

**Increasing HPV Vaccination Rates Among Adolescent Girls**

By

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### **Abstract**

Human Papillomavirus (HPV) infection is so common that nearly every person will at one point become infected with at least one type of HPV. Despite HPV being the most common sexually transmitted infection, low vaccination rates are a huge concern to the public in the United States of America as there are nearly 35,000 new cancer cases in both men and women every year due to HPV infection. In the fourth quarter in 2019, only 66.6% of females completed the vaccination series in North Dakota. This falls far below Healthy People 2020s goal to vaccinate 80% of adolescents. The objective of this project was to increase HPV vaccination rates among adolescent females between the ages of 9 and 26 in a primary care setting through enhanced patient education in the form of a curated handout, asking about HPV vaccination at sick visits, and same day recommendation of vaccination administration as other vaccinations (such as Tdap, MMR, and etc.). Methods to increase HPV vaccination rates were researched from the literature and a project plan to improve those rates was formulated using a multi-method approach. This project occurred in a rural setting in North Dakota where HPV vaccination rates are low. It improved patient care and provided evidence-based practices that may serve as resources for other healthcare providers on how to increase HPV vaccination rates. This project can shape the future for increasing HPV vaccination rates and for decreasing HPV infection rates.

*Keywords:* HPV, vaccination, immunization, adolescents, sexually transmitted infections, infection, cancer, females, sick visits, education

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## **Chapter I: Introduction**

### **Increasing HPV Vaccination Rates Among Adolescent Girls**

The topic of HPV vaccination compliance was selected due to my past clinical experiences in a primary care setting where there was a hesitancy by parents to have their children vaccinated against HPV. Vaccination against HPV is intended to be routinely given to age appropriate individuals in a clinic setting across the nation. Vaccination against HPV is recommended as strongly by the United States government as the Measles, Mumps, and Rubella (MMR) and the Tetanus, Diphtheria, and Pertussis (Tdap) vaccinations, with some states making HPV vaccination a requirement to attend school in that state (Centers for Disease Control and Prevention [CDC], 2019). The goal is to increase HPV vaccination rates among adolescent girls between the ages of 9 and 26 years in a primary care setting. By implementing this project, it will positively contribute not only to the intended patients, but also to society through decreased infection rates. Increasing HPV vaccination rates would not only help providers and the clinic comply with the CDC's recommendations of HPV vaccination, but it would also help prevent HPV infections. Since vaccination against HPV is recommended just like school-aged vaccinations, why is the compliance rate for vaccinations down nationally?

### **Background and Significance**

Human papillomavirus, or HPV, is a nonenveloped, double-stranded deoxyribonucleic acid (DNA) virus (L. Grossman, 2014, p. 1417). Infection of HPV begins with viral inoculation into the stratified squamous epithelium (L. Grossman, 2014, p. 1417). It is important to remember that for the spread of viruses, there needs to be a host for the virus to replicate as viruses cannot replicate outside of a living cell (S. Grossman, 2014, p. 254). Viruses need to penetrate a susceptible living cell, using the biosynthetic structure of the cell in order to produce



viral progeny (S. Grossman, 2014, p. 255). The virus may go on to cause proliferative lesions of the squamous epithelium of the host around six weeks to eight months after contact, known as genital and/or cutaneous warts (L. Grossman, 2014, p. 1417). The warts present as soft, raised, and fleshy lesions presenting on external genitalia of the penis, vulva, scrotum, perineum, and perianal area (L. Grossman, 2014, p. 1417). The most common strains of HPV to cause genital warts include strains 6 and 11, which are low risk strains that are not oncogenic (Gardasil 9, 2019, p. 1417).

It is estimated that approximately 70% of women with HPV become HPV DNA negative within one year of infection (L. Grossman, 2014, p. 1418). It is also estimated that as many as 90% of women become HPV DNA negative within two years of infection (L. Grossman, 2014, p. 1418). If HPV retesting is negative after a previous HPV positive test, then the results may mean that either the immune system has cleared the body of HPV, or the infection is latent at this time (McGill, 2019). When an infection is latent, the level of infection is so small that laboratory tests cannot detect it due to the virus hiding deep within the affected mucosa or skin (McGill, 2019). If most HPV infections are asymptomatic and transient, with some resolving spontaneously within two years without treatment, then why is HPV so dangerous and why is it so important to vaccinate the adolescent population (L. Grossman, 2014, p. 1418)? There are three main reasons to vaccinate against HPV. One reason is that research results have shown that HPV is a much bigger problem than initially thought. The second reason that HPV is so dangerous is due to its ability to lay dormant after the viral replication cycle (S. Grossman, 2014, p. 255). The replication cycle is when the HPV virus has inserted its genome into the host cell (S. Grossman, 2014, p. 255). The virus can remain in a latent, nonreplicating state for an unset period of time (S. Grossman, 2014, p. 255). At this time, the HPV virus does not cause

immediate disease to the host while in the latent state (S. Grossman, 2014, p. 255). The virus may even remain dormant in the host for years, only to reactivate later (S. Grossman, 2014, p. 255). Reactivation of the virus can occur if the immune system is weakened from pregnancy, illnesses, aging, and etc. (McGill, 2019). The final and third reason to vaccinate against HPV is that HPV is also referred to as an oncogenic virus (S. Grossman, 2014, p. 256). Oncogenic viruses have the capability of transforming normal host cells into malignant cells during the replication cycle (S. Grossman, 2014, p. 256). Due to HPV being the most common sexually transmitted infection, low vaccination rates are a huge concern to the public (CDC, 2019).

### ***How is HPV Spread?***

HPV is spread through direct and intimate skin-to-skin contact (CDC, 2019). Human papillomavirus is a group of more than 200 related virus (National Institutes of Health [NIH], 2019). Of the 200 viruses identified, more than 40 viruses have been shown to be spread through direct sexual contact (NIH, 2019). HPV is spread through having vaginal, anal, or oral sex with an HPV infected individual (CDC, 2019). Roughly 80% of people will become infected with HPV in his or her lifetime (CDC, 2019).

### ***HPV Classification***

Forty different viruses are known to affect the genital area of the host (L. Grossman, 2014, p. 1417). HPV can be classified into three categories according to the likelihood of the virus inducing dysplasia and carcinoma including: low-risk, intermediate-risk, and high-risk (L. Grossman, 2014, p. 1417). The low-risk group includes HPV types 6 and 11 (L. Grossman, 2014, p. 1417). Intermediate-risk HPV types include 31, 33, 35, 39, 45, 51, 56, and 58 (L. Grossman, 2014, p. 1417). Intermediate-risk HPV types are common causes of intraepithelial neoplasia, not squamous carcinoma (L. Grossman, 2014, p. 1417). HPV types 16 and 18 are

considered high-risk due to the strong association with cervical dysplasia and anogenital cancers in the host (L. Grossman, 2014, p. 1417). High-risk HPV can cause cancer in the cervix, vagina, anus, oropharynx, and vulva in women (CDC, 2019). In men, high-risk HPV strains can cause cancer in the penis, anus, and oropharynx, including the base of the tongue and tonsils (CDC, 2019). In the United States, it is estimated that HPV causes nearly 35,000 new cancer cases in both men and women every year (CDC, 2019).

### ***HPV Vaccination Recommendation Guidelines***

According to the CDC, the current recommendation is to give two doses of the HPV vaccination to all male and female adolescents at age 11 or 12 years, starting as early as 9 years (2019). The patient is considered on time with the CDC current dosing guidelines if the first dose of a 2-dose HPV vaccination is administered prior to 14 years (CDC, 2019). It is best practice to administer both doses of HPV vaccine prior to the patient's 15<sup>th</sup> birthday due the immunity protection rate being just as good, if not better, than the three doses that would be administered after 15 years (CDC, 2019). If a patient is not vaccinated against HPV prior to the 15<sup>th</sup> birthday, a 3-dose schedule is recommended (CDC, 2019). The same recommendation is given for any patients with certain immunocompromising conditions like cancer, HIV infection, autoimmune diseases, and transplants (CDC, 2019). The 2-dose and 3-dose HPV vaccination series do not need to be repeated if the dosing schedule is interrupted, since there is no maximum interval between doses (CDC, 2019).

Currently, there are three vaccines that prevent the spread of HPV infection around the world (NIH, 2019). The three HPV vaccinations include the quadrivalent Gardasil®, Gardasil® 9, and Cervarix® (NIH, 2019). High-risk HPV types 16 and 18 are prevented by all three vaccines (NIH, 2019). Both Gardasil vaccinations also prevent the infection of HPV types 6 and

11, which account for up to 90% of genital warts (NIH, 2019). Gardasil 9 prevents infection from HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 (NIH, 2019). HPV types 31, 33, 45, and 52 account for up to 20% of cervical cancers caused by HPV (NIH, 2019). Not all HPV vaccinations are approved for use in both sexes. For example, Cervarix is approved for use in females only, while the quadrivalent Gardasil is approved for use in both males and females (CDC, 2019). Currently, Gardasil 9, which is intended for males and females, is the only HPV vaccine available and recommended for administration in the United States (NIH, 2019).

### ***Healthy People 2020 Goals***

Healthy People 2020's goal for HPV vaccination is to increase the percentage of male and female adolescents aged 13 through 15 years who receive two or three doses of human papillomavirus (HPV) to 80% (Healthy People, 2019). In 2016, the vaccination rate for adolescent males was 36.4% and the HPV vaccination rate for female adolescents was 45.1% (Healthy People, 2019). If there is compelling evidence regarding detrimental effects of HPV and the effective use of vaccination against HPV infection, then why are the vaccination compliance rates so low? Why is this topic important to discuss? It is important as infection of HPV is so common, that nearly all individuals will at one point be infected with at least one type of HPV during their lifetime (CDC, 2019). Currently, almost 80 million Americans are infected with HPV (CDC, 2019). It is estimated that every year, 14 million new Americans will become infected, where 50% of the 14 million newly infected HPV persons are between the ages of 15 to 24-years-old (CDC, 2019; Gardasil, 2019). For some, HPV clears away without treatment (Gardasil, 2019). However, for the infected individuals who cannot clear HPV, they may go on to develop certain types of cancers or other diseases (Gardasil, 2019). The reason why the topic of HPV vaccination is so important is because if all adolescents are vaccinated against HPV

infection prior to becoming sexually active, it can protect them long before they are ever exposed to the virus (CDC, 2019).

### **Needs Assessment**

As a country, the United States is not meeting the Healthy People 2020's goal of vaccinating against HPV in 80% of the adolescent population by the age of 15 years in both sexes by the year 2020 (Healthy People, 2019). In 2017, only 49% of the adolescent population was vaccinated against HPV (CDC, 2019). This project will incorporate multiple ways to increase the HPV vaccination rate in the adolescent population in a rural community clinic in North Dakota. An increase in vaccination rates would lead to a decrease in the spread of HPV; decrease cervical dysplasia rates/abnormal pap smears including Atypical squamous cells of undetermined significance (ASC-US), Low-grade squamous intraepithelial lesions (LSIL), High-grade squamous intraepithelial lesions (HSIL), Atypical squamous cells, cannot exclude HSIL (ASC-H), Adenocarcinoma in situ (AIS), and/or Atypical glandular cells (AGC); decrease colposcopies; decrease LEEPs (Loop Electrical Excision procedure)/other cervical surgeries; decrease the overall cost of unnecessary healthcare cost including biopsy procedures; decrease the incidence of genital warts; and decrease the incidence of oropharyngeal, vulvar, anal, vaginal, and cervical cancers. The financial cost associated with HPV cancers is estimated to be 7 billion dollars a year in the United States (Holloway, 2018).

A SWOT analysis was done showing internal strengths that the planned intervention is evidence-based. The analysis also showed that the rural clinic providers support the current HPV recommendations set forth by the governing bodies. Potential internal weaknesses include poor communication with guideline recommendations from providers and/or nurses with regards to the way the guideline is recommended, poor communication of the guideline recommendations

to parents prior to the appointment (lack of vaccination reminders sent out), and/or time constraints of appointment with regard to proper education. Opportunities for the external factors include increased awareness of HPV from parents and/or legal guardians, reduced number abnormal Papanicolaou tests found through preventative screening that detects cervical cell changes (such as ASC-US, LSIL, HSIL, ASC-H, AIS, and/or AGC) starting at age 21 years, increased HPV vaccination compliance, future reduction of cervical, anal, and esophageal cancers caused from HPV, and future reduction of HPV related genital warts. Possible external threats include inability to contact parents/patients in a timely manner, inability to give proper education in a time-constrained setting of an appointment, inability of parents' compliance regarding education, and vaccination apprehension culture.

### **Problem Statement**

The problem is that HPV infection is so common that nearly every person will at one point become infected with at least one type of HPV (CDC, 2019). In the course of a patient's life, statistically speaking, he or she will more than likely be infected with at least one type of HPV (CDC, 2019). This statistic is not delving into how many types of HPV strains a person may become infected with during his or her lifetime. According to the CDC, every year 14 million new Americans will become infected (2019). At least half of those infected every year are adolescents (CDC, 2019). HPV is the most commonly spread sexually transmitted disease (CDC, 2019). The only way to protect individuals from HPV infection is through the proper and timely administration of the HPV vaccination (CDC, 2019).

### **Purpose and Objectives**

The purpose of this DNP project is to increase timely HPV vaccination administration in adolescent females in a rural primary care clinic in North Dakota by increasing patient awareness

through using an educational handout. In the fourth quarter in 2019, only 66.6% of females completed the vaccination series in North Dakota (CDC, 2019). By increasing HPV vaccination rates in rural North Dakota, this practice is in compliance with the CDC's recommendations of having the vaccination series completed by the age of 26 years (CDC, 2019). The objective is to increase HPV vaccination rates among adolescent females between the ages of 9 and 26 years in a primary care setting through enhanced patient education and same day recommendation of vaccination administration as other vaccinations (such as Tdap, MMR, and etc.). Evidence-based recommendations regarding HPV vaccination are supported by the rural clinic providers. Support from these providers will help drive change to minimize weaknesses and threats to improve HPV vaccination compliance among adolescent females.

### **PICOT Question**

The PICOT question is: In adolescent females between the ages of 9-26 years (P) would enhanced education of parents/legal guardians and/or adolescents surrounding HPV and the prevention of it (I) compared to the current educational CDC handouts provided at office visits (C) increase the rate of HPV vaccination compliance with the CDC's current HPV vaccination recommendations in the rural clinic setting in 2020 (O), compared to the vaccination rates in the fourth quarter in North Dakota in 2019(T)?

### **Congruence with Organizational Strategic Plan**

The mission statement of the rural clinic reads that providers are a "part of a regional network of primary and specialty care providers and services dedicated to preventing, managing, and treating health conditions using the most modern, science-based approaches" (Trinity Health, 2019). This DNP scholarly project aligns with primary prevention and management of health conditions through use of the science-based and modern approaches, as HPV vaccination

prevents HPV infection, which is a primary prevention (Trinity Health, 2019). This project clearly aligns with the mission statement of the clinic. The most important part of health is maintaining health and the prevention of unnecessary conditions. The clinic is dedicated to stopping preventable health conditions (Trinity Health, 2019). HPV infection is a preventable health condition in patients that needs to be addressed. One way to address this topic and help patients enhance their health is through this DNP project.

### **Synthesis of Evidence**

CINAHL and PubMed were accessed as the main databases between September and November 2019 to identify studies related to HPV, HPV vaccination, provider communication about HPV vaccination, and HPV infection results/comorbidities/after effects on the host. Searches conducted on CINAHL varied, but all searches used the following terms: ([hpv vaccine OR hpv vaccination OR human papillomavirus vaccine] AND [systematic review OR meta-analysis OR randomized controlled trial] AND [increase]). Another example that was conducted using CINAHL was using the following terms: ([hpv vaccine OR hpv vaccination OR human papillomavirus vaccine] AND [systematic review OR meta-analysis OR randomized controlled trial] AND [herd]). Searches varied on PubMed, but all searches used a combination of the following terms: ([hpv or HPV or Human papillomavirus] AND [non-sexual transmission]). Additional studies were identified through checking reference lists of papers included in this paper. Results were refined by setting the publication date between 2014-2019. This time frame ensured that articles were not outdated. Source results were not limited to only academic journals in order to analyze references and add to the project. This method yielded a very important part in this project to add to the reference list. Inclusion material for the resources included that the articles needed to be in English language and easily accessible. A total of 343 records were



screened, 50 full-text articles met the criteria and were reviewed, with a total of 23 articles included. Fourteen total Level 1 Systematic Reviews/Meta-Analysis were included. Articles were critically appraised by the CASP Checklist or the Critical Appraisal Skills Programme. Studies were excluded if the citations were abstracts and if articles were older than five years.

### ***Burden of HPV***

HPV is a huge burden globally and nationally for all sexually active individuals, medical facilities, and insurance companies. HPV infection has been found to cause an increasing rate of cancer of the vulva, vagina, cervix, penis, anus, and oropharynx, along with genital warts and infertility in both sexes (Larsen et al., 2014; Martel et al., 2017; Niccolai & Hansen, 2016; Souho et al., 2015;). Souho et al. discussed how HPV infection has been proven to cause apoptosis of sperm through DNA fragmentation, early miscarriages due to apoptosis and/or the reduced ability of the embryo to invade the uterine wall, and premature rupture of membranes. While some types of cancer that are linked to a specific HPV strain, Souho et al. point out that there are limited studies on the role of HPV being genotype dependent for the infertility. Due to this limitation, more studies need to be conducted on which HPV strains affect fertility. It is important for patients and providers to be educated on the effects of HPV and infertility as infertility can be very common for couples trying to conceive. Infertility takes a toll on couples both physically and emotionally. If patients and/or parents had known about the link to HPV and infertility at the time that the HPV vaccination was offered to them, they may have agreed to vaccinate. More patient education and studies need to be done regarding this topic.

Providers are left to treat preventable health conditions caused by HPV, while patients suffer from the unnecessary health conditions. A common theme noted is that while many infections caused by HPV infection are asymptomatic and transient, this is not always the case

(CDC, 2019; Niccolai & Hansen, 2015). The CDC and Martel et al. (2017) add that there are approximately 570,000 new cases of HPV infection in women every year, half of these cases being diagnosed in women under 50 years of age. Two articles add unique evidence when both Larsen et al. (2014) and Martel et al. discussed that there is a general lack of knowledge in the medical community about the prevalence of HPV strain 16 causing the majority of systemic cancers attributable to HPV. This is concerning as many patients are only solely aware of HPV strain 16 causing cervical cancer (CDC, 2019; Larsen et al., 2014; Martel et al., 2017; Niccolai & Hansen, 2015). Truly, there is a lack of knowledge regarding HPV in the general population, so this poses a major problem to the health of all. When patients are unaware of comorbidities and are asymptomatic, provider visits will be less likely to occur for screening or discussion on the topic. If patients are not aware of the total burden of HPV, then HPV vaccination compliance will be low. More education needs to be done with providers, healthcare facilities, and patients regarding the total burden of HPV.

The CDC (2019) and Martel et al. (2017) discuss a unique contribution to the total articles by describing the only effective secondary prevention of HPV through means of Papanicolaou testing that is routinely started at 21 years of age in the United States in women, as there are no effective screening tests for cancer of the vulva, vagina, penis, anus, and oropharynx. This is an important detail that needs to be discussed more with patients in the clinic setting since HPV affects all people. Larsen et al. (2014) add that it is very hard to test certain types cancers like oropharyngeal for the presence of HPV. Since there is only one mode of secondary prevention, primary prevention is the most important way to prevent HPV infection through the vaccination. Vaccination compliance needs to be increased in order to prevent HPV infection and HPV-attributable cancer cases as both can be prevented through universal high-

coverage HPV vaccination (CDC, 2019; Martel et al., 2017; Niccolai & Hansen, 2015). It is clear with these described articles that enhanced patient education needs to take place in the clinic setting.

### ***Not Just Sexually Transmitted***

Niccolai and Hansen (2015) added that at least half of all HPV infections occur from the first sexual partner. There is a theme regarding the huge lack of knowledge among healthcare professionals and patients regarding exactly how HPV can be spread. Many people ultimately view HPV as being spread through vaginal, oral, or anal intercourse and cannot be spread through other means or condoms. This is false. Actually, HPV infection has been proven to stem from skin-to-skin contact, including hand-to-hand and hand-to-genital contact as demonstrated through HPV infection in virgins, children not sexually active, and individuals using barrier methods like condoms (CDC, 2019; Liu et al., 2015; Ryndock & Meyers, 2014). Adding unique evidence to the synthesis, HPV infection has also been proven to be spread through vertical and horizontal transmission (Liu et al., 2015; Ryndock & Meyers, 2014; Sabeena et al., 2017; Skoczynski et al., 2019; Souho et al., 2015). Vertical transmission is described as transmission of HPV infection from the mother or father at any point from conception to delivery, where horizontal transmission is described as auto- and heteroinoculation transmission, along with fomite transmission from infected objects like towels and healthcare equipment (Liu et al., 2015; Ryndock & Meyers, 2014; Sabeena et al., 2017; Skoczynski et al., 2019; Souho et al., 2015). More studies need to be done regarding the exact modes in which HPV can be spread, as there is varying research on other methods like toilet seats and breast milk possibly spreading HPV (Liu et al., 2015; Ryndock & Meyers, 2014). It is important to educate patients on all modes of transmission for HPV infection as many educational handouts only describe sexual transmission.

Healthcare providers are creating a disservice to patients by not educating patients on how HPV can be spread, and leaving them to believe that intercourse is the only way to become infected with HPV. If patients were thoroughly informed of all modes of transmission, HPV vaccination may become more widely accepted by patients and parents.

### *Vaccine Hesitancy*

Facciola et al. (2019) described vaccine hesitancy as the delay in acceptance or refusal of vaccine administration despite the availability of the vaccination. Many patients have vaccine hesitancy and it can be summed up due to the lack of providers recommending the vaccination, providers being uncomfortable discussing sex or sexually transmitted infections, the lack of parental or adolescent knowledge regarding the vaccine, the fear that the child will become sexually active after receiving the vaccine, the belief that the vaccine is unnecessary due to the child not being sexually active, belief that the vaccine will cause long-lasting health problems, the high cost of the vaccine without insurance, and the belief that the vaccine is unnecessary itself (Facciola et al., 2019; Gilkey et al., 2016; Gilkey et al., 2014; Gilkey & McRee, 2015; Holloway, 2018; Voss & Wofford, 2016). Facciola et al. added that vaccine hesitancy is influenced from perceived knowledge and/or past experiences. The refusal of vaccinations is not always universal in a clinic setting, as many parents will pick and choose which vaccinations the child will receive. An example of this is parents agreeing to the Tdap vaccination, but refusing the influenza vaccination (Facciola et al., 2019). Understanding vaccine hesitancy can help providers break barriers with patients and facilitate HPV vaccination.

Healthcare providers play a huge role in vaccination compliance with patients due to the ability to influence patients and parents about vaccination acceptance. Unfortunately, half of healthcare providers will forget or fail to recommend the HPV vaccination to patients during a

scheduled visit whether due to personal beliefs or forgetfulness (Gilkey & McRee, 2015; Holloway, 2018). If providers have a high confidence in the HPV vaccination, they are more likely to recommend it to patients (Gilkey & McRee, 2015). If healthcare providers are not recommending the vaccination, patients will be left unprotected from HPV infection.

Dempsey et al. (2018) and Holloway (2018) argued that one of the best ways to facilitate change in the number of patients who receive HPV vaccinations is to recommend the vaccine at every encounter that the patient is seen, including sick visits. This practice provides ample opportunities for the patient to get vaccinated, which is especially important since HPV vaccination is not a school entry requirement (Gilkey & McRee, 2015; Holloway, 2018). Dempsey et al. demonstrated that recommending the HPV vaccination at every visit has been shown to decrease missed opportunities in HPV vaccination, as far more patients present for acute illness visits than wellness exams or sports physicals. There are so many missed opportunities for vaccinations. Patients or parents who were against vaccinating for HPV may agree to it at a different visit later on, but that would ultimately get missed if not offered to patients at every visit.

By discussing vaccinations at every visit, this can help increase HPV compliance rates, thus ultimately helping meet Healthy People 2020's goals. Drolet et al. (2015) point out that if HPV compliance rates increase, it can help a significant portion of the population that is not vaccinated, known as herd immunity. Facciola et al. (2019) add that it is generally accepted that a high rate of vaccination coverage of at least 95% is needed to eradicate diseases that vaccines fight against. Drolet et al. note that in countries, including the United States, with female vaccination coverage of at least 50%, HPV type 16 and 18 infections decreased significantly between the pre-vaccination and post-vaccination periods by 68%, along with anogenital warts

decreasing by 61% in girls between the ages of 13 and 19 years. Drolet et al. also point out that those results suggest herd effects in the population due to countries with female HPV vaccination coverage being lower than 50%, there were significant reductions in HPV types 16 and 18 infection. This means that herd immunity is a promising and compelling argument that should be noted since there was a significant part of the population that had a decreased prevalence of HPV, without ever being protected by the HPV vaccination (Drolet et al., 2015). These results point out a compelling argument for herd immunity and HPV vaccination. So, if a significant portion of the population can reduce the prevalence of the vaccine-targeted HPV types in the population, it is imperative that the HPV vaccination compliance and series completion rates increase in all individuals (Drolet et al., 2015; Martel et al., 2017). This is a topic about which providers, patients, and parents should be thoroughly educated.

HPV vaccination rates are low with only 30% of females between the ages of 13 and 17 years and only 10% of males of the same age group have received the complete HPV series vaccination in 2014 (Voss & Wofford, 2016). Personal beliefs and knowledge regarding vaccination, along with Caucasian ethnicity, and level of income and education, affect who is vaccinated against HPV (Facciola et al., 2019; Holloway, 2018; Voss & Wofford, 2016). Interestingly enough, Gilkey et al. (2016) noted there to be no association with ethnicity or education level on vaccination rates. Either way, there are certain factors that need to be taken into consideration when talking to patients and parents about vaccinations as people perceive and learn differently due to many internal and external influences. Even though “newer” vaccines generate a bigger hesitancy in patients, healthcare providers can adequately help patients and parents make the right decision using professional knowledge and evidence-based practice (Facciola et al., 2019).

Holloway (2018) reports the belief that receiving the HPV vaccination may cause the child to become sexually active is not scientifically proven. Parents displaying this way of thinking was first introduced by Wilde in the 1980s as Risk Homeostasis Theory or RHT (Kasting et al., 2016). Kasting et al. described RHT in relation to HPV vaccination as introducing the vaccination itself will lead to risk compensation by the individual receiving the vaccine. In other words, through individuals receiving the HPV vaccination, a false belief of certain protection from other risks is created along with unnecessary risk taking like unprotected intercourse (Kasting et al., 2016). This false idea leads patients to have an ill belief of protection from other sexually transmitted diseases (STDs) through the HPV vaccination. However, this is just not the case and has been proven to be false (Gilkey et al., 2016; Holloway, 2018; Kasting et al., 2016). Contrasting to popular belief by parents, Kasting et al. showed that not only were individuals who received the HPV vaccination less likely to engage in sexual intercourse, they were also less likely to become infected with an STD due to the increased use of condoms after HPV vaccination. These important findings not only debunk the myth of RHT, but they show that vaccinated individuals against HPV are less likely to have intercourse, less likely to have unprotected intercourse, and less likely to have other STDs like Chlamydia. Administering HPV vaccinations to adolescents helps provide awareness about HPV, safe intercourse, and other STDs. When adolescents are vaccinated, important education takes place that can protect them from future preventable harm. Healthcare providers, along with CDC handouts, should keep informing patients and parents that the HPV vaccination does not prevent other STDs or increase intercourse rates. It is imperative to educate patients and parents at every visit.

*Effective HPV Strategies*

Effective methods that have demonstrated increased HPV vaccination compliance include the use of short text message reminders; reminder and recall systems that include e-mails, phone calls, and letters; school-based education; announcement technique rather than discussing the vaccine; face-to-face-interventions; web-based interventions; administration of HPV at sick visits; and multi-method approaches that incorporate many different practices (Brewer et al., 2017; Dempsey et al., 2018; Gilkey et al., 2014; Gilkey & McRee, 2015; Grandahl et al., 2015; Holloway, 2018; Kaufman et al., 2018; Niccolai & Handsen, 2015; Pot et al., 2017; Rand et al., 2014). Kaufman et al. added that the effective use of a single, short face-to-face intervention of less than 10 minutes with parents regarding HPV immunization compliance has also been demonstrated as an effective measure to increase HPV compliance. However, with only moderate certainty, face-to-face interventions have been found to change parents' beliefs and attitudes regarding acceptance towards HPV vaccination (Kaufman et al., 2018). As a result, face-to-face interventions may be more effective in populations with a lack of awareness or understanding of the importance of vaccination against HPV (Kaufman et al., 2018). It is important to not disregard this method in practice, however. Providers are to have face-to-face discussions with parents regarding HPV vaccination when there are questions or concerns. What a provider should not do, is just simply hand an informative sheet to the parent(s) and/or patient and wait for a response. While a handout is a great demonstrative tool, it should never supersede a face-to-face conversation or "intervention."

Holloway (2018) adds that during conversations with parents and patients about HPV vaccination, there are three main components that need to be done correctly in order to demonstrate effective communication. The first component is the strength of the



recommendation that is given for HPV vaccination (Holloway, 2018). The majority of literature, including Holloway, maintained that using the announcement technique, compared to discussing the vaccine, is associated with higher HPV vaccination uptake. In the announcement technique, providers will announce that the child is due for said vaccination, easing any concerns that transpire (Brewer et al., 2017; Holloway, 2018). Pot et al. (2017) also point out a friendly reminder for providers to remember that the mother is usually the primary decision maker in whether or not the child is vaccinated against HPV, since the mother is usually with the patient at the time of the visit. The second component of communication that needs to be relayed to parents of patients and patients is that the vaccine does prevent cancer in all patients who receive the vaccination (Gilkey & McRee, 2015; Holloway, 2018). The third and final component is to strongly recommend that the HPV vaccine is to be administered the same day as the visit, bundled with the other vaccinations that are due (Brewer et al., 2017; Gilkey & McRee, 2015; Holloway, 2018). Gilkey and McRee discussed that if HPV is not bundled with the other vaccinations that are due that same day, it has a higher likelihood to be perceived as an option by patients and parents. Practicing these steps ensures that the vaccination series is started and completed. A simple change of wording during conversations with patients, along with being aware of the primary parental decision maker can make a huge impact on the compliance of parents and patients. Utilizing these components ultimately spreads awareness, increasing the protection rate against HPV infection. This practice of enhanced communication should be implemented at all patient encounters as the validity remains high.

While literature points out that text messaging reminders, along with reminder and recall systems have been evaluated as effective in boosting HPV vaccination rates, there is conflicting evidence on which method or methods to use that increases HPV compliance the most (Niccolai

& Hansen, 2015). Holloway (2018) points out that if text message reminders are used, it is important to keep the message brief and under 160 characters, as this is what most provider carriers will allow. Important items to include in the text message provided include name of the immunization, the child's name, and the information of the provider to contact (Holloway, 2018). Rand et al. (2014) proposed two limitations with using text message reminders, including that not all phones may receive text messages and few facilities use text message reminders. As a result, this may not be the most helpful way to increase HPV rates. Literature demonstrates that a more effective approach is to include multiple methods like standardized orders and to set individual provider goals to increase HPV rates (Gilkey et al., 2014; Holloway, 2018; Niccolai & Hansen, 2015). Combining multiple methods should be incorporated into practice as it has been proven to enhance patient and/or parent knowledge of vaccination, vaccination compliance, and vaccination series completion rates.

From this review of literature for this DNP project, there are numerous articles found online with verified search sites discussing the importance of vaccinating against HPV for all eligible candidates. There have been many studies conducted across the U.S. and world regarding the harmful effects of HPV on women with high validity and reliability. Increasing studies regarding the harmful effects of HPV on men are being done, but little evidence on how to accurately screen for HPV infection in men has been published. This is a problem due to increasing HPV infection rates being spread between males and females. More research needs to be conducted on not only how HPV is actually spread without intercourse, but also how HPV rates can be increased. What is evident from the literature is that vaccination compliance rates need to increase to not only help prevent the spread of HPV infection, but also to help promote herd immunity. Research shows that the best intervention to increase HPV vaccination rates is to

immunize all eligible adolescents through a multi-method approach, with emphasis on proper communication with the patient and/or parent. This synthesis of evidence supports introducing alternative methods to implement in a clinic setting in order to increase HPV rates.

### **Conceptual/Theoretical Framework**

The Health Behavior Framework (HBF) was used to guide the project (Figure 1). The HBF is based on the idea that multi-faceted behaviors can only be influenced through using a multi-dimensional model stemming from varying theoretical orientations (Bastani et al., 2010; Bastani et al., 2011). It represents a mixture of varying parts of theoretic formulations in the area concerning health behavior (Bastani et al., 2010). Parts of the Social Cognitive Theory, Health Belief Model, Theory of Planned Behavior, Transtheoretical Model of Change, and Social Influence theory are included in the Health Behavior Framework (Bastani et al., 2010). For example, it includes perceived individual and societal barriers stemming from the Health Belief Model and elements of the action and maintenance of change from the Transtheoretical Model of Change (Simpson, 2015). The HBF considers the context in which the desired behavior and behavior change are culminated (Bastani et al., 2010). This framework helps identify factors that are fundamental to health behaviors and the relationships between those factors (Maxwell et al., 2010).

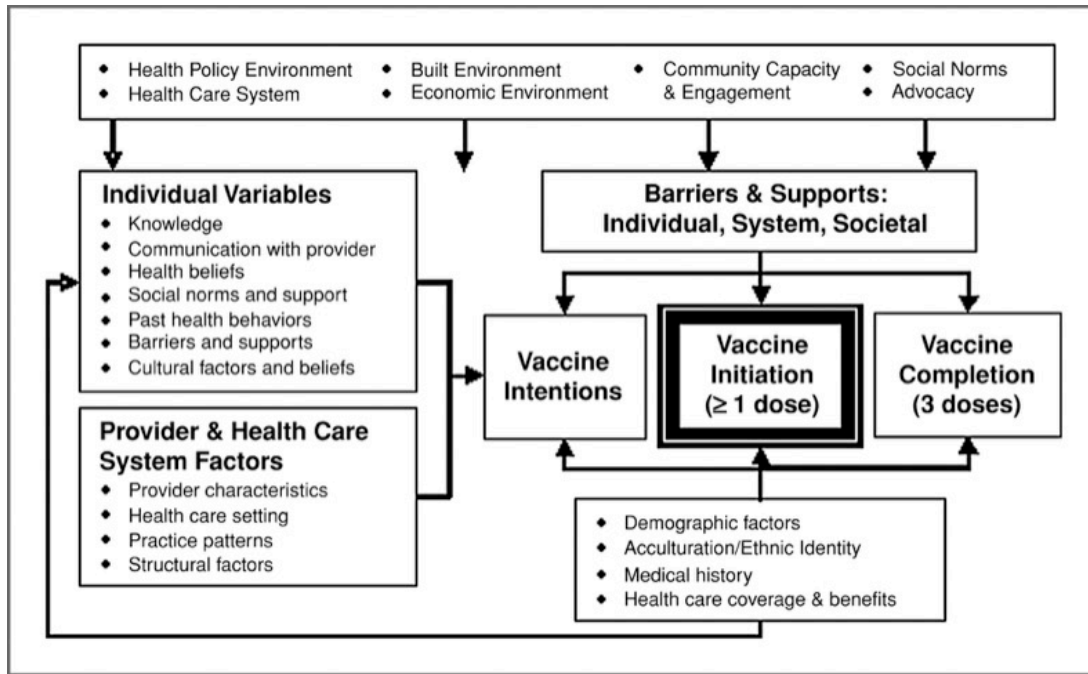
There are three main groups affecting individual choices that the HBF takes into consideration including individual variables, barriers and supports, and provider and healthcare system factors (Bastani et al., 2010). It acknowledges the influence of characteristics of the healthcare setting, provider, larger community, and society (Bastani et al., 2010). It also incorporates important constructs like self-efficacy, social support, and cultural factors that influence health behavior and can be potentially mutable through interventions (Maxwell et al.,

2010). The whole goal of the HBF is to promote and enhance health in a multifaceted manner. This framework works specifically well for vaccinations as it takes into consideration the multifaceted nature of patient and parent decision making on whether or not to vaccinate as a result of personal experiences, healthcare influences, cognitions, and desired outcomes. For example, there are individual variables that the HBF model takes into consideration which include health beliefs, social normal, past health behaviors, and barriers and supports (Bastani et al., 2011).

This model supports the PICOT question. In the PICOT question, the DNP student is specifically looking into the barrier of individual patient knowledge, patient health beliefs, and practice patterns within the healthcare system. There is a lack of patient knowledge on HPV and HPV infection that leads to patients forming health beliefs that are incorrect surrounding the topic of HPV. In current practice, providers will either verbally educate patients on HPV, give a CDC handout to them, or a combination of the two during wellness visits. However, these practices are failing to increase low HPV vaccination rates. By changing the healthcare policy environment and the healthcare system through different approaches to HPV education as demonstrated the PICOT question and supported in the HBF, patients will naturally start to have different vaccine intentions and be more likely to initiate the first dose of the series, along with complete the series. The HBF will be adequately and efficiently used to facilitate change within the healthcare system through understanding patients' personal factors that help them make decisions, and ultimately encourage health promoting behavior.

**Figure 1**

*Health Behavior Framework*



*Note.* Health Behavior Framework. From “Understanding suboptimal human papillomavirus uptake among ethnic minority girls,” by Bastani, R., Glenn, B.A., Tsui, J., Chang, L.C., Marchand, E.J., Taylor, V.M., Singhal, R., & Singal, T., 2011, *Cancer, Epidemiology, Biomarkers, & Prevention*, 20(7), p. 1466.

## **Chapter II: Methodology**

### **Project Design**

This DNP project implemented a quality improvement project to increase timely HPV vaccination administration in adolescent females. Quality improvement is a systemic and formal approach to both the analysis and efforts of practice and improve performance (American Association of Family Physicians [AAFP], 2018). Quality improvement is necessary for any practice that is interested in not only improving efficiency, but also for improving patient safety and enhancing clinical outcomes (AAFP, 2018). For quality improvement to take place, an organization must determine and prioritize areas of potential weakness (AAFP, 2018). An area of weakness for all clinics across the United States is low vaccination rates, specifically for HPV (CDC, 2019). The quality improvement project offered patients, who initially refused HPV vaccination at the time of the visit with the healthcare provider, an educational intervention that provided instruction to the patients regarding the prevalence and detriment of human papillomavirus.

### **Setting**

The DNP project was implemented at a primary care clinic in the Midwest. The services offered at this clinic include family medicine, internal medicine, women's health, radiology, vision services, occupational medicine, behavioral health, ambulatory surgery services, and specialty services including rheumatology, audiology, cardiology, urology, and ear, nose, and throat that are available by traveling providers at least once a month. The facility has three floors, with approximately 32 rooms for patients to be evaluated daily. The Nurse Practitioner (NP) who implemented the DNP project utilizes three of these examination rooms. The facility was chosen

as it is a main clinic in the area where there is a high volume of adolescent patients that are evaluated.

### **Population/Sample**

The participants of this DNP project included all the patients who met the inclusion criteria. Since the project did take place during the summer when there are fewer patients naturally being evaluated in a clinic setting, there was no way to anticipate the potential number of participants. As a result, the approximate size of the patient population included all patients who met the inclusion criteria, which are listed below. In order to increase the patient population and reach as many eligible patients as possible, this plan was implemented on well visits and on sick visits.

### ***Inclusion Criteria***

Inclusion criteria included English-speaking female patients who were 9 to 26 years of age, had either not started the HPV vaccination series or had not finished the HPV vaccination series, and presented for any well or sick visit. For the patients who were under the age of 18 and were not able to consent, a parent provided verbal consent for the patient and parent to be educated about HPV and the detriments of HPV infection in order to be included in this DNP project. Participants were included in the educational program after it had been determined that the patient and/or parent did not want the HPV vaccination to be administered after the provider had notified the patient that she was due for the HPV vaccination.

### ***Exclusion Criteria***

Exclusion criteria for the project included male patients, female patients who fell out of the age inclusion criteria, patients/parents who did not wish to participate in the project, and patients who had completed the HPV vaccination series or were on time to receive boosters.

**Tools and/or Instruments**

The evaluation log form for the HPV project (data collection tool) was created by the DNP student. Please see form in Appendix A. This data collection tool was used to record data from the patient visit. The room number, date, and subject ID number were recorded as well as the discussions with the patient and/or parent to decline HPV vaccination, accept HPV vaccination same day, or receive HPV vaccination at a future visit. In addition, a short anecdotal note as to why the patient and/or parent decided to vaccinate or not to vaccinate against HPV was included.

**Project Plan**

Face-to-face interventions and the implementation of HPV vaccination education and administration at sick visits have been proven to be effective in improving HPV vaccination rates (Dempsey et al., 2018; Kaufman, 2018). Part of face-to-face interventions include illustrative handouts which provide enhanced education due to the visualization of the material being discussed with the participants. Outcomes were measured to establish the success of implementing the change through the collaboration of the DNP student, DNP mentor, and DNP project team chairperson.

Permanent staff members included in this HPV project included the NP who implemented the project, the NP's nurse who administered the HPV vaccination, and the nursing supervisor who is in charge of vaccination reminders. Current practice for the primary care clinic includes review of patient charts and North Dakota's Immunization Information System (NDIIS) by the nursing supervisor to create a list of patients who are due for immunizations and/or immunization boosters (NDIIS, 2020). The nursing supervisor then mails all patients on the list



reminder postcards that an immunization appointment needs to be scheduled to update missing vaccinations and boosters. This practice is completed monthly.

Once participants arrived for their appointments and were seen by the NP, each was assigned a subject ID number in chronological sequence. The first participant was labeled 01, the second participant 02. This information was recorded on the data collection tool, not on the EMR by the NP seeing the patient. (See document in Appendix A.) In addition to the participant's number, additional information included whether the participant declined HPV vaccination, agreed to HPV vaccination administration on the same day, or scheduled an immunization administration visit for a future date with the nurse. The NP ensured that decisions regarding refusal or acceptance of HPV vaccination were documented appropriately on the data collection tool. In addition, the date the patient was seen and a short anecdotal note where the reason for receiving or refusing the HPV vaccination was recorded. The NP collaborated with the DNP student on making the data collection sheet and as a result, did not need to be trained on how to collect the data. No demographic identifying was recorded on the data collection tool. There was one data collection tool for each of the three examination rooms the NP utilized. Each data collection tool had a space for the room number to be included. Data collection forms were kept in a file folder in each room where the only people with access included the DNP student, NP, nursing supervisor, Nurse, and Administrator of the clinic. Once every two weeks, the DNP Student came to the clinic to review the data collection tools and met with the NP and discussed progression of the project.

### ***Step One***

The first part of the project plan included creating a one-sided, one-page handout that provides the patient and/or parent of fast-facts on what HPV is, how it is spread, the adverse

effects of HPV infection, and reasons to vaccinate against HPV. The handout is found in Appendix B. The handout has black text with impactful words colored red or underlined/bolded, providing statistical facts regarding HPV and the detriment of HPV infection. This handout was created in collaboration with the DNP student and NP (who is also the DNP scholarly mentor). The educational handout was used as an enhanced learning tool with face-to-face intervention.

### ***Step Two***

In step two the DNP student curated, printed, and laminated a small label sheet that read “Ask about HPV Vaccination”. (See Appendix C.) This laminated label was applied to the upper right-hand corner of the computer in each of the three examination rooms and served as a reminder for the NP to discuss HPV with each eligible patient who met the inclusion criteria.

### ***Step Three***

The HPV educational project was implemented by the NP during well or sick appointments. If the patient met the inclusion criteria, the NP then reviewed the HPV Educational Handout with the patient and/or parent, with a total presentation time of one minute. This time frame did not include time for questions that may have occurred during or following the presentation as not all patients had questions. The NP took any amount of time deemed necessary to competently answer each question until both parties were comfortable with the knowledge received.

### ***Step Four***

After the HPV education presentation had been given and all patient questions had been answered, the participants were thanked for their time and notified that if they preferred to not vaccinate, they may check out at the front desk and schedule their next visit as needed. Or, if participants chose to vaccinate, they may stay in the examination room and the nurse will

administer the vaccination the same day. If same day vaccination did not work for the patient or parent(s), the nurse offered to set the patient up for a separate HPV vaccination appointment with the nurse on a different day. The data collection tool was completed including the anecdotal portion regarding patients' primary decision to proceed with vaccination or refusal of vaccination.

### ***Step Five***

The NP then charted in the appropriate patient's chart regarding the discussion of HPV and HPV vaccination in the Plan section of the note as well as the decisions regarding HPV vaccination, whether the vaccination was received on the same day or planned to in a future visit.

### ***Primary Outcome***

The primary outcome for the project was for patients to receive the first vaccination of the HPV vaccination series if they had not started it, or receive the HPV vaccination booster for patients who had started and not completed the series.

### ***Evaluation and Sustainability Plan***

The resulted data will be collected, analyzed, and presented to the clinic administrator and NP where the project was implemented. In this meeting, the clinic's administrator will be consulted on sustainability measures that will be put into place to prevent regression of the project. Such measures may include keeping a HPV handout hung up in each room and having providers address the handout with patients at all visits. The ideal goal would be to eventually adopt this into practice at the clinic as an intervention to improve HPV vaccination rates.

### ***Timeline***

The implementation of the project occurred over the course of three months, with the goal to include as many patients/participants as possible. (The timeline document is found in

Appendix D.) Submission and IRB approval occurred on April 3, 2020. The project was implemented from August 10, 2020 through to October 30, 2020. Data analysis occurred from October 31, 2020 through November 8, 2020. The formulation of the final paper occurred after completion of the data analysis completed in November 2020, with final edits to the paper occurring after.

### **Data Analysis**

The data was analyzed by the DNP student. The results collected from the data collection tool (Appendix A) were entered into the statistical tool's databases including Microsoft Word, Microsoft Excel, and JASP. The database was stored on a personal computer that is protected with a passcode known only by the DNP student and fingerprint code that is specialized to only the DNP student. The DNP student used descriptive analysis for the quantitative variables. Information was used to measure frequency and central tendency. A frequency distribution table was used to show how many times a patient included in the project either refused HPV vaccination administration, accepted HPV vaccination administration the same day, or accepted HPV vaccination administration at a future visit. A pie graph displayed the percentage of patients who were receptive to the educational project, through either opting to receive the vaccine the same day or a different day, when compared to the patients who refused the vaccine. The anecdotal reasons for why the patient refused or accepted to be vaccinated against HPV was grouped and displayed in a bar graph. A *t* statistic test was used to determine if there was a statistical significance between the mean values of the two groups that either vaccinated or chose to not vaccinate against HPV infection (Moran, 2020). A *p* value was used to show how likely it was to get the same results if the null hypothesis was true, showing the significance of the project (Moran, 2020).

**Institutional Review Board/Ethical Issues**

Some female participants included in the DNP scholarly project were part of a vulnerable population due to being under the age of 18. The NP who will be evaluating and treating patients already has consent to do so and will need verbal consent from the patient(s) and/or parent(s) in order to participate in the HPV educational project. Written consent is not needed. Project approval was sought from the clinic's Institutional Review Board (IRB) April 3, 2020. Full IRB permission was given to the student after the Medical Executive Committee met on July 8, 2020. The next step was approval from Bradley University Committee on the Use of Human Subjects that was granted on August 6, 2020, with implementation of the project beginning August 10, 2020.

### **Chapter III: Organizational Assessment and Cost-Effective Analysis**

#### **Organizational Assessment**

Interprofessional collaboration with the primary care clinic has been a very seamless process. The staff members are very supportive in their collaboration with the DNP student to enhance patient care and are ready to establish change. Written approval from the local primary care clinic, the Administrator (See Appendix E), and the parent organization to implement the project at the local clinic has been granted to the DNP student (See Appendix F).

Anticipated barriers to implementation of the DNP scholarly project includes the NP forgetting to ask patients about HPV and their immunization status if it is not recorded in the NDIIS. If this happens, then the NP would fail to remember to educate patients about HPV with the HPV Educational Handout if they are eligible for HPV vaccination. Another anticipated barrier may be the NP forgetting to document on the data collection tool due to time constraints in the clinic. Another barrier includes the DNP student not meeting with the NP to review the data collection tool.

Anticipated facilitators to implementation of the DNP scholarly project include the DNP Student's Mentor being a Women's Health Nurse Practitioner, who is very passionate about enhancing the number of eligible patients who receive the HPV vaccination. All nurses and providers at the clinic agree that HPV vaccination should be administered according to the CDC's recommendations and should be done in an announcement technique as stated in the Synthesis of Evidence.

Unexpected benefits to the DNP scholarly project include facilitating the use of the DNP student's HPV Educational Handout in the future. The HPV Educational Handout could be posted in all clinic rooms for patients to educate themselves while waiting for the provider or by

giving the handout to patients during discussions of HPV. Another way the project may be sustained by the clinic is by asking patients about their HPV vaccination status at all visits instead of wellness visits. Unexpected problems with the DNP scholarly project may include lack of communication as stated earlier.

## **Cost Factors**

### *Expenses*

Cost Assessment can be found in Appendix G. Costs are minimized with the project intervention through the interprofessional collaboration between providers, nurses, and nursing assistants. The DNP student has a laminator that will be used for the project; however, the DNP student will print out the handouts at the facility. Costs include the paper and printer ink that will be used for the educational handout, along with the laminator for the reminder sheet. For a 500 pack of paper at the cost of \$25, each blank sheet would cost approximately \$0.005 or rounded up to \$0.01. The approximate cost of laminating three reminder strips of paper using the students own will be approximately \$0.10 total, plus using it at \$1.00 as it has already been purchased. For each printer cartridge costing approximately \$100 and being able to print at least 200 sheets, the approximate cost per sheet is \$2.00. If there are 30 handouts printed for thirty patients with six data collection tool sheets printed, the approximate cost would be \$72.36. The cost of the three folders provided in each room will be approximately \$3.00. Regarding transportation costs, the DNP student lives next to the clinic. As a result, transportation expenses will be minimal to none as the project will be implemented in the summer months and the student will walk to the clinic the majority of the time. Personal expenses were calculated with a clinic nurse wage of \$22.50. The DNP student presenting to the clinic weekly for eight weeks to monitor the program, combined with spending four hours to work on the handout, total costs for personal is roughly

\$247.50 as the handout was done in conjunction with the Nurse Practitioner. The total cost of the project is estimated to be approximately \$333.96.

### *Savings*

There are savings with this DNP scholarly project that prove to be beneficial in the implementation of the project. In order to appreciate the savings, the approximate number of patients who have HPV infection related testing every year needs to be addressed.

Approximately 29.4 million pap tests are done at office visits each year, with more than 3 million of the pap tests acquired producing unclear or abnormal results (AAFP, 2019). It is estimated that every year there are over 1.2 million colposcopies performed in the United States at the national average estimated cost of \$363.00 per colposcopy (Huh et al., 2019; MD save, 2020).

There are also approximately over a half a million Loop Electrosurgical Excision Procedures (LEEP) done of the uterine cervix in the United States every year with the average estimated cost ranging from \$1,804 to \$9,178 per LEEP performed (MD save, 2020; Sklavos et al., 2014). The cost of having an HPV infection affects more than just patients as clinics may and will have to cover the leftover costs from patients' visits if they are not covered or not paid by patients. In 2015, cervical cancer caused \$3.3 billion in direct and indirect costs in the United States (Nwankwo et al., 2019). The total direct medical costs of cervical cancer in 2015 was \$1,087,008,804 in the United States (Nwankwo et al., 2019).

HPV infection is truly an economic burden for society. In 2020, it is estimated there will be approximately 13,800 new cases of invasive cervical cancer diagnosed, with approximately 4,290 women dying from invasive cervical cancer (American Cancer Society [ACS], 2020). In North Dakota in 2016, there were 26 new cases of cervical cancer alone (CDC, 2019). It is very important to remember with these statistics that cervical precancer develops far more frequently



in patients than invasive cervical cancer (ACS, 2020). The way to reduce these costs from unnecessary HPV infection is to vaccinate each and every eligible patient. Vaccinating women between the ages of 9 and 26 years is projected to reduce the diagnosis of grade two or three cervical intraepithelial neoplasms (CIN) by 80% or roughly 13 million over the next 100 years when compared to no vaccination in that same age group (AAFP, 2020). Again, vaccinating women between the ages of 9 and 26 years is projected to reduce the number of cases of cervical cancer by 59% (653,000) over the next 100 years when compared to no vaccination in that same age group. (AAFP, 2020). Over a projected 100-year time frame, vaccinating against HPV has a moderate impact on the estimated cost per quality adjusted life year (QALY) (Chesson et al., 2019). This QALY is gained by HPV vaccination, which also averts medical costs (Chesson et al., 2019). It is estimated that catching-up vaccination of teenagers and young adults will reduce the estimated cost per QALY by about \$12,400 per person (Chesson et al., 2019).

The economic burden of HPV infection is steep and almost unmeasurable. Billions of dollars every year are used to manage HPV infection and the repercussions of it in the United States. It is truly hard to estimate how much money will be saved by the implementation of the project due to the varying costs of medical procedures and factoring insurance. However, implementing the project will help save lives and save money over time. There is so much to be gained by vaccinating every eligible patient against HPV infection, both personally, but also economically.

## Chapter IV: Results

### Analysis of Implementation Project

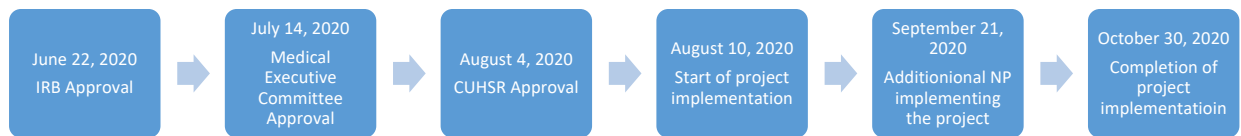
Data was collected from the participants of the DNP project from the beginning of implementation which occurred on August 10, 2020, until the end collection date of October 30, 2020. All participants in the DNP project were eligible for participation in the project. Participants who qualified for DNP project were adolescent English-speaking females between the ages of 9 and 26 years who have either not started the HPV vaccination series or have not finished the HPV vaccination series, and presented for any well or sick visit. Data from these participants were collected over a course of twelve weeks on the evaluation log form as the data collection tool. Data collected includes patients' decisions regarding HPV vaccination, whether the vaccination was received on the same day or planned to in a future visit, and the patients' anecdotal reasoning for the decision. Results were collected from each participant and were analyzed to assess the efficacy of the program. The total sample size in the project was 11 participants ( $n = 11$ ).

In order to include more patients into the project, another nurse practitioner was asked to implement the project along with the DNP mentor. This change occurred well into the data collection phase during the seventh week of implementation and allowed three additional patient rooms during the data collection phase, as opposed to the initial plan. In total, there were six patient rooms being utilized at any given time and two nurse practitioners implementing the project. As the data collection phase progressed, the patient population base grew. This indicated that the extension to utilize another nurse practitioner in the project was a success. As shown in Figure 2, this was the only modification made to the intervention during the project.

The timeline of this project was altered and pushed back multiple times due to circumstances beyond control, including obtaining IRB approval from the site where the project was implemented. This will be discussed in detail in Deviations from Project Plan.

## Figure 2

### *Time-line Diagram for Project Implementation*



*Note.* This figure demonstrates the time-line diagram for project implementation.

## Analysis of Project Outcome Data

### *Statistical analysis*

In addition to patient's decisions regarding HPV vaccination, covariates controlled for or otherwise included in the HPV project were: reason for HPV vaccination acceptance or refusal. Analysis was performed using a combination Microsoft Word for Mac version 16.39, Microsoft Excel for Mac version 16.39, and JASP version 0.14. The mean and standard deviation was recorded for all continuous variables using JASP. For any categorical variables, the frequency and percentages were recorded using Microsoft Excel and Word. There was a total of 11 participants in the project ( $n = 11$ ). Of the 11 participants included in the project, six patients declined HPV vaccination after receiving educational instruction via the curated handout from the NP, representing 55% of the patient population. Five patients, representing 45% of the patient population, accepted HPV vaccination the same day as the appointment. Zero patients accepted to receive HPV vaccination at a future visit. The mean was shown to be six, while the standard deviation was 3.317. Measures of frequency and central tendency for the data are

represented in Tables 1, 2, 3, and 4. Multiple frequency tables showed how many times a patient included in the project either refused HPV vaccination administration, accepted HPV vaccination administration the same day, or accepted HPV vaccination administration at a future visit.

**Table 1**  
*Descriptive Statistics Demonstrating Central Tendency*

	<b>Subject</b>	<b>Declined HPV Vaccination</b>	<b>Accepted HPV Vaccination Same Day</b>	<b>Received HPV Vaccination at a Future Visit</b>
Valid	11	6	5	0
Missing	0	5	6	11
Mean	6.000			NaN
Std. Deviation	3.317			NaN
Minimum	1.000			$\infty^a$
Maximum	11.000			$-\infty^a$

*Note.* This table describes the central tendency of the data set.

<sup>a</sup> Infimum (minimum) of an empty set is  $\infty$ , supremum (maximum) of an empty set is  $-\infty$ .

**Table 2**  
*Frequencies for Declined HPV Vaccination*

<b>Declined HPV Vaccination</b>	<b>Frequency</b>	<b>Percent</b>	<b>Valid Percent</b>	<b>Cumulative Percent</b>
Yes	6	54.545	100.000	100.000
No	5	45.455		
Total	11	100.000		

*Note.* This table describes the frequency of declined HPV vaccinations versus acceptance.

**Table 3***Frequencies for Accepted HPV Vaccination Same Day*

<b>Accepted HPV Vaccination Same Day</b>	<b>Frequency</b>	<b>Percent</b>	<b>Valid Percent</b>	<b>Cumulative Percent</b>
Yes	5	45.455	100.000	100.000
No	6	54.545		
Total	11	100.000		

*Note.* This table describes the frequency of accepted HPV vaccinations the same day versus declined.

**Table 4***Frequencies for Accepted HPV Vaccination on a Different Day*

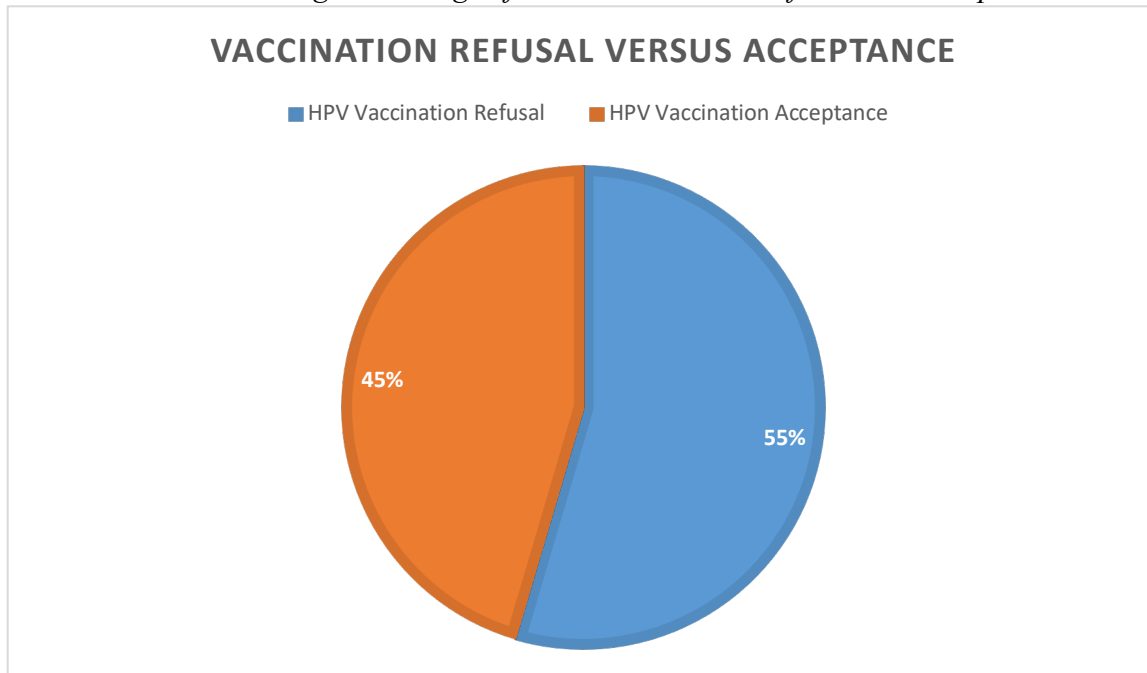
<b>Accepted HPV Vaccination on a Different Day</b>	<b>Frequency</b>	<b>Percent</b>	<b>Valid Percent</b>	<b>Cumulative Percent</b>
Yes	0	0.00	100.000	100.000
No	11	100.000		
Total	11	100.000		

*Note.* This table describes the frequency of accepting HPV vaccination on a different day versus accepting on the same day or declining altogether.

Figure 3 shows a pie chart that was developed to demonstrate the percentage of patients who were receptive to the educational project by including the acceptance versus refusal rates of HPV vaccination after education. Overall, 100% of the patients included in the project were responsive to the HPV education as provided by the NP. In total, 45% of patients were receptive to the project itself, accepting and consenting to HPV vaccination. Fifty-five percent of patients declined the HPV vaccination altogether and were not receptive to starting the vaccination series.

**Figure 3**

*Pie Chart Demonstrating Percentage of HPV Vaccination Refusal and Acceptance*

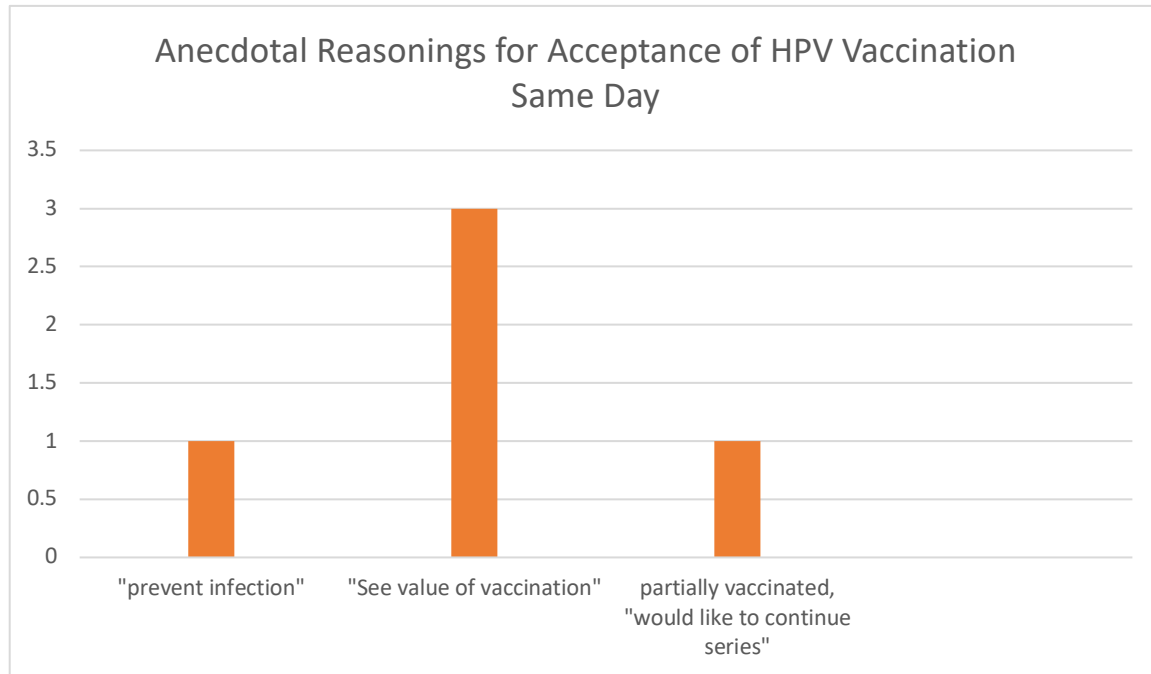


*Note.* This figure describes the number of patients who accepted HPV vaccination at 45%, versus the number of patients who declined HPV vaccination at 55%.

Anecdotal reasonings for accepting HPV vaccination were grouped together based upon patient responses into three different categories: “prevent infection”, “see value of vaccination”, or patient was partially vaccinated and “would like to continue the series”. Please see Figure 4. The grouping with the highest positive response to accepting HPV vaccination was due to the patient being able to “see the value of vaccination” at three patients total. The other two groups represented one patient each, respectively.

**Figure 4**

*Bar Graph Demonstrating Anecdotal Reasonings for Acceptance of HPV Vaccination*

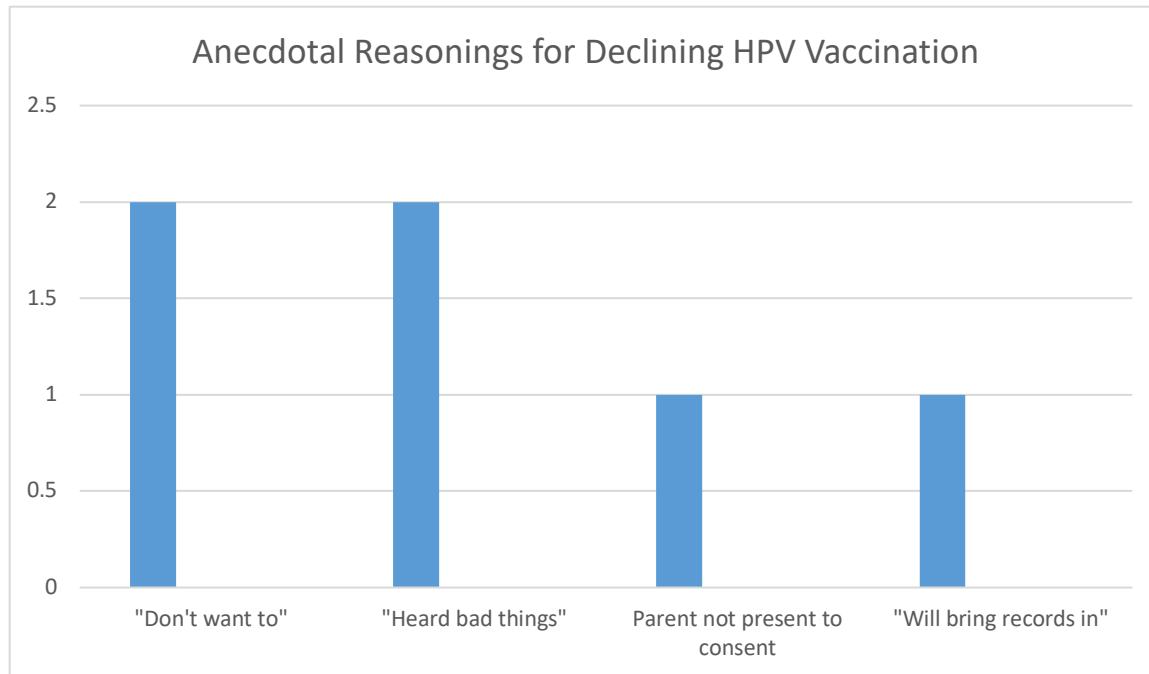


*Note.* This figure demonstrates the anecdotal reasonings for acceptance of HPV vaccination on the same day as the appointment. “See value of vaccination” was the highest recorded anecdotal note from patients at a total of three patients for the reasoning on why they accepted HPV vaccination the same day.

Anecdotal reasonings for declining HPV vaccination were grouped together based upon responses into four different categories: “don’t want to”, “heard bad things”, parent was not present to consent to vaccination, or “will bring records in”. Please see Figure 5. The grouping with the highest response to declining vaccination against HPV was tied with two patients each in the groups of “don’t want to” and “heard bad things”. The other two groups represented one patient each, respectively.

**Figure 5**

*Bar Graph Demonstrating Anecdotal Reasonings for Declining HPV Vaccination*



*Note.* This figure demonstrates the anecdotal reasonings for declining of HPV vaccination on the same day as the appointment. “Don’t want to” and “heard bad things” were the highest recorded anecdotal notes from patients at a total of two patients each for the reasonings on why they declined HPV vaccination.

A one sample *t*-test was done showing the difference between vaccine acceptance prior to education, versus vaccination acceptance after HPV education. The *t*-value of 2.887 was reached and can be seen in Table 5. When compared to the 10<sup>th</sup> degree of freedom at 2.23, this showed that the calculated *t*-value is higher. This means that the null hypothesis that HPV vaccination acceptance by patients and parents is not determined by education, both verbal and visual, provided by the Nurse Practitioner is rejected, showing statistical significance of the project. In fact, the program demonstrated statistical significance for HPV vaccination acceptance by patients and parents through verbal and visual education by the NP. The calculated *p*-value of 0.016 is less than 0.05, which shows a statistically significant difference in HPV vaccination



acceptance after education as seen in Table 5. Again, the *p*-value shows that the implemented program proves statistical significance for HPV vaccination acceptance by patients and parents through verbal and visual education by the NP.

**Table 5**

*T-Test*

	<b>t</b>	<b>df</b>	<b>p</b>
Difference	2.887	10	0.016

*Note.* This table shows a one sample *t*-test or Student *t*-test demonstrating the difference between vaccine acceptance prior to education, versus vaccination acceptance after HPV education. The *t*-value is 2.887. The *p*-value of the data is 0.016

A paired samples *t*-statistic test was used to determine if there is a statistical significance between the mean values of the two groups that either vaccinated or choose to not vaccinate against HPV infection (Moran, 2020). This is shown in Tables 6 and 7. The null hypothesis assumes that the mean difference between the paired samples is zero (Statistic Solutions, 2020). This would explain that all observable differences are explained at random variation (Statistic Solutions, 2020). The alternate hypothesis assumes that the mean difference between paired samples is not equal to zero (Statistic Solutions, 2020). The mean difference is 0.091. This means that the null hypotheses would be rejected and the alternate hypotheses accepted. This shows that all observable differences are not explained at random variation (Statistic Solutions, 2020). However, statistical significance is determined by examining the *p*-value as it gives the probability of obtaining a result like the one that was observed if the null hypothesis was true (Statistic Solutions, 2020). In this case, the *p*-value is at 0.770. This is greater than 0.05, so the null hypothesis is failed to be rejected. In this case, the project itself did not develop significant results in the number of patients who accepted to vaccinate the same day, versus those who

declined HPV vaccination. Failing to reject the null hypothesis does not mean that the data is not statistically significant to the patient population. It means that there was not sufficient data to conclude that the effect exists. The lack of evidence does not mean that an effect does not exist; it just was not captured with the available data. This can be due to multiple reasons such as limitations of the data itself. As a result, additional data collection and research is required to prove statistical findings of the program when comparing accepting versus declining rates of HPV vaccination. Further research and development of this project could lead to securing promising results for the community and state.

**Table 6**

*Paired Samples T-Test*

Measure 1	Measure 2	t	df	p	Mean Difference	SE Difference	Cohen's d
Declined HPV Vaccination	Accepted HPV - Vaccination Same Day	0.289	10	0.779	0.091	0.315	0.087

*Note.* This table shows a pared samples t-test to show statistical significance between the mean values of the two groups that either vaccinated or choose to not vaccinate against HPV infection. The *t*-value is 0.289. The *p*-value is 0.779.

**Table 7***t-Test: Paired Two Sample for Means*

	<i>Variable 1</i>	<i>Variable 2</i>
Mean	0.54545455	0.45454545
Variance	0.27272727	0.27272727
Observations	11	11
Pearson Correlation	-1	
Hypothesized Mean Difference	0	
df	10	
t Stat	0.28867513	
P(T<=t) one-tail	0.3893627	
t Critical one-tail	1.81246112	
P(T<=t) two-tail	0.7787254	
t Critical two-tail	2.22813885	

*Note.* This table shows a different view of a paired samples t-test to show statistical significance between the mean values of the two groups that either vaccinated or choose to not vaccinate against HPV infection. It includes measures of central tendency. The *t*-value is 0.289. The *p*-value is 0.779.

## Chapter V: Discussion

### Findings

#### *Primary Objective*

The primary objective for the project was for patients to receive the first vaccination of the HPV vaccination series if they had not started it, or to receive the HPV vaccination booster for patients who have started and had not completed the series. Data collection indicates that this objective was partially met. Of the 11 patients that were included into the project, five (45%) of them did receive the first vaccination of the HPV vaccination series if they had not started it, or they received the HPV vaccination booster if they had not completed the series. This is an important clinical outcome of 45% of the participants included in the project. The rate of vaccination was considered a success; any patient that chose to start HPV vaccination or finish the series is another patient that is advocating for themselves in terms of their future health. One more person vaccinated means one less person infected with HPV who may go on to develop HPV related cancers, warts, or infertility.

The rate of vaccination also means that implementing face-to-face HPV education with an educational handout at every visit, including sick visits, does increase HPV vaccination rates. Face-to-face interventions have demonstrated a valuable way for improving HPV vaccination rates (Kaufman et al., 2018). This project has demonstrated that having a tangible document for patients to examine did help to solidify the information given to them by the reviewing providers. It provided long-lasting knowledge in two different forms, both through hearing and seeing.

The most important difficulty in implementation of the project was meeting the primary objective due to patients opting not to receive HPV vaccinations, along with limitations of the

project. Of the 11 patient participants, six of them opted to not receive either the initial or booster HPV vaccination after the implementation of HPV education by the NPs. Patient fears related to HPV vaccination included “hearing bad things” about it from friends and family members from two out of the six patients. This served as a difficulty to increase HPV vaccination rates in adolescent females between the ages of 9 to 26 years.

The most important lessons learned from this project are to speak up and advocate for yourself, be patient during the process, reach out for guidance and help, and that timelines and deadlines are often not met due to unforeseen circumstances. This project has taught me the valuable lessons of patience and perseverance. With time, goals are met. Hardships may be endured during the process; however, with collaboration, a project plan, patience, and perseverance, the end goal is attainable.

### **Limitations**

There were multiple limitations for this project. The biggest limitation to this project was the lack of participants or small sample size. The lack of participants for this project was directly related to two main factors. The first factor limiting sample size was the COVID-19 Pandemic. Project implementation occurred during North Dakota’s peak outbreak. As a result, patient census at the primary care clinic where the project was implemented was abnormally low. The patient census for the NPs implementing the project was at 25-50% of the normal capacity, dependent upon the day. The low patient census may be due in part to the fear of contracting the illness at the clinic. During this time, the majority of the patients evaluated at the clinic are patients who prioritize their health, especially given the pandemic, and are usually up-to-date on their immunizations. The primary care clinic also changed their policy during implementation of the project to re-route any patient with COVID-19 like symptoms to not be allowed on campus

until they had a negative COVID-19 test done at a designated testing facility, which resulted in patients being excluded from the project that may or may not have had COVID-19. This happened during September 2020. As a direct result, the primary care clinic has seen a decrease in patient volume. During October, the clinic did start COVID-19 testing in the mornings, however patients still needed a negative COVID-19 test to be evaluated in the clinic for all other appointments. If they were symptomatic for COVID-19, they were to be evaluated in a satellite trailer in the clinic's parking lot. During the final week of project implementation, a COVID clinic was opened up in the clinic and one of the NP's, the DNP mentor, worked three days solely in the COVID clinic. This limited her implementing the project to only two days that week. COVID-19 was a huge limitation in the implementation of this project as it did severely affect patient numbers.

The second main factor that limited the lack of participants or sample size included the hard-economic times resulting in deprivation and poverty of many. The primary care facility is located in a community where many parents/patients find work in the oilfield. On April 20, 2020, oil prices hit a historic all-time low of \$-37.63. While oil prices have slowly gone back up again, hundreds of workers in the community were laid off during the Spring and Summer of 2020. As a direct result of oilfield workers being laid off, many affected families moved away from the community. The community has always been transient in nature. However, with families moving away, clinics all around the community have for the first time in at least a decade been "slow" as witnessed by the DNP student during clinical rotations and supported by the implementing providers (H. Grondahl, personal communication, November 23, 2020). The new-normal is for providers to have open spots in their schedule, something that has not been in years (H. Grondahl, personal communication, November 23, 2020). Some providers are even idle at times

and have had days where they do not see a single patient, or have only evaluated a few. Again, this has all been witnessed by the DNP student during clinical rotations. The provider implementing the project has seen a decrease in patient volume directly to her schedule. Again, in direct relation to the economic hardship of 2020, many patients have been without insurance (or jobs) and have had to cancel appointments or skip out on well-visit checks for their children.

In direct relation to COVID-19, one of the NPs implementing the project (DNP Project Mentor) was on quarantine for two weeks due to a close contact. This meant that while the second NP was implementing the project, there was still one less provider implementing the project for two weeks. As a result, fewer patients were seen who may have participated in the project. Other limitations included other sick days and vacation days for both NPs, not directly relating to COVID-19.

In addition, a new pediatric walk-in clinic has opened in the community during the Summer of 2020. Staff in the walk-in clinic saw patients needing college sports physicals, high school physicals, as well as patients seen for sick visits. This additional clinic lowers the patient volume at the clinic where the project was implemented. Dempsey et al. (2018) demonstrated that recommending the HPV vaccination at every visit has been shown to decrease missed opportunities in HPV vaccination, as far more patients present for acute illness visits than wellness exams or sports physicals. It is not known when HPV vaccination was suggested to patients during their visits to this new clinic.

Patients' preconceived negative notions surrounding HPV and "hearing bad things" about it from family and friends served as limitations for receiving the HPV vaccination. Examples of "hearing bad things" were vague and included seeing negative posts on social media or hearing through the grapevine from friends of friends about the vaccination being "bad" (H. Grondahl,

personal communication, November 23, 2020). There were no concrete facts that were presented for the providers (H. Grondahl, personal communication, November 23, 2020). As a result, the providers' responses were to revert to the handout to go over the concrete facts of HPV, along with reassuring patients that no serious adverse effects to the vaccination have been witnessed during time spent as practicing providers (H. Grondahl, personal communication, November 23, 2020). One patient also did not have a parent or guardian present at the time of the appointment to consent for them to become vaccinated, which served as a limitation as she wanted to start the HPV vaccination series.

Another limitation of the project was the fact that implementation was started in late summer, when patient volume is naturally lower. The late start date was due to the delay in IRB review and full permission granted to implement the project. In total, implementation of the project was pushed back due to IRB approval delays by over three months. This delay limited the time-frame in which the project could be implemented, thus naturally lowering the potential sample size as the project end date could not be lengthened due to the student graduating. The delay also meant that implementation of the project started just as COVID-19 spiked and continued to rise in North Dakota.

Final limitations of the project included not including patients who do not speak English, and not including patients older than 26 years. The implementing NPs both stated that the population base would have been much higher had the age range included females older than 26 years as they were seeing many patients outside of the age range that had not received the HPV vaccination series previously. The reason that females between the ages of 9 to 26 years are included in the project is because even though the United States Food and Drug Administration (FDA) has approved the expanded use of Gardasil 9 to include individuals between the ages of



27 to 45 years, the CDC as of the last update in 2019, does not recommend HPV vaccination to everyone older than 26 years (CDC, 2019; FDA, 2018). The CDC suggests for patients who are older than 26 years to consult their provider regarding HPV vaccination if they were either never vaccinated against it or if they were inadequately vaccinated (CDC, 2019).

### **Deviations from Project Plan**

The HPV project was pushed back by over three months due to IRB processing delays from the rural clinic's governing body. The proposal was initially submitted to the Educational Contact Person at the clinic's governing body on April 3, 2020. The proposal was then forwarded and submitted to the IRB on April 7, 2020 by the Educational Contact Person. However, after numerous failed attempts to contact the Educational Contact Person regarding IRB approval, the student was then granted permission to do an in-person oral defense of the proposal on June 22, 2020, with partial IRB permission granted. Full IRB permission was granted after the Medical Executive Committee met on July 8, 2020. The next step was CUHSR approval from Bradley University that was granted on August 6, 2020, with implementation of the project beginning August 10, 2020.

The other deviation from the project plan was the addition of another NP to implement the project from the seventh week on until project completion; this change was made to increase the patient population. The initial plan had only one NP, the DNP Project Mentor, to implement the project. Both NPs were educated regarding implementation of the project in the same way, via the implementation steps discussed previously.

### **Implications**

Further research is beneficial as the patient population is very small due to project limitations, including the project being limited to only females. Would this same type of project

implementation enhance HPV vaccination rates in males? Would it enhance HPV vaccination rates in males and females over the age of 26?

### *Implications for Practice*

The practices that were implemented throughout the project of asking about HPV immunization status at well and sick-visits, having a face-to-face educational discussion regarding HPV with the patient, and providing the same material discussed at the visit in the form of a handout for the patient are sustainable changes that can be made in practice. Discussions surrounding HPV naturally happen at well-child visits. However, recommending HPV vaccination at every visit has been shown to decrease missed opportunities in HPV vaccination since more patients present for acute illness visits than wellness exams or sports physicals (Dempsey et al., 2018). Implementing this change will naturally reach a higher number of patients, especially given the current pandemic. Since HPV vaccination is to be bundled with other vaccinations, providers should suggest HPV vaccination when suggesting influenza vaccination during the fall and winter months in order to sustain lasting change.

Additionally, having the provider read through the handout with the patient is a sustainable change that can continue to be implemented. HPV education naturally takes place after a patient declines vaccination. However, this project demonstrated that educating the patient face-to-face by using handout did increase HPV vaccination rates. Face-to-face interventions demonstrate a valuable way for improving HPV vaccination rates (Kaufman et al., 2018). Too often, patients leave the room forgetting what was exactly discussed with the provider. Having a tangible document for patients to examine during the educational process helps to solidify the information given to patients by the reviewing provider. All of these changes are sustainable, as

providers implement variations of these activities daily with patients. It is merely forming the habit to incorporate the combination of changes in the long term.

Potential project implementation modifications to improve future performance include broadening the inclusion criteria by asking males and patients over the age of 9 years about immunization status. Many patients over the age of 26 have not been immunized against HPV. Through implementing this change, not only would vaccination rates increase, but HPV infection rates and associated ailments would also decrease. This would in return decrease the high cost of HPV associated illnesses. While the goal is to be vaccinated against HPV prior to intercourse, with life changes that come as individuals age such as new sexual partners, it would still be beneficial for patients to be vaccinated after the age of 26 years. This applies even if insurance may not cover it.

Regarding generalizability or transferability of the intervention, it absolutely is applicable to a broader group of people than to only females between the ages of nine to 26 years as demonstrated by project implementation modifications to improve future performance. The interventions themselves are transferable to family practice, pediatric practice, walk-in clinics, public health clinics, dental offices, and obstetrics and gynecology (OB/GYN) clinics.

### ***Implications for Future Research***

Opportunities for interdisciplinary collaboration related to the topic of increasing HPV vaccination rates are abundant. This multifaceted approach to increasing HPV vaccination rates as demonstrated in this project are not only applicable to Advanced Practice Registered Nurses (APRNs), but to other healthcare providers such as physicians, physician-assistants, and dentists. It is imperative to include dentists in this category due to the amount of oropharyngeal cancers that HPV can cause. Other interdisciplinary collaboration includes working with insurance

providers and local, state, and federal agencies that deliver and pay for services (e.g., Indian Health Service, Centers for Medicare & Medicaid Services, state Medicaid agencies) (Smith, 2018).

However, another way to enhance interdisciplinary collaboration would be to implement this type of education in a school setting, which would allow a broader audience to be reached. Education in a school setting can be implemented in a health class with a nurse to educate children regarding HPV and HPV associated illnesses. A brochure regarding key points can be sent home with the children for their parents to review. Accurate knowledge is power and the more knowledge we give to the members in our society, the more informed they will be to advocate for themselves and make their own informed healthcare decisions.

Additional PICOT questions could be formulated for future projects in related areas. For example, an additional PICOT question of project would be: in adolescent males between the ages of 9 to 26 years (P) would enhanced education of parents/legal guardians and/or adolescents surrounding HPV and the prevention of it (I) compared to the current educational CDC handouts provided at office visits (C) increase the rate of HPV vaccination compliance with the CDC's current HPV vaccination recommendations in the rural clinic setting in 2020 (O), compared to the vaccination rates in the fourth quarter in North Dakota in 2019(T)? Or, in males and females over the age of nine years (P) would enhanced education of parents/legal guardians and/or adolescents surrounding HPV and the prevention of it (I) compared to the current educational CDC handouts provided at office visits (C) increase the rate of HPV vaccination compliance with the CDC's current HPV vaccination recommendations in the rural clinic setting in 2020 (O), compared to the vaccination rates in the fourth quarter in North Dakota in 2019(T)? Or, in males and females between the ages of 9 to 26 years (P) would enhanced education of

parents/legal guardians and/or adolescents surrounding HPV and the prevention of it (I) compared to the current educational CDC handouts provided at office visits (C) decrease the rate of HPV infection (O), compared to projected rate of 1 million new infections every year as stated by the CDC (T)?

Further dissemination of this project occurred through notifying the administrating NPs, nursing supervisor, clinical manager, and IRB team at the facility of the project and the results. This occurred via a project findings handout that was e-mailed to each of the members involved due to COVID-19 pandemic.

### ***Implications for Nursing***

This project is of great significance to the field of nursing. The findings in this project show that enhanced patient education of face-to-face interventions with appropriate handouts at all visits does increase HPV vaccination rates in patients. APRNs can use this evidence-based data to continuously improve the quality of healthcare that can be provided across their employed organizations. APRNs can advocate for the incorporation of this type of intervention to be utilized in their practice settings for all healthcare providers including physicians, physician assistants, and APRNs as it has been demonstrated to be effective. Nurses can also advocate for the expansion of this type of implementation practice in all healthcare systems across the United States of America. It is important for nurses to contribute to enhancing patient education regarding HPV, HPV infection, and HPV associated burdens. Billions of dollars every year are used to manage HPV infection and the repercussions of it in the United States. In 2020 alone, it is estimated there will be approximately 13,800 new cases of invasive cervical cancer diagnosed, with approximately 4,290 women dying from invasive cervical cancer (ACS, 2020). It is imperative to discuss evidence-based ways to increase vaccination rates in nursing education due

to the direct patient care that nurses demonstrate. Nurses can either positively impact or negatively impact patients' beliefs, fears, and overall health. By expanding the knowledge base of nursing on HPV and evidence-based ways in which we can increase HPV vaccination rates, enhanced protocols will naturally be incorporated in order to improve patient health and well-being. Overall, nurses play a critical role in the vaccination acceptance rates of their patients.

### ***Implications for Health Policy***

Vaccinations for preventing HPV infection have been labeled a public health priority at the federal, state, and community level. It is estimated that every year in the United States, HPV causes 32,500 cancers in men and women (U.S. Department of Health and Human Services, 2020). It is also estimated that HPV vaccination could prevent about 30,000 of these cases from ever developing (U.S. Department of Health and Human Services, 2020). This project addresses ways in which policy changes can be implemented into practice for all healthcare providers at the local, state, and federal level. The project provides an evidence-based multi-method approach to increasing HPV vaccination rates that can be utilized to shape and influence future policy changes to increase all vaccination rates, not solely for HPV. Policy changes can also be made at the educational level to enhance HPV education at the school level as stated previously. The only way to prevent HPV infection is through immunization. Immunization is much more than administering a vaccine, it is educating patients based on the current policy protocols in place. This project addresses ways to analyze current immunization policies and strengthen them using a multi-method approach, including face-to-face interventions with handouts provided at all visits, including sick visits.

## Chapter VI: Conclusion

### Value of the Project

As demonstrated through the implications for practice change, future research, impact on nursing, and health policy, this project is of value to healthcare and practice. HPV is so common, that nearly all individuals will at one point be infected with at least one type of HPV during their lifetime (CDC, 2019). Currently, almost 80 million Americans are infected with HPV (CDC, 2019). It is estimated that every year, 14 million new Americans will become infected, where 50% of the 14 million newly infected HPV persons are between the ages of 15 to 24-years-old (CDC, 2019; Gardasil, 2019). Early identification of individuals who are eligible for HPV vaccination is imperative, along with identification of individuals who are within the guidelines for vaccination that have yet to comply. This would overall help to increase vaccination compliance rates and lower HPV infection rates, thus naturally lowering the high cost of healthcare associated with HPV. Billions of dollars every year are used to manage HPV infections and the repercussions of it in the United States. There is so much to be gained by vaccinating every eligible patient against HPV infection, both personally, but also economically. Through implementing policy changes like the ones demonstrated in this project, it will help save patient lives and save money over time. This project offers evidence-based practice changes that can be implemented in providers' offices in order to increase HPV vaccination compliance. This practice is not only limited to primary care clinics, but is also applicable to dentist offices, otolaryngology clinics, pediatric clinics, OB/GYN clinics, and community clinics. Office visits are short and may be infrequent by some patients. As a result, at any visit providers need to utilize the time they are given with patients to ask about HPV vaccination status and have an educational discussion with a supporting document present that the patient can take home

surrounding the detriment of HPV. This is especially true for patients who are not sexually active yet.

## **DNP Essentials**

### ***Essential I: Scientific Underpinnings for Practice***

DNP graduates are prepared to integrate nursing science with organization, biophysical, psychological, and analytical sciences (American Association of Colleges of Nursing [AACN], 2006). The DNP graduate student will use science-based theories to determine the nature and significance of health and health care delivery (AACN, 2006). DNP Essential I underscores the importance of using science-based concepts to evaluate and enhance health care delivery and improve patient outcomes (DNP Nursing Curriculum Planning Solutions, 2016). Thorough understanding of nursing theory by the DNP student provides a solid foundation for advanced nursing practice (AACN, 2006).

The DNP project met DNP Essential I through preparing the DNP graduate, me, to possess a wide array of knowledge gleaned from the sciences and have the ability to translate that knowledge quickly and effectively to benefit patients in the daily demands of practice environments (AACN, 2006). I was able to integrate my knowledge of nursing science regarding HPV with knowledge from ethics, the biophysical, psychosocial, analytical, and organizational sciences in order to plan, implement, and complete my project. I was able to identify the detriment of HPV infection for patients and healthcare facilities. I also used science-based theories and concepts to identify and describe advanced strategies to enhance, alleviate, and ameliorate health and health care delivery phenomena as appropriate (AACN, 2006). These enhanced strategies included asking patients about HPV vaccination status at sick visits in order to decrease missed opportunities in HPV vaccination, as far more patients present for acute



illness visits than wellness exams or sports physicals (Dempsey et al., 2018). It also included using face-to-face interventions as they have demonstrated a valuable way for improving HPV vaccination rates (Kaufman et al., 2018). Combining multiple methods like the ones demonstrated in the project into practice were implemented as they been proven to enhance patient and/or parent knowledge of vaccination, vaccination compliance, and vaccination series completion rates. The development and evaluation of outcomes done during this project was based upon nursing theories and theories from other disciplines (AACN, 2006). During this project, the Health Belief Framework or model was utilized. It is based on the idea that multi-faceted behaviors can only be influenced through using a multi-dimensional model stemming from varying theoretical orientations (Bastani et al., 2010; Bastani et al., 2011). Overall, I have been thoroughly prepared to address current and future practice issues due to my basis knowledge of a strong scientific foundation for practice (AACN, 2006).

### ***Essential II: Organizational and Systems Leadership for Quality Improvement***

This essential emphasizes the DNP graduate's role in assimilating nursing science and practice with the complex needs of humankind (AACN, 2006). Key skills that are developed in the DNP graduate student include the development of clinical practice guidelines, designing evidence-based interventions, and evaluating practice outcomes (DNP Nursing Curriculum Planning Solutions, 2016). Graduates must become skilled in working within organizational and policy areas and in the actual provision of patient care by themselves and/or others (AACN, 2006).

This DNP project addressed the need to educate patients on HPV and the importance of vaccination to prevent infection, along with increasing vaccination rates. Part of educating DNP graduates mean that they must be able to assess the impact of practice policies and procedures on

meeting the health needs of the patient populations with whom they practice (AACN, 2006). Current practice policies and procedures were analyzed in order to diagnose weaknesses and changed in order to increase HPV rates. Current practice policies included asking about HPV immunization at well-visits and sports physicals, however many missed opportunities arise through not asking at every visit. Also, the CDC's handout was provided at times to patients for them to take home, however it was not read through with all patients. This project utilized a curated handout that discussed the main points of HPV that the patient could then take home with them to reference and research further.

Advanced communication skills/processes were utilized to lead quality improvement and patient safety initiatives in the healthcare setting that the project took place in (AACN, 2006). A project like this requires strong leadership skills in order to develop and implement a plan to enhance patient care. My communication and leadership skills were finessed in order to develop, implement, and evaluate my project on time due to the multiple setbacks that occurred during IRB review. Part of leadership is encouraging others during hard times. The project did not include as many patients as initially anticipated due to major limitations; however, I kept encouraging the NPs that any patient included in the project is one more patient vaccinated, which is the goal. Finally, I utilized principles of business and finance in order to develop a budget for my project (AACN, 2006).

### ***Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice***

This essential involves the translation of research into practice and the dissemination and integration of new knowledge (AACN, 2006). It focuses on the DNP graduates' roles in assuring accountability of quality care and patient safety, as well as critically examining ethical dilemmas inherent in patient care, health care organizations, and scientific research (AACN, 2006). It

enables DNP clinicians to create unique approaches to the complex issues facing modern health care (DNP Nursing Curriculum Planning Solutions, 2016).

This DNP essential was met through firstly researching literature that addressed HPV, HPV infection, increasing HPV vaccination rates, and etc. Part of this research entailed critically analyzing this information and performing a full synthesis of evidence regarding the literature gathered. I took what was gathered from the research and implemented a combination of the best evidence-based practices into practice in a rural clinic setting in order to increase HPV vaccination rates. Such evidence-based practices included multi-method approaches such as administration of HPV vaccination during sick visits, recommendation of HPV vaccination rather than suggestion, face-to-face education, and providing a handout for the patient.

***Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care***

DNP Essential IV prepares DNP providers to utilize information and patient care technologies to support practice leadership and clinical decision making (AACN, 2006). Deep understanding of technology equips the DNP provider with the skills to participate in technological innovation, evaluate the appropriateness of healthcare consumer information, and participate in resulting legal and ethical issues (AACN, 2006).

This DNP essential was met through the DNP project firstly through utilizing everyday technologies including Bradley University's online article database for the most current and up-to-date information regarding HPV. Secondly, technological systems such as Microsoft Word, Microsoft Excel, and JASP were utilized to write the paper, create a curated HPV handout and log sheet, and to analyze the data gathered from the project in order to display the project

findings. PowerPoint was also utilized to defend the project plan and will be utilized for the project dissemination.

***Essential V: Health Care Policy for Advocacy in Health Care***

DNP Essential V focuses on critically analyzing health care policy with the goal of advocating for social justice and the nursing profession as a whole (AACN, 2006). This essential prepares the DNP graduate to actively engage in health care policy to identify problems within the health care delivery system and to spearhead legislation through negotiating and consensus building (DNP Nursing Curriculum Planning Solutions, 2016). It provides the DNP graduate the ability to assume a broad leadership role on behalf of the public as well as the nursing profession (AACN, 2006).

DNP Essential V was met through designing a project to increase HPV rates, thus in return directly influencing current healthcare policies. The current healthcare policy regarding immunizations was initially analyzed at the instituting clinic in order to provide the basis for the project. Discovered weaknesses were enhanced through the DNP project plan by first having the NP ask about HPV at every visit. A part of the change included having educational discussions surrounding HPV with patients based upon the curated handout, which was provided for the patient to take home afterwards for further research. These practices were all done to advocate for patients' health. The best way to advocate for enhanced health is through primary prevention in the form of HPV vaccination. In the future, this may be utilized as an implemented policy change.

***Essential VI: Inter-Professional Collaboration for Improving Patient and Population Health Outcomes***

DNP Essential VI prepares DNP graduates to lead inter-professional teams in the analysis of multifaceted practice and systems issues through effective communication and collaborative skills (AACN, 2006). DNP students have advanced preparation in the interprofessional dimension of health care that enable them to facilitate collaborative team functioning and overcome impediments to interprofessional practice (AACN, 2006).

DNP Essential VI was met in full during the planning and implementation of the project. Inter-professional collaboration was demonstrated throughout the project through collaborating with the organization's clinic manager, nursing supervisor, NPs, IRB review team, and DNP team lead in order to plan and implement the project. Multiple meetings were coordinated throughout the duration of the semester regarding the project with each of the different professionals involved. Without inter-professional collaboration, the project would have never transpired.

***Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health***

DNP Essential VII prepares graduates to evaluate and interpret epidemiological, biostatistical, occupational, and environmental information imperative to improving the health of both individuals and communities (DNP Nursing Curriculum Planning Solutions, 2016). It equips DNP providers with the skills to synthesize the psychosocial dimensions and cultural impacts related to population health (DNP Nursing Curriculum Planning Solutions, 2016).

Clinical prevention is defined as health promotion and risk reduction/illness prevention for individuals and families (AACN, 2006). Population health is defined to include aggregate, community, environmental/occupational, and cultural/socioeconomic dimensions of health

(AACN, 2006). DNP Essential VII was demonstrated through using evidence-based practice to increase HPV vaccination rates within the community in females between the ages of 9 and 26 years who have not been immunized. Part of risk reduction is health promotion. In this case, the project was addressing reducing the risk of HPV infection through health promotion by primary prevention (immunization) and education of patients and parents.

### ***Essential VIII: Advanced Nursing Practice***

DNP Essential VIII prepares the DNP provider to demonstrate advanced levels of clinical judgement, systems thinking, and delivery of evidence-based care (AACN, 2006). It focuses on conducting comprehensive needs assessments, mentoring other nurses, and guiding patients through complex situational transitions (DNP Nursing Curriculum Planning Solutions, 2016).

Advanced levels of clinical judgement, system thinking, and delivery of evidence-based care was completed during the course of this clinical project. A comprehensive and systematic assessment of the community health was performed and it was found that there was a lack of HPV vaccination acceptance by many. A project plan was designed, implemented, and evaluated based on nursing science and other sciences for the therapeutic effectiveness (AACN, 2006). Relationships were also developed within the project itself that will be lifelong with those implementing the project. I also helped to guide and support the APRNs during the process of project implementation when patient census was low, causing overall low morale. Overall, DNP Essential VIII was met in full in order to enhance patient health throughout the course of their life through advocating for timely HPV vaccination administration.

### **Plan for Dissemination**

This scholarly project was developed, implemented, analyzed, and evaluated in accordance to the Doctor of Nursing Practice-Family Nurse Practitioner program at Bradley

University in Peoria, Illinois. Dissemination of the project will be delivered to Bradley University faculty and to the general public by an oral presentation using PowerPoint. Dissemination of the project to the implementing organizational key members including the nursing supervisor, clinical manager, and IRB committee will take place via a presentation of the project findings. The DNP project will also be published online on the Doctoral Project Repository for all to read and reference to regarding improving HPV vaccination rates. Through the oral presentation and publication of this DNP project, this will allow both professionals and the general public to become further educated upon not only the need for increasing HPV vaccination compliance, but successful ways that can be implemented to do so.

#### **Attainment of Personal and Professional Goals**

The personal and professional goals that were attained during the development, implementation, and evaluation of this project are invaluable. Personal and professional growth was developed in interprofessional collaboration, leadership, perseverance, and health promotion with risk reduction. Throughout this project, I was challenged numerous times with collaborating with individuals of other professions online during a global pandemic. I was challenged with IRB review delays and persevering through them by continually advocating for my project. I was challenged by taking a leadership role through the development and implementation of this project, something of which I have never done prior to graduate school. All of these roles were so valuable to me in order to try to make a positive change and impact in patients' lives. I am very grateful for this project and the growth that I have procured from it, with which I will take with me for the rest of my career as a Doctor of Nursing Practice-Family Nurse Practitioner.

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**Appendix A**  
**Data Collection and Evaluation Log Form**

Room # \_\_\_\_\_

Evaluation Log Form for HPV Project

Subject ID#	Date	Declined HPV Vaccination	Accepted HPV Vaccination Same Day	Receive HPV Vaccination at a Future Visit	Reason for HPV Vaccination Refusal or Acceptance



## Appendix B HPV Educational Handout

# HPV or Human Papillomavirus

### Fast Facts:

- HPV is a virus that causes genital warts and cancer of the cervix, vagina, anus, oropharynx (back of tongue, mouth, and throat), and penis.<sup>1</sup>
- Increases infertility in both sexes as it has been proven to cause apoptosis (death) of sperm, early miscarriages, and premature rupture of membranes in pregnant women.<sup>2</sup>
- HPV is the most common sexually transmitted infection.<sup>1</sup>
- Half of all HPV infections occur from the **first** sexual partner.<sup>3</sup>
- **Nearly every person become infected with at least ONE type of HPV.**<sup>1</sup>
- Every year, 14 million new Americans will become infected, half between the ages of **15 to 24-years-old.**<sup>1</sup>

### How is it Spread?

- Vaginal, anal, or oral sex<sup>1</sup>
- Direct and intimate skin-to-skin contact (hand-to-hand/hand-to-genital)<sup>4</sup>
- Condoms **do not** always prevent transmission of HPV<sup>1</sup>
- From mother or father to offspring at any point from conception to delivery, either from HPV infected sperm or oocytes or during the delivery process itself<sup>4</sup>
- From infected inanimate objects (towels) or improperly cleaned healthcare equipment<sup>4</sup>

### Can you test for HPV?

- There are no effective screening tests for HPV infection in vulva, vagina, penis, anus, or oropharynx at this time.<sup>1</sup>
- Only effective testing for HPV is done through an addition to a Pap test of the cervix.<sup>1</sup>

### Why Vaccinate?

- Protects individuals **prior** to HPV exposure, so they do not become infected.<sup>1</sup>
- HPV infection and HPV illness are preventable through vaccination.<sup>1</sup>
- 90% of female patients who are infected with HPV will become HPV DNA negative 2 years after infection.<sup>5</sup> This is either because the infection is gone or it is inactive and may reactivate **years** later when the immune system is weakened.<sup>5</sup>
- Vaccinated individuals are less likely to engage in sexual intercourse or become infected with other STD's due to increased condom use after HPV vaccination and education.<sup>6</sup>

<sup>1</sup> CDC. (2019). Human papillomavirus (HPV). *Centers for Disease Control and Prevention*. Retrieved from <https://www.cdc.gov/hpv/index.html>

<sup>2</sup> Souho, T., Benlemlih, M., & Bennani, B. (2015). Human papillomavirus infection and fertility alteration: A systematic review. *PLoS One*, 10(5), 1-9. doi: 10.1371/journal.pone.0126936

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<sup>6</sup> Kasting, M.L., Shapiro, G.K., Rosberger, Z., Kahn, J.A., & Zimet, G.D. (2016). Tempest in a teapot: A systematic review of HPV vaccination and risk compensation research. *Human Vaccines and Immunotherapeutics*, 12(6), 1435-1450. doi: 10.1080/21645515.2016.1141158

**Appendix C  
Provider Reminder**

# **Ask About HPV Vaccination**

**Appendix D  
Project Timeline**

Activities	April 2020	May 2020	June 2020	July2020	August 2020	September 2020	October 2020	November 2020
Submission of Research Proposal to Ethics Committee and Approval	✓	✓	✓	✓	✓			
Intervention					✓	✓	✓	
Data Collection					✓	✓	✓	
Data Analysis								✓
Formulation of Final Paper								✓
Final edits and Presentation								✓

*Increasing Low HPV Vaccination Rates Among Adolescent Girls*

Planned Milestones:

1. Submission of Research Proposal to Ethics Committee
2. Intervention
3. Data Collection
4. Data Analysis
5. Formulation of Final Paper
6. Final Paper Edit with Presentation Final

**Appendix E  
Trinity Approval Number One**

**Bradley University  
Department of Nursing  
Doctor of Nursing Practice Program  
DNP Project Site Administrator Approval Form**

*To be completed by student:*

**Name of Student:** Brittany Bollinger

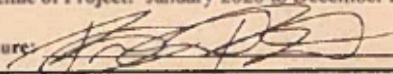
**Proposed Scholarly Project Title:**  
Increasing HPV vaccination compliance in adolescent boys and girls between the ages of 9 and 18.

**Overview of Project Needs Assessment (current state, how project could address findings, and potential project impact):** As a county, we are not meeting the Healthy People 2020's goals of vaccinating 80% of the adolescent population with HPV vaccination by the age of 15 in both sexes by 2020. This project could address different ways to increase the average HPV vaccination rate in the adolescent population in Williston in order to lower the spread of HPV, decrease cervical dysplasia rates/abnormal pap smears (including ASC-US, LSIL, HSIL, ASC-H, and/or AGC), decrease the incidence of genital warts, and decrease the incidence of oropharyngeal, vulvar, anal, vaginal, and cervical cancers.

**Clinical Question:** Why are parents hesitant to vaccinate against HPV in adolescent children, particularly in boys?

**Project Purpose and Objectives:** The purpose of this project is to increase awareness of HPV and the importance of vaccination in males and females prior to intercourse, along with increasing vaccination rates in order to comply with the CDC's recommendations of having the vaccination series completed by the age of 26.

**Projected Timeline of Project:** January 2020 to December 2020

**Student Signature:**  **Date:** 10/25/2019

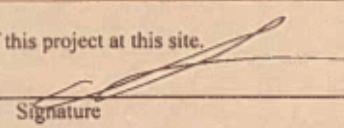
---

*To be completed by site administrator:*  
Please verify by checking a box below:

I support the implementation of this project at this site.

I support the implementation of this project at this site with the following modifications:  
Make Superior Park would be agreed receive as well as designated mentor.

I do not support the implementation of this project at this site.

**Site Administrator:** Tessah Robinson  10/28/19  
Printed Name Signature Date

**Appendix F**  
**Trinity Approval Number Two**



Dear Bradley University,

Brittany Annett-Audra Bollinger has permission to implement her DNP Scholarly Project to improve HPV rates at the Trinity Community Clinic- Western Dakota under the supervision of Heidi Grondahl, FNP. If you have any questions, please feel free to contact me.

Warmly,

**Ashley Busch**  
Education Specialist

Trinity Health  
701-857-3668  
Twenty Burdick Expwy. W, Minot, ND 58702  
[trinityhealth.org](http://trinityhealth.org)



**Appendix G  
Budget**

Project Period: Three months

<b>Particulars</b>	<b>Amount in USD</b>	<b>Rationale</b>
<i>Personnel</i>		
Academic personnel including Nurse	247.50	To compensate for a salary wage based at \$22.50
<i>Equipment</i>		
Computer/Laptop	Provided by student/facility	Will use facility's own
Printer	Provided by facility	Will use facility's own
IT	Provided by facility	Will use facility's own
<i>Materials and Supplies for Intervention</i>		
Stationary	0.36	To be used for documentation forms and for handouts
Ink	72	To use for handouts
Folders	3	To store data collection tools in each exam room
Laminator	1.10	To laminate handout/provided by student
<i>Transportation</i>		
Travel costs of investigator	10	Based on 3-month estimate
<b>Total</b>	<b>333.96</b>	<b>Total</b>

## Appendix H Approval During COVID-19 Pandemic

July 16, 2020  
Committee on the Use of Human Subjects in Research  
Bradley University  
1501 W Bradley Avenue Peoria, IL 61625


Dear CUHSR Committee Chair,

Please note that Brittany Bollinger Bradley University graduate student has permission of Trinity Community Clinic-Western Dakota to conduct quality assurance project activities at our healthcare facility for his/her project. "Increasing HPV Vaccination Rates Among Adolescent Girls"

While the healthcare community is actively fighting against COVID-19, we understand that quality assurance is critical to patient safety and overall improved patient health outcomes. Given that understanding, we will continue to follow the appropriate organizational and CDC guidelines when and if Brittany Bollinger may have human-to-human interaction throughout the implementation period of the project. Human interaction will be limited when possible and even replaced in some situations with remote or virtual alternatives.

If there are any questions, please contact my office.

Signed,



Kaseah Richardson  
Regional Director  
Trinity Western Dakota

**Appendix I  
IRB Approval**



August 27, 2020

Brittany Bollinger, RN

**Re:** Increasing HPV Vaccination Rates Among Adolescent Girls

To Whom It May Concern:

This letter is to inform you that the Trinity Institutional Review Board has granted IRB approval for the above new study.

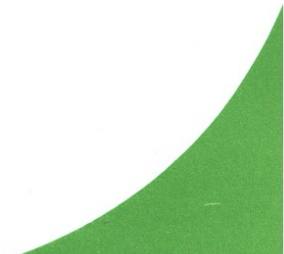
**Date of Approval:** IRB 06/22/2020; MEC 07/14/2020; BOD 8/27/2020

Upon completion of the study, the IRB asks that you submit the final results/outcome of the study. This report should then be shared with the full IRB membership.

Sincerely,

A handwritten signature in black ink, appearing to read "John M. Kutch".

John M. Kutch  
President / CEO





## Appendix J CUHSR Approval

DATE: 04 AUG 2020

TO: Brittany Bollinger, Deborah Erickson  
FROM: Bradley University Committee on the Use of Human Subjects in Research

STUDY TITLE: Increasing HPV vaccination rates among adolescent girls  
CUHSR #: 20-044-Q  
SUBMISSION TYPE: Initial Review

ACTION: Approved  
APPROVAL DATE: 04 AUG 2020  
REVIEW TYPE: Quality Assurance

Thank you for the opportunity to review the above referenced proposal. The Bradley University Committee on the Use of Human Subject in Research has determined the proposal to be NOT HUMAN SUBJECTS RESEARCH thus exempt from IRB review according to federal regulations.

The study has been found to be not human subject research pursuant to 45 CFR 46.102(i), not meeting the federal definition of research (not contributing to generalizable knowledge). Please note that it is unlawful to refer to your study as research. A waiver of documentation of consent is granted.

Your study does meet general ethical requirements for human subject studies as follows:

1. Ethics training of project personnel is documented.
2. The project involves no more than minimal risk and does not involve vulnerable population.
3. There is a consent process that:
  - Discloses the procedures
  - Discloses that participation is voluntary
  - Allows participants to withdraw
4. Consent process is part of the ordinary vaccination protocol of the clinic – focus of the project is vaccination rates from de-identified data collection.
5. Adequate provisions are made for the maintenance of privacy and protection of data.
6. [Your study is exempt for HIPAA regulations in that the covered entity will de-identify the health information used in your study pursuant to 45 CFR 164.502 (d).

Please submit a final status report when the study is completed. A form can be found on our website at <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/>. Please retain study records for three years from the conclusion of your study. Be aware that some professional standards may require the retention of records for longer than three years. If this study is regulated by the HIPAA privacy rule, retain the research records for at least 6 years.

Be aware that any future changes to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review. These changes include the addition of study personnel. Please submit a Request for Minor Modification of a Current Protocol form found at the CUHSR website at <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/> should a need for a change arise. A list of the types of modifications can be found on this form.

While no untoward effects are anticipated, should they arise, please report any untoward effects to CUHSR immediately.

This email will serve as your written notice that the study is approved unless a more formal letter is needed. You can request a formal letter from the CUHSR secretary in the Office of Sponsored Programs.