Name: _____

DOB: _____

Medical Record #: _____

I, _____, are giving
consent to willingly participate in a quality improvement DNP
project, an education and reminder initiative to decrease sexually
transmitted infections and increase HPV vaccinations in primary
care. I understand participation includes, but not limited to personal
and medical information, medical testing, labs, and follow up care. I
understand the information provided will be for quality
improvement purposes.

_____ Signature

_____ Name Printed

_____ Date

Appendix E

Risk	Impact	Countermeasure	Facilitators	Barriers
1. Confidentiality concerns/ Afraid of parents becoming aware of STD testing and treatment	Decrease the amount of participants which will lead to small sample size.	Ensure confidentiality and HIPPA guidelines.	HIPPA consents signed and documented on file.	Lack patient's knowledge regarding HIPPA
2. Unwillingness to participant and disclose information regarding their sexual health	Decrease the participants and may result in a low sample size	Ensure privacy and confidentiality on the information provided. Allow patient to remain anonymous	Provider developing a good rapport with patients to make them comfortable to share their personal sexual health with patients	Parents not allowing their minor to participate
3. Inability to follow up after initial visit due to school/activity schedules	Result in incomplete data and the inability to post test their learning experiences	Call the patients and work around their school/work schedule for scheduling appts.	Send out reminders of appointments.	Patient's school/work schedules

Figure 1: Risk Assessment Table

Appendix F

STD Educational Handout

Leader's Resource

STD Facts: True or False?

- 1. A person can always tell if she or he has an STD.**

False. People can and do have STDs without having any symptoms. Women often have STDs without symptoms because their reproductive organs are internal, but men infected with some diseases like chlamydia also may have no symptoms. People infected with HIV, the virus that causes AIDS, generally have no symptoms for some time, even years, after infection.
- 2. With appropriate medical treatment, all STDs except HIV can be cured.**

False. Herpes, an STD caused by a virus, cannot be cured at the present time.
- 3. Condoms are the most effective safeguard against the spread of STDs.**

False. Abstinence from sexual intercourse is the best way to prevent the spread of STDs. Condoms are the next best thing, but only abstinence is 100 percent effective.
- 4. Using latex condoms will help prevent the spread of STDs**

True. Latex condoms can help prevent the spread of STDs, but they must be used correctly. Latex condoms are not 100 percent effective because they can occasionally break or come off during intercourse. Lambskin condoms are ineffective and should not be used.
- 5. The organisms that cause STDs can only enter the body through either the woman's vagina or man's penis.**

False. STD bacteria and viruses can enter the body through any mucus membranes, including the vagina, penis, anus, mouth and, in some cases, the eyes. HIV can also enter the body when injected into the bloodstream from shared IV drug needles.
- 6. Women who have regular Pap smears will also find out if they have an STD.**

False. The Pap smear is a test specifically designed to detect cervical cancer and may detect a herpes infection, but it will not indicate the presence of other STDs. A woman who thinks she may have been exposed to an STD, must be honest with her health practitioner and ask for STD tests.

Adapted from *Teen Outreach: Youth Development Through Service and Learning* Association of Junior Leagues, International Inc., New York, N.Y., 1994.

Life Planning Education, Advocates for Youth, Washington, DC

7. **Teenagers can receive testing and treatment for STDs without having their parents notified.**

True. In every state, minors—12 years or older in most states, 14 years and older in some states—can be tested and treated for STDs without a parent's permission or notification. Records are confidential, so that no one can go to the health clinic and find out if a teenager was treated there. Many community health clinics provide STD tests and treatment at no cost, or for a small fee, to adolescents or other patients who cannot pay.

8. **You cannot contract an STD by masturbating, or by holding hands, talking, walking or dancing with a partner.**

True. STIs are only spread by close contact with an infected person. Anyone can be infected by having oral, anal or vaginal intercourse with a partner who is infected. In the case of HIV, a person can also be infected by sharing needles or works to use IV drugs with an infected partner.

9. **STDs are a new medical problem.**

False. STDs have existed since people began recording history. There is evidence of medical damage caused by STDs in ancient writings, art and skeletal remains. Writers of the Old Testament, Egyptians writing on papyrus and the famous Greek physician Hippocrates all mention symptoms of diseases and sufferings which we know today was caused by STDs. Cures for most STDs were not found until the 1900s, and some still cannot be cured.

10. **STDs can cause major health problems and some can even result in death.**

True. HIV infection, which can be spread through sexual contact, is at present always fatal. Genital herpes appears to be related to cervical cancer in women, and can damage babies born to infected women. Some STDs such as gonorrhea and chlamydia can cause pelvic inflammatory disease (PID). If untreated, PID may lead to sterility, heart disease or death.

11. **Only people who have vaginal, anal or oral intercourse can contract an STD.**

False. Infants can contract STDs such as herpes, gonorrhea and HIV infection during their mother's pregnancy and/or during the birth process.

12. **It does not hurt to put off STD testing and treatment after you think you have been infected.**

False. Once an STD infects a person, it begins damaging health. If someone waits weeks or months before getting tested and treated, her or his health may

Adapted from *Teen Outreach: Youth Development Through Service and Learning* Association of Junior Leagues, International Inc., New York, N.Y., 1994.

Life Planning Education, Advocates for Youth, Washington, DC

be permanently damaged, even after treatment begins. In addition, the person can spread untreated STDs to sexual partners.

13. **A woman using oral contraceptives should still insist that her partner use a latex condom to protect against STDs.**

True. Oral contraceptives do not prevent STDs, so a condom is still necessary for protection.

14. **Washing the genitals immediately after having intercourse may help prevent some STDs.**

True. Personal cleanliness alone cannot prevent STDs, but washing away a partner's body fluids right after intercourse may be somewhat helpful. Washing does not, however, prevent pregnancy or stop HIV from entering the body through the mucus membranes in the mouth, anus, penis or vagina

15. **It is possible to get some STDs from kissing.**

True. It is we but possible to be infected by syphilis through kissing, if the infected person has chancres (small sores) in or around the mouth. The herpes virus can also be spread by kissing if active lesions are present.

16. **Oral is a safe way to have sex if you do not want to get a disease.**

False. It is possible to be infected with HIV, gonorrhea and herpes from oral sex.

17. **People usually know they have an STD within two to five days after being infected.**

False. Many people never have symptoms and others may not have symptoms for weeks or years after being infected. HIV infection may not show symptoms for years, but the infected person is capable of infecting other partners during that time;

18. **The most important thing to do if you suspect you have been infected by an STD is to inform your sexual partner or partners.**

False. The most important thing to do is to seek immediate medical treatment. Symptoms of an STD may never appear, or may go away after a short time, but the infection continues inside the person's body. She or he can suffer serious physical damage and can continue to infect others. Once medical treatment is begun, the person or a health practitioner can inform sexual partners. In the meantime, it is also important for the infected person to abstain from any sexual contact.

Adapted from *Teen Outreach: Youth Development Through Service and Learning* Association of Junior Leagues, International Inc., New York, N.Y., 1994.

Life Planning Education, Advocates for Youth, Washington, DC

Adapted from: Advocates for Youth (2019).

Appendix G

STD Educational Handout

STDs and HIV - CDC Fact Sheet



If you have an STD, you are more likely to get HIV or transmit it to others.

Are some STDs associated with HIV?

Yes. In the United States, people who get syphilis, gonorrhea, and herpes often also have HIV, or are more likely to get HIV in the future.

Why does having an STD put me more at risk for getting HIV?

If you get an STD, you are more likely to get HIV than someone who is STD-free. This is because the same behaviors and circumstances that may put you at risk for getting an STD also can put you at greater risk for getting HIV. In addition, having a sore or break in the skin from an STD may allow HIV to more easily enter your body. If you are sexually active, get tested for STDs and HIV regularly, even if you don't have symptoms.

What activities can put me at risk for both STDs and HIV?

- Having anal, vaginal, or oral sex without a condom;
- Having multiple sex partners;
- Having anonymous sex partners;
- Having sex while under the influence of drugs or alcohol can lower inhibitions and result in greater sexual risk-taking.

What can I do to prevent getting STDs and HIV?

The only 100% effective way to avoid STDs is to not have vaginal, anal, or oral sex. If you are sexually active, you can do the following things to lower your chances of getting STDs and HIV:

- Choose less risky sex activities;
- Use a new condom for every act of vaginal, anal, and oral sex throughout the entire sex act (from start to finish);
- Reduce the number of people with whom you have sex;
- Limit or eliminate drug and alcohol use before and during sex;
- Have an honest and open talk with your healthcare provider and ask whether you should be tested for STDs and HIV;
- Talk to your healthcare provider and find out if either pre-exposure prophylaxis, or PrEP, or post-exposure prophylaxis, or PEP, is a good option for you to prevent HIV infection.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention



CS280191D

Adapted from: CDC
(2017b)

Appendix H

HPV Educational Handout

Human Papillomavirus (HPV): Questions and Answers



INFORMATION ABOUT THE DISEASE AND VACCINES

How common is HPV in the United States?

HPV is the most common sexually transmitted infection in the United States. About 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that most sexually active men and women will get at least one type of HPV at some point in their lives.

An estimated 30,700 cancers attributed to HPV occur annually in the U.S., including an estimated 11,500 HPV-attributed cancers in males. Of the HPV-attributed cancer, approximately 64% are caused by HPV types 16 and 18, which are included in all three HPV vaccines that have been available in the United States and about 12% are caused by the 5 HPV types included in Gardasil 9.

How does HPV spread?

HPV is spread through contact with infected skin, usually through sexual contact. Most infected people have no symptoms and are unaware they are infected and can transmit the virus to a sex partner. Rarely, a pregnant woman passes HPV to her baby during vaginal delivery.

What are the symptoms of HPV?

Most people who become infected with HPV have no symptoms. Some people develop visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.

Genital warts usually appear as soft, moist, pink, or flesh-colored swellings, usually in the genital area. They can be raised or flat, single or multiple, small or large, and sometimes cauliflower shaped. They can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. After sexual contact with an infected person, warts may appear within weeks or months, or not at all.

How serious is HPV?

Most HPV infections don't cause any symptoms and eventually go away, as the body's own defense system clears the virus. Women with short-term HPV infections may develop mild Pap test abnormalities that go away with time.

A small percentage of people infected with HPV develop persistent (chronic) HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing cervical cancer precursor lesions (abnormal cells on the lining of the cervix) and cervical cancer.

What are possible complications from HPV?

Cancer is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The American Cancer Society (ACS) estimates that in 2016, approximately 12,990 new cases of invasive cervical cancer will occur in the U.S. and about 4,120 women will die from the disease. Worldwide, cervical cancer is the second most common cancer in women; it is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis, and anus. For example, ACS estimates that this year there will be about 2,030 new cases of penile cancer in the U.S. and 340 men will die from it. Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. It is estimated that approximately 360,000 cases of genital warts occur each year in the U.S. among sexually active people.

Occasionally, low-risk HPV infections can be transmitted during birth, resulting in respiratory tract warts in infants and children.

How is HPV infection diagnosed?

Genital warts in men and women are diagnosed by visual inspection.

Most women are diagnosed with HPV infection on the basis of abnormal Pap tests. Also, a specific test is available to detect HPV DNA in women. The test may be used in women with mild Pap test abnormalities or in women more than age 30 years at the time of Pap testing. In April 2014 the U.S. Food and Drug Administration approved the first HPV DNA test for women age 25 years and older that can be used alone to help

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Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p4207.pdf • Item #P4207 (2/17)

a health care professional assess the need for additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

No HPV tests are available for men.

Can genital HPV infection be cured?

There is no cure for HPV infection, although the immune system usually eliminates the virus from the body. Approximately 90% of women with HPV infection become HPV-negative within two years. However, a small percentage of infected people remain infected for many years, which may result in genital warts or cancer.

There are treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina, and anus.

Visible genital warts can be removed by medications the patient applies, or by treatments performed by a health-care provider. No one treatment is best. Warts might return, especially in the first 3 months after treatment. It is not known whether treatment of genital warts will reduce the chance of passing the virus on to a sex partner. If left untreated, genital warts may go away, remain unchanged, or increase in size or number.

How can people reduce their risk for acquiring genital HPV infection?

The surest way to eliminate risk for genital HPV infection is to refrain from any genital contact with another individual.

For people who are sexually active, a long-term, mutually monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. However, it is difficult to determine whether a partner who has been sexually active with another partner in the past is currently infected.

It is not known how much protection a condom provides against HPV, since skin that is not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer. People can also reduce their risk by getting the HPV vaccine.

When were the HPV vaccines licensed?

The first HPV vaccine (Gardasil, Merck) was licensed for females in 2006. Gardasil protected against four HPV types: 16, 18, 6, and 11. About 80% of cervical cancers are caused by HPV types 16 and 18, and more than 90% of genital warts are associated with HPV

types 6 and 11. In 2009, Gardasil was licensed for use in males. In 2009, a second HPV vaccine was licensed (Cervarix, GlaxoSmithKline) for use in females. Cervarix protected against HPV types 16 and 18. In 2014, a new version of Gardasil was licensed. This vaccine, called Gardasil 9, protects against the four HPV types included in the original Gardasil as well as 5 additional cancer-causing HPV types. These 5 additional types account for about 11% of all HPV-associated cancer in the United States (14% of HPV-associated cancers in females and 4% in males). As of late 2016, only Gardasil 9 is distributed in the United States.

What kind of vaccine is it?

HPV vaccine is an inactivated (not live) vaccine.

How is this vaccine given?

This vaccine is given as an injection in the deltoid muscle of the arm.

Who should get this vaccine?

The CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of boys and girls at age 11 or 12 years with catch-up vaccination for females through age 26 years, and for males through age 21 years; males age 22 through 26 years may be vaccinated. In addition, vaccination is recommended for men age 22 through 26 years who have sex with men or are immunocompromised as a result of disease (including HIV) or medication. The vaccination series can also be started as young as age 9 years, at the clinician's discretion.

How many doses are needed and on what schedule?

The schedule for HPV vaccine depends on the age at which the first dose is given. For people starting the vaccine series before age 15 years, the recommended schedule is 2 doses, separated by 6 to 12 months. If vaccination is started at age 15 years or older, the schedule is 3 doses. The second dose should be given one to two months after the first dose and the third dose should be given six months after the first dose and at least 12 weeks after the second dose. The vaccine can be administered at the same visit as other needed vaccines.

The vaccine provides the best protection when given before onset of sexual activity. However, people who are sexually active also may benefit from vaccination. People who have not been infected with any vaccine HPV type

CONTINUED ON THE NEXT PAGE ►

would receive the full benefit of vaccination. Those who already have been infected with one or more HPV types would still get protection from the vaccine types they have not acquired. HPV vaccine can be given to females who have had an abnormal Pap test or genital warts. However, the vaccine will not have any helpful effect on existing Pap test abnormalities, HPV infection, or genital warts (that is, the vaccine is not a treatment for HPV infection or HPV-related disease).

Why is HPV vaccine not licensed for adults older than 26 years?

HPV vaccine was tested in people age 9 through 26 years. Although Gardasil has been tested in women age 27 through 45 years and found to be safe, data on the effectiveness of the vaccine in this age group was inconclusive, mainly because many of the participants in the trial had already been infected with HPV types included in the vaccine. The FDA will consider licensing the vaccines for older people if additional research shows that it is effective for them.

Should individuals be screened before getting vaccinated?

No. Girls/women do not need to get an HPV test or Pap test to find out if they should get the vaccine.

How effective are the HPV vaccines?

All three HPV vaccines are highly effective in preventing infection with types of HPV included in the vaccines. Studies have shown that all three vaccines prevent nearly 100 percent of the precancerous cervical cell changes caused by the types of HPV included in the vaccine for more than 10 years after vaccination. Among males, efficacy of Gardasil for prevention of genital warts was 89% and efficacy for the prevention of precancerous lesions of the anus was 78%.

How long does vaccine protection last? Will a booster shot be needed?

The length of immunity is usually not known when a vaccine is first introduced. So far, studies have shown people to still be protected after more than 10 years. More research is being done to find out how long protection will last, and if a booster dose will eventually be needed.

Who recommends HPV vaccine?

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG) all recommend routine HPV vaccination of boys and girls at 11 or 12 years of age.

What side effects have been reported from HPV vaccine?

Mild problems may occur with HPV vaccine, including pain, redness, swelling, and itching at the injection site. These problems do not last long and go away on their own. Fainting has been reported among adolescents who receive HPV vaccine (and other recommended vaccines as well). It's best for the patient to sit during vaccine administration and remain seated for 15–20 minutes after receiving the vaccine.

Like all vaccines, HPV vaccine is being monitored for more serious or unusual side effects.

Can HPV vaccine cause HPV?

No. HPV vaccines are inactivated so they cannot cause disease-like symptoms or HPV disease.

We've heard stories in the media lately about severe reactions to HPV vaccine. Is there any substance to these stories?

No. While serious events, including death and Guillain-Barre syndrome, have been reported among women who had recently received HPV vaccine, CDC and FDA follow-up on these reports has not found that the events occurred more frequently among vaccinees than among the general population, and has detected no pattern that would indicate an association with the vaccine. You can find complete information on this and other vaccine safety issues at www.cdc.gov/vaccinesafety/index.html.

Do women still need to get a Pap test if they've been vaccinated against HPV?

Yes. Women should continue to receive regular cervical cancer screening for three reasons. First, the vaccine does not provide protection against all types of HPV that cause cervical cancer. Second, women may not receive the full benefits of the vaccine if they do not complete the vaccine series. Third, women may not receive the full benefits of the vaccine if they were infected with HPV before receiving the vaccine.

CONTINUED ON THE NEXT PAGE ►

In addition, vaccinated people should continue to practice protective sexual behaviors since the vaccine will not prevent all cases of genital warts or other sexually transmitted infections.

Does the vaccine protect against all types of HPV?

No. Although there are more than 100 types of human papillomaviruses, only four (HPV 6, 11, 16, and 18) were included in Gardasil, 9 are included in Gardasil 9 (HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58) and only two (HPV 16 and 18) were included in Cervarix. HPV 16 and 18 (included in all three vaccines) are responsible for 66% of cervical cancers; HPV 6 and 11 causes approximately 90% of genital warts.

What if a person doesn't get all of the recommended doses?

It is not known how much protection people would get from receiving fewer than the recommended number of doses of the vaccine. For this reason, it is very important to receive all recommended doses of the vaccine. If there is a gap in the schedule longer than the recommended time, the series should be continued from where it left off—there is no need to restart the series. A person who starts the series before the 27th birthday should complete the series even if he or she is now older than age 26 years.

Can an HPV vaccine series begun with Cervarix or Gardasil be completed with Gardasil 9?

Yes. Any HPV vaccine may be used to continue or complete the series.

Does CDC recommend revaccination with Gardasil 9 for people who previously received a series of Cervarix or Gardasil?

CDC has not recommended routine revaccination with Gardasil 9 for persons who have completed a series of another HPV vaccine. There are data that indicate revaccination with Gardasil 9 after a series of Gardasil is safe. Discuss this issue with your healthcare provider to decide if the benefit of immunity against 5 additional oncogenic strains of HPV is worth the time and expense of revaccination.

My 12-year-old received the first 2 doses of the HPV series 2 months apart according to the 3-dose schedule. Is his HPV vaccine series complete or does he need a third dose?

Adolescents age 9 through 14 years who received 2 doses of HPV vaccine separated by less than 5 months should receive a third dose 6–12 months after dose #1 and at least 12 weeks after dose #2.

Do women and men whose sexual orientation is same-sex need HPV vaccine?

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

Who should NOT receive HPV vaccine?

Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine (such as baker's yeast), or to a previous dose of HPV vaccine, should not get the vaccine.

Pregnant women should not get the vaccine. Although the vaccine appears to be safe for both the woman and developing baby, this issue is still being studied. Inadvertently receiving HPV vaccine during pregnancy is not a reason to consider terminating the pregnancy. Patients and healthcare providers should report any exposure to HPV vaccine during pregnancy to the manufacturer of the vaccine, at (800) 986-8999.

Breast-feeding women can safely get the vaccine.

People who have a moderate or severe acute illness should wait until their condition improves to be vaccinated.

Is HPV vaccine covered by insurance plans?

Many health insurance plans cover vaccines recommended for children and adolescents. The Vaccines for Children (VFC) program provides free vaccines to children and adolescents younger than 19 years of age, who are Medicaid-eligible, American Indian, or Alaska Native, uninsured, or receiving care in a Federally Qualified Health Clinic or Rural Health Center. This includes boys as well as girls. For adults, if you're not certain about your healthcare coverage, contact your health insurance plan for further information. If you don't have health insurance or if your plan doesn't cover this vaccine, ask your doctor or your local health department how you can obtain this vaccine.

Appendix I

HPV Vaccine educational handout

VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis.

1 Why get vaccinated?

HPV vaccine prevents infection with human papillomavirus (HPV) types that are associated with many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, HPV vaccine prevents infection with HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. HPV vaccine can prevent most of these cases of cervical cancer.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away on their own and not cause serious problems. But thousands of women and men get cancer and other diseases from HPV.

2 HPV vaccine

HPV vaccine is approved by FDA and is recommended by CDC for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Most adolescents 9 through 14 years of age should get HPV vaccine as a two-dose series with the doses separated by 6-12 months. People who start HPV vaccination at 15 years of age and older should get the vaccine as a three-dose series with the second dose given 1-2 months after the first dose and the third dose given 6 months after the first dose. There are several exceptions to these age recommendations. Your health care provider can give you more information.

3 Some people should not get this vaccine

- Anyone who has had a severe (life-threatening) allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any serious problems with it.

Mild or moderate problems following HPV vaccine:

- Reactions in the arm where the shot was given:
 - Soreness (about 9 people in 10)
 - Redness or swelling (about 1 person in 3)
- Fever:
 - Mild (100°F) (about 1 person in 10)
 - Moderate (102°F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)



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Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/.

5

What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7

How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/hpv

Vaccine Information Statement HPV Vaccine

12/02/2016

42 U.S.C. § 300aa-26

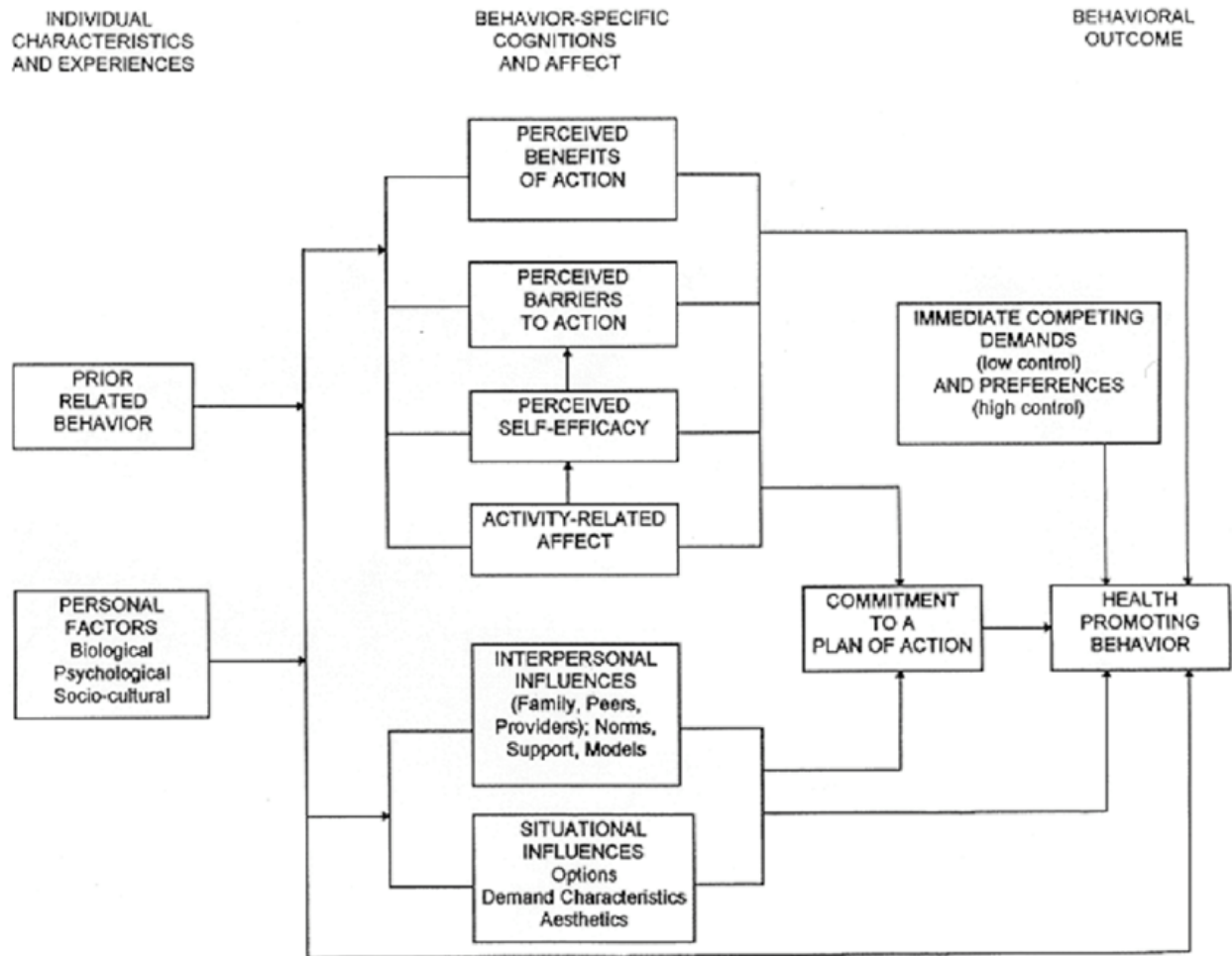
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Adapted from:
CDC (2016).

Appendix J

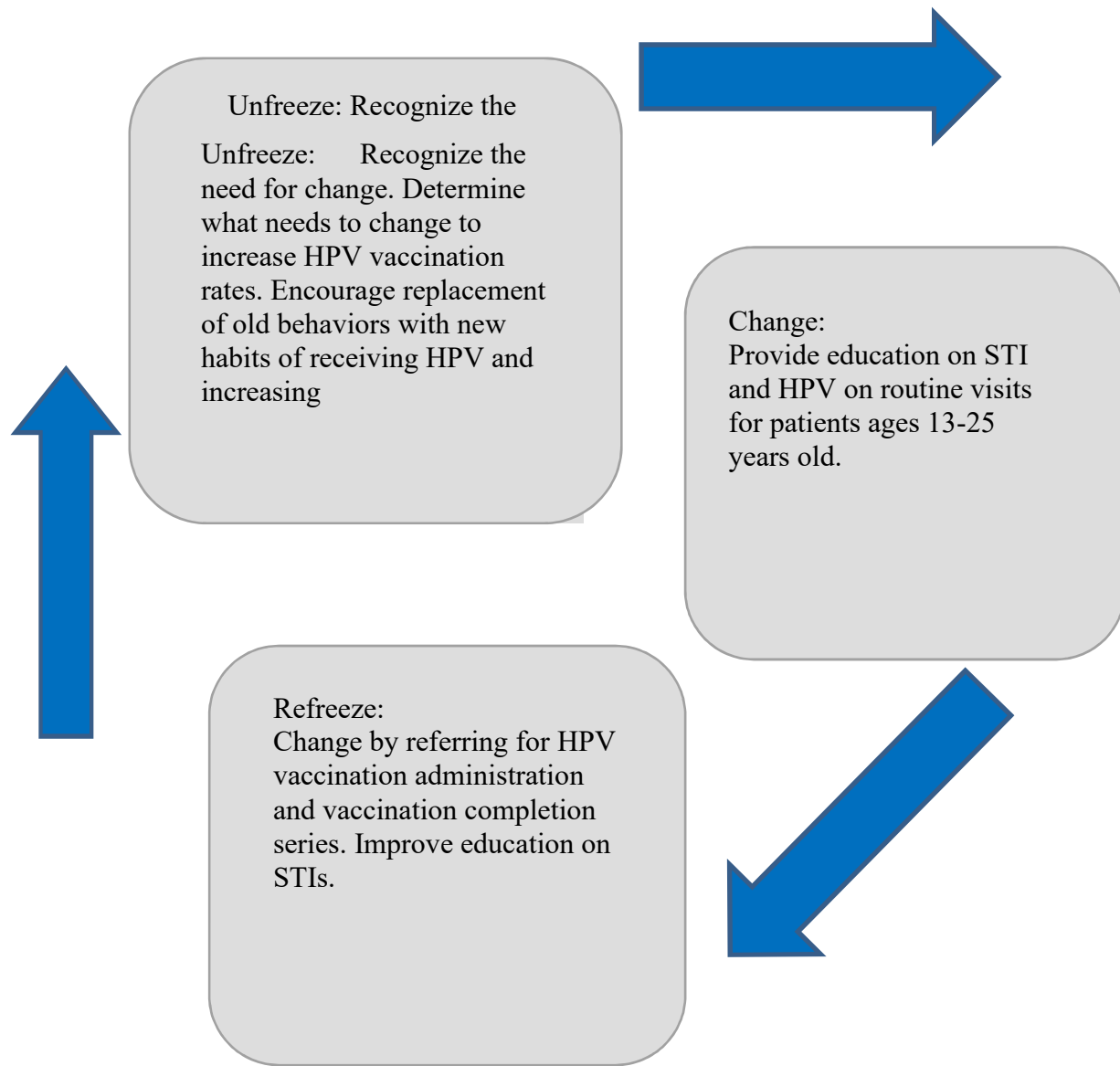
Figure 1: Pender's Health Promotion Model (PHPM)



Source: Valek, Greenwald, & Lewis (2015).

Appendix K

Figure 2: Lewin's Change Theory Model



Source: Visual Paradigm online (2020).

Appendix L

Table 2: Data Collection Form

[illegible]

Appendix M

Project Timeline

Project Phase	Milestone	Estimated completion date							
		Oct	Nov	Dec	Jan	Feb	Mar	May	July
Initiation	Full Proposal approved	10/15							
Planning	IRB submission w/letter of support		1/17						
	Proposal presentation		1/19						
	Data collection			Starts: 12/2			Ends: 3/2		
Implementation				Starts: 12/2			Ends: 3/2		
Monitoring				12/16 (2-weeks)	1/13 (6-weeks)	2/24 (12 weeks)			
Reporting/Finalizing								5/25	
Presentation									7/8

Appendix N

STD Educational Survey: Fill in the blanks

Name: _____

Date: _____

Please write in the name of the STD to the correct description: *Chlamydia, Gonorrhea, Genital herpes, Genital warts, HIV/AIDS, Syphilis.*

1. A viral infection that causes cold sores around mouth; spreads through unprotected sex and can be transmitted with no signs or symptoms; no cure but medications help outbreaks:

2. Caused by a strain of human papilloma virus (HPV) with symptoms of bumps/lesions in and around genitals; spread through sexual contact and skin to skin contact; vaccination helps prevent this disease.

3. Caused by *Neisseria gonorrhoeae* bacterium; often shows no symptoms however if occurs can be painful urination and vaginal/penile discharge; treated with antibiotics; untreated infections can cause infertility, pain, and joint problems

4. Most commonly caused by a bacterial infection that is spread through unprotected sex and skin to skin contact; in which can cause discharge, pain, and burning during urination however may not have any symptoms at all; untreated infections can cause infertility, pelvic inflammatory disease (PID) and other serious long term complications.

5. Bacterial infection that is contracted through unprotected sex and skin to skin contact; three stages; early stages can be treated with antibiotics; later stages can affect eyes, heart, eyes, and brain; if left untreated, can increase risk of HIV

6. Transmitted from direct contact with blood or body fluid from an infected person; symptoms may take 10 years to show; once appears, can lead to life-threatening conditions

Adapted from: KidsHealth (2017)

True/False STD Educational Survey:

Name: _____

Date: _____

Please CIRCLE “True” or “False” to the following questions:

1. Many individuals with STDs don’t even know they have an STD? TRUE FALSE

2. People who start having sex at a younger age are more likely to get an STD?

TRUE FALSE

3. Condoms can only prevent pregnancy, not STDs?

TRUE FALSE

4. If you have had unprotected sex once, you don’t need to worry about an STD?

TRUE FALSE

5. The only way to know if you have an STD is to get tested by a medical profession.

TRUE FALSE

6. If you ignore signs and symptoms of an STD, it will just go away.

TRUE FALSE

7. “The Pill” can protect females from an STD?

TRUE FALSE

8. A person can only get one STD at one time?

TRUE FALSE

9. Having many different sexual partners can increase risk of getting an STD?

TRUE FALSE

10. If a person is not sexually active while having an STD or symptoms, their partner
Will not get it?

TRUE FALSE

Adapted from: KidsHealth (2017)

STI Educational Survey: “True or False”

Name: _____

Date: _____

Please answer the following questions:

1. Which age group has the highest rates of STD infections?
 - a. 13-24 years of age
 - b. 25-35 years of age
 - c. 36-50 years of age
 - d. 51-60 years of age
2. When should you see your doctor:
 - a. Before you become sexually active
 - b. Every year for testing if you become sexually active
 - c. when the first sign or symptom start
 - d. all of the above
3. Most of all STDs:
 - a. Are extremely painful
 - b. Have no symptoms
 - c. Can cause high fevers
 - d. Can cause flu symptoms
4. The only behavior that is 100% effective with preventing all STDs are:
 - a. Only having one sexual partner
 - b. Only having oral intercourse
 - c. Contraceptive use
 - d. Abstinence

Adapted from: KidsHealth (2017)

Appendix O

STI Educational Survey: True/False

Name: _____

Date: _____

Please CIRCLE “True” or “False” to the following questions:

- | | |
|--|------------|
| 1. Someone can have a sexually transmitted infection and not know it | TRUE FALSE |
| 2. Its normal for females to have vaginal discharge | TRUE FALSE |
| 3. Chlamydia and gonorrhea can cause pelvic inflammatory disease | TRUE FALSE |
| 4. A pregnant female with an STI can pass to newborn or fetus | TRUE FALSE |
| 5. Most STIs will go away without treatment and just waiting. | TRUE FALSE |
| 6. Condoms can prevent STIs. | TRUE FALSE |
| 7. Birth control is the most effective protection from STIs | TRUE FALSE |
| 8. STIs can cause infertility if left untreated. | TRUE FALSE |
| 9. If your know your sexual partner, then you cannot get an STI | TRUE FALSE |
| 10. Chlamydia is the most common STI | TRUE FALSE |

Adapted from: Planned Parenthood Federation of Canada (2001)

Appendix P

Analyses plan for Outcome Objectives

Outcome	Improving patient's education in regards to transmission, symptoms, complications, and treatment of STDs by 70% within a 3-month period	Increasing HPV vaccinations within the population of 13-24 years of age by 70% within a 3-month period
How will it be measured?	STD quiz survey	EMR review and vaccination records from health department
Who will measure it?	Medical assistances and/or nurse practitioner/DNP student	Medical assistances and/or nurse practitioner/DNP student
When will it be measured?	Initial visit and each follow up visits	Initial and 12 follow up visit
What methods used to be measured?	Statistical test: t-tests	Bar chart (histogram)

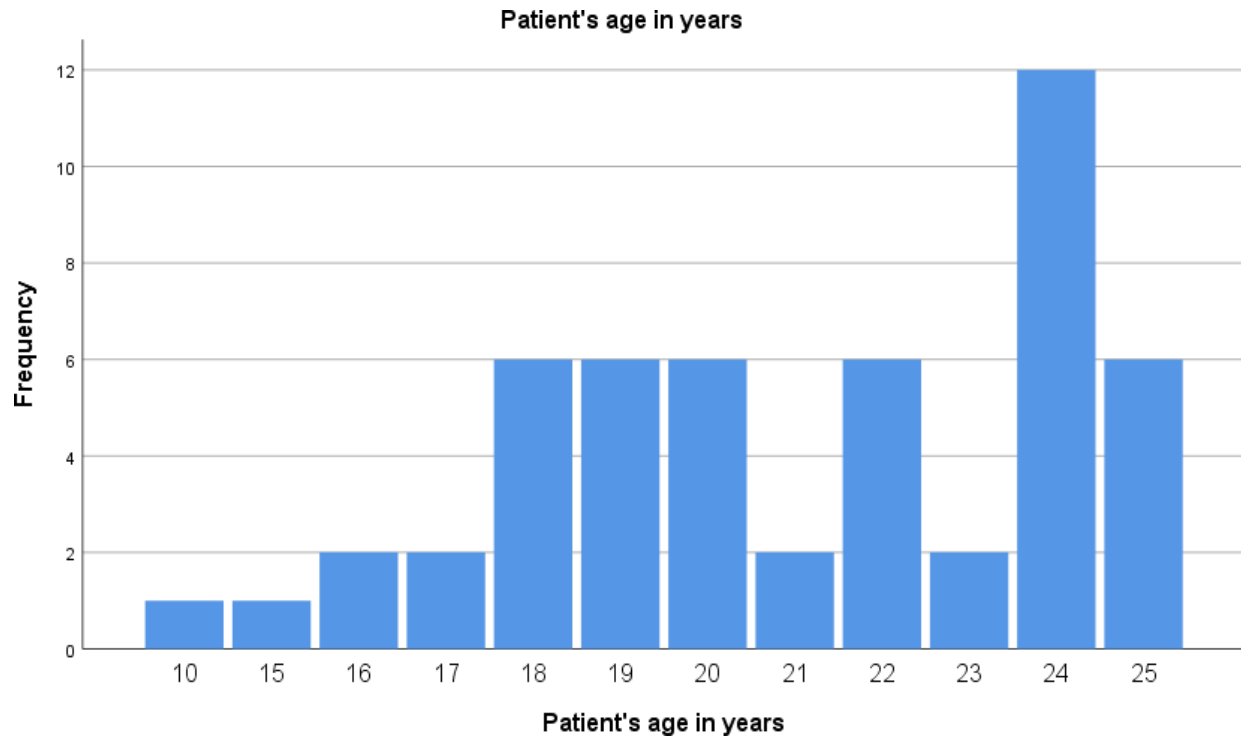
Appendix Q

Collected Data

Patient ID	DOB	Age	Gender	Ethnicity	Insurance	exposure	Lab results	Sexually Active	HPV vaccine initiated	HPV vaccine completed	Follow Up Visit	PreTest STD Knowledge	PostTest STD Knowledge	PreTest STD True/False	PostTest STD True/False	PreTest STI	PostTest STI	HPV Vaccine Referral	HPV Vaccine Received
101	11/3/2001	19	1	1	1	2	2	1	1	0	2	80	100	60	90	66	80	1	2
102	4/15/1995	25	0	2	1	2	2	1	0	0	2	60	80	60	80	73	93	1	2
103	7/28/1995	24	0	2	1	1	2	1	1	0	2	40	90	50	90	53	73	1	2
104	9/16/1995	24	1	2	1	2	2	2	1	0	1	40	90	50	100	46	80	1	2
105	4/24/2000	20	1	2	2	1	1	1	0	0	2	80	100	70	100	73	86	1	2
106	9/13/2001	19	0	1	2	1	2	1	0	0	1	70	100	60	90	73	86	1	2
107	5/14/1996	24	0	1	1	1	1	1	1	1	2	60	100	60	90	66	80	2	2
108	11/28/2001	18	1	1	2	1	1	1	0	0	1	70	80	50	100	80	86	1	2
109	8/16/1999	20	0	2	1	1	2	1	0	0	1	90	100	70	80	73	93	1	2
110	11/8/1994	25	1	2	1	2	2	2	0	0	2	70	100	60	90	73	100	1	2
111	7/3/1997	22	1	1	1	2	2	2	0	0	2	90	100	50	90	80	100	1	2
112	7/23/1999	20	1	2	2	2	2	2	1	0	1	80	90	70	80	73	93	1	2
113	3/9/2000	20	1	1	2	2	2	2	0	0	2	50	80	40	80	33	86	1	2
114	4/27/2003	17	1	2	2	2	2	2	1	0	0	40	80	30	70	60	80	2	2
115	11/15/1995	24	1	2	2	2	2	2	1	1	1	80	90	60	90	73	80	2	2
116	12/31/1997	22	1	2	1	2	2	2	0	0	2	70	80	50	90	66	80	1	2
117	12/29/1994	25	1	2	1	2	2	2	0	0	2	60	70	50	80	60	86	1	2
118	2/18/2001	19	1	2	1	2	2	2	0	0	2	60	60	60	70	53	73	1	2
119	8/2/1997	22	1	2	1	1	2	1	0	0	2	60	80	70	80	73	93	1	2
120	7/1/1995	24	1	2	1	2	1	1	0	0	2	70	90	60	60	66	86	1	2
121	5/17/1996	24	1	1	1	2	1	1	0	0	0	90	100	80	90	60	86	2	2
122	7/11/1995	24	1	1	1	2	2	2	0	0	0	80	80	90	90	80	93	2	2
123	5/26/2001	10	0	1	1	1	1	1	0	0	2	80	90	80	90	86	86	1	2
124	4/30/1996	24	1	1	1	2	1	1	0	0	2	70	100	70	60	73	80	1	2
125	5/2/2002	18	0	2	1	2	2	2	0	0	2	90	90	60	80	80	80	1	2
126	10/31/2000	19	0	1	1	2	2	2	0	0	2	80	100	70	90	60	100	1	2
127	12/8/1995	24	1	2	2	2	2	2	1	1	1	40	80	60	90	53	100	2	2
128	1/5/1998	22	1	2	1	1	2	1	0	0	1	60	90	50	90	46	86	1	2
129	5/10/1998	22	1	2	2	2	1	1	1	0	2	50	90	50	90	53	80	1	2
130	8/12/2002	17	0	2	1	1	1	1	1	0	1	30	90	40	80	53	73	1	2
131	4/14/1996	24	1	1	2	1	2	1	0	0	1	80	80	60	80	60	66	1	2
132	4/2/1995	25	0	1	2	2	2	2	0	0	0	20	70	40	70	46	73	2	2
133	4/30/2004	16	0	1	2	1	2	1	0	0	1	80	100	60	100	73	86	1	2
134	8/23/1995	24	0	1	1	2	2	2	1	1	2	70	100	50	100	60	86	2	2
135	4/6/1999	21	0	2	1	2	2	2	0	0	1	70	100	40	80	66	80	1	2
136	2/7/1996	21	1	1	1	2	2	2	1	0	1	90	100	70	90	80	93	1	2
137	12/23/2003	16	0	1	1	2	2	1	1	0	1	80	90	60	90	80	93	1	2
138	8/20/2001	18	1	1	1	2	2	1	0	0	1	80	90	60	70	66	86	1	2
139	11/3/2001	18	1	1	1	1	2	1	0	0	2	70	90	60	80	73	86	1	2
140	9/5/2001	18	1	1	1	1	2	1	0	0	1	60	80	70	80	60	73	1	2
141	2/6/2002	18	1	2	1	2	2	2	0	0	2	80	90	50	80	80	80	1	2
142	4/24/1995	25	1	1	1	2	2	1	0	0	1	50	100	40	80	66	80	1	2
143	9/24/1999	20	1	1	1	2	1	1	1	1	2	80	100	50	90	80	93	2	2
144	8/21/2000	19	0	1	1	2	1	1	1	0	2	90	100	70	100	73	86	1	2
145	5/21/1996	24	1	1	1	1	1	1	0	0	1	100	100	70	100	93	86	1	2
146	5/31/1997	23	1	2	1	2	1	1	1	0	1	80	90	80	90	73	93	1	2
147	12/2/2004	15	1	2	1	1	2	1	0	0	2	90	100	60	80	66	100	1	2
148	11/29/1996	23	1	2	1	1	2	1	1	0	2	70	100	60	90	66	100	1	2
149	2/16/2001	19	0	2	1	2	2	2	0	0	2	80	100	70	80	66	80	1	2
150	5/2/1995	25	1	2	1	2	2	2	0	0	1	60	80	50	80	53	66	1	2
151	8/18/1997	22	1	2	2	2	2	2	0	0	1	40	80	70	70	53	86	1	2
152	2/9/2000	20	0	2	1	2	2	2	0	0	2	70	100	60	90	73	80	1	2

Appendix R

Chart 1 Patient ages in Years



Appendix S

Table 3-Descriptive Statistics

	Descriptive					
	N Statistic	Minimum Statistic	Maximum Statistic	Mean		Std. Deviation Statistic
HPV vaccine initiated	52	0	1	.33	.066	.474
HPV vaccine completed	52	0	1	.10	.041	.298
PreTest STD Knowledge	52	20.00	100.00	68.8462	2.43550	17.56264
PostTest STD Knowledge	52	60.00	100.00	90.5769	1.38440	9.98302
PreTest STD True/False	52	30.00	90.00	59.2308	1.66696	12.02060
PostTestr STD True/False	52	60.00	100.00	85.0000	1.35929	9.80196
PreTest STI	52	33.00	93.00	66.5962	1.63490	11.78943
PostTest STI	52	66.00	100.00	85.1923	1.18628	8.55441
HPV Vaccine Referral	52	1	2	1.17	.053	.382
Valid N (listwise)	52					

Statistics