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# Implementation of an Evidence-Based Intervention to Improve Human Papillomavirus

(HPV) Vaccination Rates of Children Newly Admitted to a Residential Facility

by

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Paper submitted in partial fulfillment of the requirements for the degree of

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#### Abstract

**Background:** The Centers for Disease Control and Prevention (CDC) estimates that more than 42 million Americans are presently infected with the Human Papillomavirus (HPV). The nurse practitioner (NP), who provided primary care to children at the residential facility, reported that only 60-70% of children were consented for HPV vaccination.

**Purpose:** The purpose of this evidence-based intervention was to have 90% of newly admitted children consented and vaccinated for HPV. The specific aims of this project were to (1) increase staff HPV/HPV vaccine knowledge, (2) implement an updated evidence-based consent form, and (3) increase the HPV consent and vaccination rates.

**Methods:** This descriptive longitudinal project assessed the effectiveness of an educational presentation on staff HPV knowledge by comparing pre-and post-test scores. A retrospective chart review determined the pre- and post-intervention HPV consent and vaccination rates.

**Interventions:** The CDC presentation, You Are the Key to HPV Cancer Prevention, educated staff on making an effective recommendation for the HPV vaccine. The second area for targeted improvement was the lack of an evidence-based HPV consent form.

**Results:** There was an increase in the mean pre/post-test scores from 68% to 82% (t=-2.75; p=0.052). There was an increase in HPV vaccine consent rates from 66.67% to 81.8%; there was a decrease in children vaccinated for the HPV vaccine from 50% to 44% post-intervention.

**Discussion:** After the HPV/HPV vaccine education and the new evidence-based consent, consent rates increased. While consent rates increased, vaccination rates decreased due to unforeseen factors with the vaccine administration.

Keywords: human papillomavirus, HPV, HPV vaccine, human papillomavirus vaccine, vaccination, consent, adolescent, child, vaccine rate

# Implementation of an Evidence-Based Intervention to Improve Human Papillomavirus (HPV) Vaccination Rates of Children Newly Admitted to a Residential Facility Introduction/Background/Problem Significance

# **Problem Statement**

The residential psychiatric treatment facility in this project provided therapeutic foster care for up to 160 children and adolescents aged six to 18 located in Kentucky (KY). Many of these children have experienced various traumas and have high adverse childhood event (ACE) scores (personal communication, 2022). As research has shown, children with high ACE scores often partake in risky behaviors and this can include sexual behaviors and earlier initiation of sexual activity (Song & Qian, 2020). This arguably makes it even more essential that this population receive this cancer prevention vaccine as recommended. The nurse practitioner (NP), who provided primary care to the pediatric population at the facility reported that only 60-70% of children were consented to be vaccinated against the human papillomavirus (HPV). Based upon national guidelines and feasibility for this facility, the NP identified a goal to consent and vaccinate at least 90% of the newly admitted children. This quality improvement project aimed to increase HPV consent and vaccination rates for newly admitted children at the residential psychiatric treatment facility by implementing an evidence-based educational program for all staff members involved in healthcare delivery and obtaining informed consent for the HPV vaccine. This project also included updating the current consent form to one that is evidencebased.

#### **Background and Significance of the Problem**

HPV is common throughout the United States (U.S.) and worldwide. While the body can naturally resolve all strains of the infection, the strains that linger can progress to various cancers. The Centers for Disease Control and Prevention (CDC) (2021a) estimates that more than 42 million Americans are presently infected with multiple strains of HPV, and approximately 13 million Americans become infected annually. The current HPV vaccine, Gardasil 9, protects against seven of the most prominent cancer-causing strains while also protecting against two strains that cause genital warts (Rosenblum & Wodi, 2022). The main barriers to HPV vaccination include a lack of parental and healthcare team members' knowledge about the vaccine, a lack of a strong provider recommendation, parental safety concerns, and the parental belief that the child is not sexually active (Holloway, 2019). These barriers must be addressed to increase HPV vaccination rates.

## **National Benchmarks and Recommendations**

In 2020, only 58.6% of U.S. adolescents between the ages of 13 and 17 years old were up-to-date (UTD) on their HPV vaccines (Pingali et al., 2022). Subsequently, in 2021, vaccination rates increased to 61.7% (Pingali et al., 2022). However, when children younger than 13 years old were included, only 38.6% of children among nine to 17 years old had received one or more HPV vaccine doses in 2022 (Villarroel et al., 2024). The U.S. Department of Health and Human Services (2020) has established a goal for at least 80% of children and adolescents to be vaccinated against HPV by 2030. However, with the current trajectory of HPV vaccination trends among 13- to 15-year-olds, this goal will not be reached until 2040 (Saxena et al., 2024). If the healthcare team began recommending the HPV vaccine for children starting at age nine, with a projected one percent increase annually in vaccination rates, the goal of 80% of children vaccinated could be achieved by 2037 (Saxena et al., 2024). When discussing vaccinations, the topic of herd immunity is often mentioned. Herd immunity is the indirect protection of a population from an infectious disease that occurs when most of a population is vaccinated or has

developed immunity from a previous infection (World Health Organization, 2020). Since the Food and Drug Administration's (FDA) approval of the four-valent HPV (4vHPV) vaccine in 2006, herd immunity has become a topic for emerging research studies. "By 2015-2018, compared with the pre-vaccine era, 4vHPV-type prevalence declined 85% overall among sexually experienced 14- to 24-year-old females, 90% among vaccinated females, and 74% among unvaccinated females" (Kaltwasser, 2022, para. 9). 4vHPV-type vaccines target the HPV strains 16 and 18 which cause approximately 66% of cervical cancer cases and most of the other HPV-associated cancers (CDC, 2016). Emerging data supports that the HPV vaccine could eventually reach herd immunity and help protect unvaccinated people (Kaltwasser, 2022).

The HPV vaccine is not required in most states; however, Hawaii, Rhode Island, Virginia, Washington D.C., and Puerto Rico require their students to receive it for school attendance. Rhode Island has an HPV vaccination rate of 83%, while 73.9% of adolescents in Hawaii are UTD on their HPV vaccines (National Conference of State Legislature, 2020). According to America's Health Rankings (n.d.), KY HPV vaccination rates in 2021 among male and female adolescents aged 13 to 17 years old were 57%, just slightly below the national average of 63% (CDC, 2022b). However, in 2022, Kentucky ranked 44<sup>th</sup> in state HPV vaccination rates among 13 to 17-year-olds with only 55% having received all doses in the series (Close, 2024). Locally, according to the KY Cabinet for Health and Family Services (2019), in 2019, among 13-year old's, 55.04% were fully vaccinated for HPV in Jefferson County; among 17-year old's only 37.15% were fully vaccinated for HPV in Jefferson County. From the evidence provided, low HPV vaccination rates are an issue nationally and locally.

### **Evidence-Based Solutions Prominent in Literature**

Existing literature focused on improving HPV vaccination rates revealed that multimethod intervention approaches were critical to creating positive and significant change. When the studies evaluated a single method, the evidence was often not statistically significant and yielded a lower increase in HPV vaccination rates (Constable et al., 2022; Holloway, 2019); however, when multi-method interventions were evaluated, the evidence became significant, and HPV vaccination rates increased (Constable et al., 2022; Holloway, 2019). The most common interventions in the multi-method studies included training on communication techniques (using a strong presumptive communication style), provider and healthcare staff education on HPV and the HPV vaccine, motivational interviewing (MI), and cancer prevention verbiage (Beck et al., 2021; Constable et al., 2022; Holloway, 2019).

#### Strong Provider/Healthcare Staff Recommendation and Communication Techniques

The most prominent and widely used intervention in studies was the training and implementation of a strong healthcare staff recommendation. The existing literature recommends that a strong communication style using presumptive words like "due" or "needed" increased vaccine uptake when compared to weak recommendations utilizing words such as "maybe" or "if you want" (Constable et al., 2022; Efua Sackey et al., 2022; Oh et al., 2021; Vollrath et al., 2018). With a strong healthcare staff recommendation, there were five to 18 times greater odds of vaccine initiation for those patients when compared to a weaker recommendation (Vollrath et al., 2018).

#### **Education for Guardians and Healthcare Staff Members**

It is a misconception that all healthcare professionals are fully educated in all areas of medicine. Guardians may believe that all healthcare staff members have adequate knowledge surrounding every vaccine, but this is not always the case. The most prominent barrier to healthcare professionals' recommendation of HPV vaccination was their lack of education regarding the HPV vaccine, which leads to hesitancies, low self-efficacy, and decreased confidence when communicating with parents (Efua Sackey et al., 2022; Leung et al., 2019; Perkins et al., 2020; Vollrath et al., 2018). When the healthcare staff members adopted better communication techniques, acquired more training and education on HPV and the HPV vaccine, and provided parents with fact sheets and education, healthcare staff's confidence and parental attitudes were improved and HPV vaccine series initiation and completion rates increased (Efua Sackey et al., 2022; Leung et al., 2019; Vollrath et al., 2018). Survadevara et al. (2019) performed a longitudinal intervention in which the healthcare staff in six pediatric clinics received education on the HPV and the HPV vaccine; then, the parents and adolescents (N=22,383 adolescents) received an educational booklet on the HPV vaccine. The population was studied again 12 months after the implementation, and the researchers concluded that three practices had a 10% HPV vaccination initiation increase, and at least five practices had a five percent increase (Suryadevara et al., 2019). Educational training sessions that empowered healthcare staff and parents were one of the most common quality improvement initiatives that subsequently increased HPV vaccination rates (Khalid et al., 2023). The most common topics discussed during education sessions included the burden of HPV and HPV-related diseases, the HPV vaccination schedule, and ways to communicate effectively with parents and children about the HPV vaccine.

#### **Motivational Interviewing**

While speaking with guardians regarding a new vaccine, the healthcare staff members must be able to answer all questions and address parental concerns. In a randomized control trial (RCT) by Reno et al. (2018), it was found that within the eight clinics that received the intervention, 72-90% of the medical staff (N=46) in the study used motivational interviewing (MI) in practice, while 88% stated it helped address parents' concerns and increased self-efficacy among healthcare team members when addressing HPV vaccine-hesitant parents. However, the healthcare staff were not evaluated for correct MI use and MI was not explicitly evaluated alone since it was part of a multi-method intervention. In similar studies, clinicians perceived MI as a successful strategy to decrease parental concerns, fears, and distrust of the HPV vaccine (Constable et al., 2022). Dempsey et al. (2018) performed a clustered RCT (N=43,132 adolescents and 188 medical professionals) that included a multi-method intervention with communication training on the presumptive approach followed by MI. The intervention group was compared to a control group within the same geographical area, and it was concluded that within the intervention practices, there was a 9.5% increase in HPV vaccine series initiation (p<0.001) and a 4.4% increase in completion. Healthcare professionals reported the most valuable part of the intervention was the communication training and the fact sheets for the guardians. MI has not been studied alone as an intervention but as part of a multi-method intervention (Dempsey et al., 2018; Reno et al., 2018). Healthcare staff also used MI more often when encountering vaccine-hesitant guardians to ease their fears and concerns (Dempsey et al., 2018).

#### **Cancer Prevention Verbiage**

In the years following the approval and administration of the HPV vaccine, it was initially thought of by guardians as a sexually transmitted disease (STD) prevention or cancer prevention mechanism for adolescent girls (Cartmell et al., 2018). The primary purpose of the HPV vaccine is to prevent the contraction of the most common cancer-causing strains of HPV, not to prevent STDs. There has been a push to educate healthcare staff to change this verbiage and express that the vaccine is cancer prevention (Rosenblum & Wodi, 2022). While some research has shown that cancer prevention verbiage alone had mixed efficacy, it was effective when combined with a strong healthcare staff recommendation (Constable et al., 2022). Similarly, a multi-method intervention that included cancer prevention verbiage to address parental concerns led to all 24 adolescents in the study becoming vaccinated (Beck et al., 2021).

## **Effect of Low HPV Vaccination Rates**

Vaccines are the primary prevention of disease. The CDC (2021b) estimates that around 85% of people will have an HPV infection in their lifetime and recommends that children aged 11 to 12 years old should receive two doses of the HPV vaccine, but HPV vaccination may start as early as 9 years of age. HPV can lead to various cancers (cervical, anal, oropharyngeal, penile, vulvar, and vaginal) and significantly impact a person's quality of life (Rosenblum & Wodi, 2022); therefore, the interventions in this project aimed to increase HPV consent and vaccination rates for this at-risk population.

HPV-related illnesses and treatments are also very costly. An estimated \$9.36 billion annually in the U.S. is spent on screening for and treatment of HPV-related diseases (Clay et al., 2023). The average two-year cost for a cervical cancer patient from 2011-2017 was \$93,200 (Clay et al., 2023). HPV-related healthcare expenditures could be significantly decreased with increased HPV vaccination and the movement toward herd immunity.

Not only would increased HPV vaccination decrease healthcare expenditures, but it could also impact mortality. An average of 4,000 women die annually in the U.S. from cervical cancer (CDC, 2023a). The American Cancer Society (2023) reports that in KY, 9.8 people per 100,000 will develop an HPV-associated cancer annually. This is the highest rate among all states. The literature shows that HPV is a common problem, especially in KY. In the Appalachian and rural parts of KY, the death rate from cervical cancer is twice the national rate (Ellis, 2023). The children and adolescents at the DNP project facility came from various parts of KY, with the majority inhabiting rural and micropolitan areas.

#### **Evidence-Based Intervention**

The first targeted area for improvement was to increase healthcare staff HPV and HPV vaccine knowledge. The CDC (Rosenblum & Wodi, 2022) provides an education-based program titled You Are the Key to HPV Cancer Prevention (see Appendix A), which educates healthcare staff on making an effective HPV vaccine recommendation and answering parents' questions about HPV vaccination (Rosenblum & Wodi, 2022). This program includes information on the four evidence-based strategies mentioned previously that have been shown in the literature to be effective at increasing HPV vaccine rates. This presentation is updated every few years with the most current and recent evidence about the HPV vaccine and HPV prevalence.

The second targeted area for improvement was the facility's parental HPV consent form, which was not evidence-based. The original consent form (see Appendix B) stated that the vaccine is "given as a three-dose vaccine over a six-month period." CDC (2022) guidelines now recommend that children aged nine to 14 only receive two doses over six months to a year (Rosenblum & Wodi, 2022). The second and third sentences of the consent form (see Appendix B) stated, "HPV is so common that nearly all sexually active men and women get it at some point in their lives. There are many different types of HPV." The HPV vaccine is a cancer prevention vaccine; however, when the vaccine was first marketed, it was promoted as an STD vaccine, as previously discussed. The current consent form (see Appendix B) suggested that the HPV vaccine is a vaccine for only sexually active adolescents. Additionally, the HPV vaccine consent form was separate from the required KY vaccine consent form, implying that this

vaccine was in some way different from the other CDC-recommended vaccines or not as necessary as the other vaccines. Combining all the vaccines into one consent form (see Appendix C) helped provide an equitable recommendation for all vaccines. Thus, a reconstruction of the consent form was a crucial part of this evidence-based intervention.

The third area targeted for improvement, as part of the multifaceted intervention, was a strong healthcare staff recommendation for the HPV vaccine. The NP cannot attend all admission sessions; therefore, a provider recommendation letter/video from the NP was to be provided at the beginning of the vaccine consent process to emphasize, encourage, and endorse all vaccinations equally. This letter (see Appendix D) explained the role of the NP at the facility and provided a strong and equal recommendation for all vaccines. There was to be a QR code for the guardians to scan, directing them to a video of the NP reading the provider recommendation letter. The NP expressed that the parents and legal guardians have various educational backgrounds, and a video would be the most appropriate method for them to receive the information. At the end of the letter, the NP provided contact information, allowing parents to call or email her with questions regarding their child's care.

#### Synthesis of the Evidence-Based Solutions Found in Literature

Throughout the analyzed literature, a majority of the articles and studies utilized a multimethod intervention approach and did not study individual interventions and their impact on vaccination rates (Beck et al., 2021; Efua Sackey et al., 2022; Holloway, 2019; Perkins et al., 2020; Vollrath et al., 2018); therefore, it is hard to distinguish which intervention alone was most effective. However, the needs of this facility, staff members, and guardians indicate that a multimethod intervention is most appropriate for these populations. The evidence showed that any intervention needs to target the healthcare staff, as they will educate the families and children, ultimately influencing consent and vaccination rates.

It is important to note that none of the literature specifically mentioned a singular vaccine consent form for all the recommended CDC vaccines. However, the facility had four separate consent forms for the vaccines, thus singling out and recommending the influenza, COVID-19, and HPV vaccines separately from other vaccines. Per the literature, the vaccines are to be recommended together as described above; therefore, reconstructing the consent is vital (Brewer et al., 2017; Constable et al., 2022; Shah et al., 2021; Suryadevara et al., 2019).

# **Rationale for the QI Project**

#### **Previous Vaccination Consent Process**

Understanding the vaccine consent process at this facility was imperative when identifying targeted areas for quality improvement. Consent was obtained during a child's admission, often lasting one to two hours and during this time, the guardians' and children's emotions may be heightened. The admission packet was over 25 pages long, filled with various educational materials and consent forms. Individuals included in the admission process include the program assistant, guardian (child protective services caseworker or family member) or parent, the child, a therapist, and nursing staff. The nursing staff was responsible for completing an admission assessment, including inquiring about immunization status. The therapist then spoke with the child and guardian about the reason for admission; the therapist often asked questions about self-harm, sexual practices, abuse, suicide, and drug use. Then, the program assistant would go through the admission packet with the parent or guardian and obtain consent for treatment by the facility NP, required KY vaccines, and consent for the HPV, Influenza, and COVID-19 vaccines separately. When presenting the vaccine consent forms, staff members often

said, "These are the required vaccines for school and this other consent is a recommended but optional vaccine for HPV." The current consent was not evidence-based and did not utilize recommended words like "due" and "needed" when referencing the HPV vaccine (Constable et al., 2022; Efua Sackey et al., 2022; Oh et al., 2021; Vollrath et al., 2018). The admission packet included the standard CDC Vaccine Information Statement (VIS) handout regarding the HPV vaccine, but the guardians rarely read this before signing or declining the vaccine consent. No medical staff member is guaranteed to be present at every admission; therefore, a non-medically trained staff member, often the program assistant, obtained consent. Once this packet was completed, the guardians would say goodbye to the child and leave the facility.

#### **Current Facility Data**

The NP tracked all the vaccine consent forms (assents and declinations) and immunization records, which served as the internal evidence needed to support an evidencebased initiative and quality improvement project. The facility NP estimated that approximately 60-70% of children at this facility have consented to be vaccinated for HPV and subsequently received HPV vaccinations.

#### **Facility Barriers to Intervention Implementation**

Anticipated barriers to this intervention included the staff's current habits and beliefs regarding the HPV vaccine. The intervention focused on the overarching themes and importance of the HPV vaccine. Lunch was provided since the staff attended the educational session during their lunch hour. At the end of the presentation, to aid staff with real-world concerns and questions, there was a section regarding the most frequently asked questions with the most appropriate responses for the staff to review.

Another anticipated barrier to this project was healthcare staff time and possible burnout. This project aimed to help staff understand the importance of the HPV vaccine and not weigh them down with unnecessary information. This project was performed promptly to avoid preoccupying the staff members from their daily duties.

The third anticipated barrier was obtaining the facility's pharmacy and therapeutics committee approval or a delay in the approval of the updated evidence-based vaccine form and the new provider recommendation letter/video. Information on the need for a new evidencebased HPV vaccine consent form was presented to the committee, including the medical director. This included examples of other evidence-based consents as well as an explanation of the importance of and rationale for this change. With the support of the NP, the changes to the consent form were accepted. Once the committee approved these interventions, upper management also needed to approve the changes.

The one unanticipated and final barrier to the intervention implementation was facility staffing changes. The original intervention plan was to include the provider recommendation letter/video; however, it was no longer feasible for the facility due to staffing changes. As the education session and consent change unfolded, it became clear the provider recommendation letter/video could not be implemented at the facility within the duration of this project.

## **Purpose and Specific Aims**

The purpose of this project was to implement an evidence-based intervention to increase HPV vaccination rates and evaluate its effectiveness. The goal of this project was to have more than 90% of newly admitted children and adolescents consented and vaccinated for HPV. The specific aims of this project were to (1) increase staff HPV and HPV vaccine knowledge as evidenced by increased pre- and post-test scores, (2) implement an updated evidence-based consent form and a provider recommendation letter/video, and (3) increase the vaccination rates as evidenced by an overall increase in post-intervention rates when compared to pre-intervention rates.

# **Quality Improvement Framework Model**

The Model for Improvement developed by the Associates in Process Improvement (Institute for Healthcare Improvement [IHI], n.d.) is used to improve various healthcare processes and patient outcomes. The model has three fundamental questions and the Plan-Do-Study-Act (PDSA) cycle. The first of the three questions must be answered: What are we trying to accomplish? In this intervention, the goal was to increase the HPV consent and vaccination rate to 90% of children admitted to the residential psychiatric treatment facility. The second question is how we will know that a change is an improvement? The improvement in the vaccine rates was measured by collecting pre-intervention vaccination rates and then comparing them to the post-intervention vaccination rates. The final question that the Model for Improvement asks is, what change can we make that will result in improvement? The changes included an educational intervention for all staff members involved in healthcare delivery or obtaining vaccination consent. As previously discussed, the educational intervention is backed by extensive evidence and this empowered healthcare staff to feel comfortable advocating for this vaccine and answer any questions guardians may have. The second necessary change was updating the HPV vaccine consent form to highlight the importance of the vaccine as a cancerpreventative measure and provide an equal recommendation for all vaccines.

The Plan-Do-Study-Act (PDSA) cycle, as illustrated in Figure 1, is described by the Institute for Healthcare Improvement (n.d.) as a sequence for testing a change. Within the first step, Plan (see Figure 2), the objective of the quality improvement project, and the plan to test the change will be stated. In this intervention, the primary objective was to increase vaccine consent and vaccination rates, all while educating the staff to sustain this initiative for the future. In the second step, Do (see Figure 2), the intervention of the educational session and updating and administering the new consent form was implemented. This step also included data collection or the pre-and post-test scores. The third step, Study (see Figure 2), included completing the data analysis, comparing the data to the end goal of having 90% of the newly admitted children consented and vaccinated for HPV, and summarizing and reflecting on the limitations and strengths of the project. The final step, Act (see Figure 2), determined what modifications must be made for future quality improvement projects or interventions. During this phase, the facility determined if they would either adopt, adapt, or abandon the interventions and quality improvement strategies.

#### Figure 1

### Model for Improvement



(Institute for Healthcare Improvement, n.d.)

### Figure 2

PDSA Cycle for the DNP Project



# Methods

# Design

This quality improvement project assessed whether a new HPV vaccine consent form and an educational session provided for the staff members would improve HPV vaccination rates. This descriptive longitudinal project, which involved looking at the same variable over a specific amount of time, compared staff HPV knowledge via a pre-and post-test (see Appendix E) after they attended an educational session. Staff members were identified and were recruited to participate in this portion of the project. The NP requested and strongly recommended that all healthcare staff members participating in the healthcare delivery or consent administration attend this educational session to gain evidence-based knowledge about the vaccine and be introduced to the new vaccine consent form. A retrospective chart review was performed to determine the pre-intervention HPV vaccination rates for the previously admitted children at this facility. This was a sample of convenience as the children had already been admitted to the facility. For inclusion criteria, the child must have currently resided at the facility, thus not requiring recruitment of the children. All residents admitted to the facility three months before and after the intervention were included in this project; however, if the child was previously fully vaccinated, they were not followed throughout the project and were only included in preintervention vaccination rates. If children were previously fully vaccinated and not identified, this could skew the data. Once consent was obtained, the vaccine was able to be administered within 30 days of admission per the facility policy. The goal was to have all the children in this project fully vaccinated. However, if only one vaccine was obtained in the project window, it becomes the facility's responsibility to complete the series. The facility NP followed the series to completion.

# **Setting (Environment)**

The residential facility provided residential treatment, therapeutic foster care, and adoption, as well as community-based resources to help assist children with higher education, career development, and development of independent living skills to children from all over the state of KY (facility website, 2023). This intervention could affect up to 160 children at any given time. However, currently, one facility is closed due to low census; therefore, all the children followed in this project resided at one facility. This intervention was performed on-site in the conference room, so the staff members did not need to travel. While the children were at the facility, they attended an onsite public school and lived in on-site cottages with children of the same gender and similar age.

#### Sample

The target population for this intervention was the staff members involved in healthcare delivery, obtaining consent, or recommending and administrating the vaccines. The staff members did not need to be recruited as they were already identified. Six total staff members

were invited to participate in this intervention: one nurse practitioner, one nursing director, one registered nurse (RN), one licensed practical nurse (LPN), one medical assistant (MA), and one program director's assistant. Staff members were excluded from this project if they did not participate in healthcare delivery or did not participate in the consent process.

A retrospective chart review determined the pre-intervention rates and included the children admitted three months prior to the implementation of the intervention. Children younger than nine were excluded from this project because nine is the youngest age a child can receive the HPV vaccine. The post-intervention rates measured the rates of the newly admitted children to the facility in the three months following the implementation of the intervention. Within the past four months (October 2023-December 2023), there were eight total admissions to the facility; these served as the pre-intervention participants. The children previously admitted to the facility before the implementation of the intervention were excluded from the post-intervention vaccine rates. A chart auditing tool (see Appendix F) with a corresponding legend (see Appendix G) was used to determine consent and vaccination status for the newly admitted children. It is important to note that while three months of data were studied, the data was collected for four months pre- and post-intervention because the facility has 30 days to vaccinate the children after admission.

#### Context

The potential root causes of the problem included: staff learning needs regarding HPV and the HPV vaccine, an HPV vaccine consent that was not evidence-based, and the HPV vaccine being recommended separately from all other vaccines. The stakeholders were the nursing director, NP, RN, LPN, MA, program assistant, the medical director, the guardians, and the children. The staff attended the educational session to assist with educating the guardians with the most up-to-date information when obtaining informed consent. The primary facilitators of change included the new facility policy requiring children to become vaccinated within 30 days of admission, the stakeholders' buy-in, and the NP, who was very motivated to help promote this project. The NP stated that upper management was open to a change regarding the consent form and was willing to facilitate this intervention section.

The NP identified a few barriers to change. The staff's habits, lack of time, and possible resistance to change were potential barriers to change as they have been using the existing admission process for years and may be hesitant to adopt new practices. When interviewing staff members, there was a consensus that they do not "push" the HPV vaccine since it can be administered to adults up to 45 years of age. While this is true, it is not the recommended vaccination practice by the CDC due to the increased risk for exposure and potential transmission of HPV and subsequent increased risk for developing HPV-related cancers (CDC, 2021c). To mitigate this barrier, education was needed for all staff who interacted with the children's guardians.

Another possible barrier was the guardians' resistance to change when presented with educational materials regarding the vaccine during admission. The admission packet includes the CDC Vaccine Information Sheets (VIS) handout regarding education on the HPV vaccine (CDC, 2023c); however, based on observations from multiple admissions, the guardians rarely read over the VIS. If the guardians are not receptive to education on HPV and the HPV vaccine during the admission process, this creates a barrier as the admission is one of the few times staff directly interacts with the guardians. Education for the staff helped address and mitigate this barrier. Having an updated evidence-based consent form helped the guardians better understand the importance of the vaccine. Another barrier was getting the new consent approved by the

pharmacy and therapeutics policy committee and upper management. Having the consent printed, approved, and implemented in time to begin the intervention was the final barrier.

# **Ethical Considerations/Permissions**

This DNP quality improvement project and proposal was submitted to the University of Louisville (UofL) IRB for approval before implementation. Following UofL IRB approval, approval was obtained from the facility's pharmacy and therapeutics committee and facility upper management for all portions of the intervention. In restructuring the consent form, the facility's pharmacy and therapeutics policy committee evaluated and approved the changes. The pharmacy and therapeutics team consisted of a psychiatric medical representative, a family care provider, the director of nursing, the vice president of residential programming, the vision director for residential services, a policy coordinator, and an administrative leader. After the committee approved the change, it was sent to executive leadership for approval.

This project followed all procedures and policies in accordance with the Health Insurance Portability and Accountability Act (HIPAA). For coding, there was a separate code sheet where the medical record numbers (MRN) were listed, as well as the project number they corresponded to with all deidentified patient information. For example, MRN #XXXXX coincided with chart #1 of the project, and so on. This information of the corresponding chart numbers was kept in the facility in a secure location as a digital document kept on a password-protected computer within the office of the facility NP. All de-identified patient information was stored on a passwordprotected computer and backed up on the secure site CardBox. Only the DNP student and the DNP committee members for this project had access to this information. Upon project completion, the participant code sheet and all deidentified patient data were destroyed in a protected, secure manner. When analyzing and reporting staff knowledge via the pre-and post-test scores, the scores were reported as frequencies of percentages, therefore this will continue to allow for the anonymity of all staff members. Educational session participant confidentiality and anonymity were maintained by having the participants write the last four numbers of their phone numbers on the top right-hand corner of the pre-and post-tests. The DNP student did not have access to the participants' phone numbers.

### **Procedure/Intervention Implementation**

The intervention consisted of two major components: an educational session for staff and an updated vaccine consent form provided to guardians. The educational session was a modified version (with CDC permission) of the CDC's You Are the Key to HPV Cancer Prevention (Rosenblum & Wodi, 2022). The presentation provided current information regarding HPV infections, HPV vaccines, and methods to effectively communicate with guardians about the vaccination (Rosenblum & Wodi, 2022). The second part of the intervention encompassed updating the existing consent form. The updated consent combined all vaccines on one form to provide an equitable recommendation for all CDC-recommended vaccines (see Appendix C). The current forms separated the influenza, COVID-19, and HPV vaccines, implying that these vaccines were in some way different.

The Doctor of Nursing Practice (DNP) student worked with staff members to determine the best educational session date (see Table 1). Five of the six identified staff members (NP, nursing director, LPN, MA, and program director's assistant) attended a singular educational session. If necessary, multiple dates would have been held to provide the information, however, this was not necessary. The DNP student provided lunch and refreshments for the staff members who attended as the session was held during the staff's lunch hour. Before the educational component of the intervention, an Internal Review Board (IRB) approved preamble (see Appendix H) was provided to gain the staff participants' informed consent to participate in the intervention. After the preamble was reviewed, the pre-test for You Are the Key to HPV Cancer Prevention (CDC, 2023) was provided to all staff members in attendance to establish baseline knowledge (see Appendix E). The pre- and post-tests were administered via paper. The CDC granted permission and supplied this test for use.

To protect the staff member's identity, they wrote the last four numbers of their phone numbers on the top right-hand corner of the pre-and post-tests. The NP student does not have access to this information; therefore, this allowed for staff confidentiality and allowed the DNP student to assess and compare the pre-and post-test scores. The DNP student then presented the modified education presentation, You Are the Key to HPV Cancer Prevention, also available from the CDC (see Appendix A). There was a short question-and-answer session after the presentation was completed. During the question-and-answer session, the new consent was introduced, and education was provided on how to present the new form to the guardians. Following the question-and-answer session, the post-test was provided by the DNP student. Any questions regarding the vaccine were also answered during this time. The educational session lasted 60 minutes, which included: 10 minutes for the pre-test, 30 minutes for the educational presentation, 10 minutes for the question-and-answer session, and 10 minutes for the post-test. Since the DNP student provided the educational session, an intervention team was not required for the session itself. However, the staff (the NP, LPN, MA, nursing director, and program director's assistant) were a part of the new consent form intervention team since they are the sole presenters of the new consent to the guardians.

The auditing tool (see Appendix F) was used to collect the demographic and other data for the children participants. The physical copies of the consents were stored in a secure location at the facility. If the facility was lacking the demographic and vaccination status of the child, the DNP student and the NP manually audited the KY Immunization Registry (KYIR) to obtain this information. The HPV vaccines necessary for completion of the series were monitored and tracked to find the number of children who completed the series or if the series' completion fell outside the intervention project window. This audit was vital to determine if there was a change in consent and overall vaccination status of the children for quality improvement outcomes.

Four weeks after the educational intervention (see Table 1), the DNP student visited the facility and met with the NP and the program director's assistant to address all remaining questions and concerns the staff had regarding the educational session information. Since the consent was implemented four weeks after the educational intervention, the DNP student conducted an eight-week follow-up to determine and address any issues with the new consent roll-out.

#### Table 1

	October	November	December	January	February	March	April	May	June
	2023	2023	2023	2024	2024	2024	2024	2024	2024
Pre-	Х	Х	Х	Х					
Intervention									
Data Collection									
Educational					Х				
Session (Feb									
1 <sup>st</sup> )									
Consent						Х			
Implementation									
and Four Week									
Program									
Check-in									
Eight Week							Х		
Consent									
Check-In									

Intervention and Data Collection Timeline

Post-	Х	Х	Х	Х	
Intervention					
Data Collection					
Program					Х
Completion					

# **Resources and Supplies**

Various supplies were needed for this project to be a success. Since the staff members donated their lunch hour, the facility was not required to pay them for their participation in the intervention. The average hourly wage for a registered nurse with five years' experience is \$34/hour (RN with five years' experience at Norton Healthcare). This determined the average cost the DNP student had accrued for their time spent with this project presenting the information and collecting the data to be \$595. The facility's meeting room was supplied free of charge. Lunch and refreshments from Panera Bread cost \$92, with an average of \$15 per person including beverages, and was based on a catering package.

A projector that connected to the student's laptop cost \$79.99 based on Amazon's current market price. According to Target, a 500-count stack of paper was \$5.59, and only 30 pages were needed for this project. This included four pages for pre-and post-test (two pages per test), one for the preamble, and one for the new consent, for a total of 30 pages, which amounted to 33 cents for paper. Ink, on average, per Office Max costs 6.9 cents per page, bringing the project ink total cost to \$2.10. Office supplies needed were six pens with a total price of 54.5 cents; on Amazon, a 60-count was \$5.44. Also, folders were needed to help organize each educational material for the staff. A 12-pack of folders on Amazon was \$18; therefore, folders cost \$9. The total budget for this project was \$778.64 (see Table 2). The DNP student covered all costs associated with this project.

#### Table 2

**Project Budget** 

Item	Expenses
Meeting Room for Presentation	\$0
Projector for Presentation	\$79.99
Time taken by this student to present and	\$595 (\$34/hour)-17.5 hours
collect information from consent forms	
Lunch and Refreshments from Panera Bread	\$92
Office Supplies: 6 folders, 6 pens, copied	\$11.98
handouts (including ink)	
Laptop	\$0
Protected Information System (CardBox)	\$0
Total:	\$778.64
Revenue Change for the facility	\$0
Improved quality of care and safety	Average cost of a 2-year treatment for
(decreases in morbidity and mortality for	cervical cancer \$93,200
children in the future)	

#### **Measures and Proposed Evaluation Plan**

This multi-method intervention aimed to increase HPV vaccination and consent rates at the residential facility. The goal was for the process change to lead to the overall project objective and benefit the facility's current and future children via increased HPV vaccination rates.

## **Process Measures**

Process measures included staff adherence to providing accurate HPV information during the admission process (reviewed during the educational session), which was verified at the postintervention four-week check-in. The second process measure, staff adherence to using the new consent, was delayed, due to the consent not being approved until four weeks after the educational session, and was verified at the week eight check-in. The final process measure was guardians HPV vaccine consent rates which were measured in week 16.

#### Pre/Post-Test of HPV/HPV Vaccine Knowledge

The participants who attended the educational session took the post-test, which consisted of 10 multiple-choice questions, (see Appendix E) created by the CDC (2023b) for continuing

education credit after the presentation of You Are the Key to HPV Cancer Prevention (see Appendix A). The post-test was used as a pre-test to evaluate the baseline understanding and knowledge of the staff regarding HPV and the HPV vaccine before the educational intervention. The test included topics such as the current recommended dosing schedule, reasons guardians decide to vaccinate, the importance of clinician recommendation, common cancers caused by HPV in both men and women, and examples of effective recommendations. There was no need to create a new test to evaluate the effectiveness of the educational session, as this one was already created. Unfortunately, there were no posted validity or reliability statistics regarding this test. The pre- and post-tests were scored on a scale from zero to 10. Scoring a zero would indicate answering all 10 questions incorrectly (0%) and scoring a 10 would indicate all questions were answered correctly (100%). The CDC granted permission (see Appendix I) to use their post-test and the educational PowerPoint.

#### **Retrospective Chart Audit of HPV Consent and Vaccination Rates**

The project goal was to have at least 90% of the newly admitted children consented and vaccinated for HPV. This was determined by conducting retrospective chart reviews to determine the HPV vaccination status of newly admitted children between October through December 2023 via the chart auditing tool for pre-intervention data. Post-intervention data was collected through the months of February through April 2024 (see Table 1).

Due to the new 30-day vaccination policy, three months of admissions were monitored over four months since the children admitted in month three may not become vaccinated until the fourth month. If children were discharged from the facility, vaccination status was verified in the KYIR.

#### Demographic Data

Demographic data was limited to what data and information the facility had available on the resident via their charting system or the KYIR. The facility had access to the residents' current vaccination status, consent status, age, race, gender, geographic location, insurance type, and guardianship status. The NP stated that when the parent was the legal guardian, more demographic data was available; however, some information was limited if the legal guardian was a social worker. If the resident was discharged from the facility, fewer demographic variables were accessible; therefore, demographic data was limited to what was available in the KYIR. Demographic data of the staff was not collected in order to maintain staff confidentiality.

#### **Data Analysis**

IBM Statistical Package for the Social Sciences (SPSS) Statistics Version 28.0.1.1 was used to analyze the quantitative data obtained from this project. The pre- and post-intervention HPV vaccination and consent rates were compared by calculating the percent of change. A statistical analysis via a paired sample t-test of the average scores was performed on the pre- and post-test scores. A paired sample t-test was the most appropriate statistical test to perform since the same participants were assessed using the same measurement tool; however, due to the small sample (n=5) for the educational session, it was unlikely to achieve statistical significance.

Descriptive statistics were used to analyze demographic data and characteristics of the children. Age is a continuous variable and was reported in terms of measures of central tendency (mean, median, mode, and range). Race, gender, insurance status, and guardianship status were all nominal data and were reported as population percentages. A Pearson's chi-square analysis was run to assess for a significant relationship between the children's county of residence and whether they were consented and vaccinated within 30 days of admission. The children were either residing in a rural, micropolitan, or metropolitan county based on their zip codes compared

to the 2020 census (U.S. Census, 2020). Pre-intervention HPV vaccine consent and vaccination rates were compared to post-intervention consent and vaccination rates. This was continuous data, and the total number of children consented to and vaccinated was divided by the total population who could receive the vaccine. The percentage of change was calculated to show an increase or decrease in rates.

To evaluate the process components, staff's continued usage of the educational session information was evaluated at four and eight weeks after the intervention. Additionally, eight weeks after the educational session, an evaluation of the implementation of the new consent form was conducted.

Barriers to data analysis and collection included the facility's current process of utilizing paper consents during the admission process. This information must then be analyzed by the staff members and input into the computer system, thereby, allowing for possible human error and potentially inputting the wrong information into the system. After the vaccine records were uploaded to the facility's computer system and the KYIR, the facility NP evaluated each child's vaccination status and identified which vaccines were needed. The NP then placed the order in the child's chart and communicated with another staff member to place the child on the schedule for the next vaccine clinic day. The vaccines were then ordered accordingly and given during vaccine clinic hours.

Another barrier to evaluation was the vaccination series completion falling outside the research window. While the intervention was implemented for each child newly admitted to the facility, some children received an HPV vaccine outside the evaluation window mainly due to needle supply issues. A final barrier to data analysis and collection was the prompt disposal of the child's electronic medical record when they were discharged from the facility. The NP stated

that vaccination statuses and consents were available on the KYIR, but demographic data may be limited. The discharge date was also difficult to ascertain as this is not easily found in the medical record or stored after the child is discharged.

Facilitators to the evaluation process included the implementation of the facility's new policy requiring newly admitted children to have all missing vaccines updated within 30 days of the first physical exam performed by the facility's NP.

#### Results

#### **Pre-Intervention Demographic, Consent, and Vaccination Rates**

Prior to the educational intervention, eight participants (see Table 3) were identified as having met the inclusion criteria. The mean age of the pre-intervention participants was 13.38 years old and the median and most common age was 13 years old (see Table 4). Two of the eight children were already fully vaccinated (25% of the population); therefore, their guardians were not eligible to consent to the HPV vaccine and these children were not followed through to completion of this project. Of the six children who needed to complete or initiate the HPV vaccine series, only four guardians consented to the vaccine for an initial consent rate of 66.67% for newly admitted children (see Table 6). Of the four children who were consented to and could receive the vaccine, only two children received the HPV vaccine within the month policy indicating that there was a 50% pre-intervention vaccination rate (see Table 6).

#### Table 3

	Pre-In	tervention (n=8)	Post-In	tervention (n=18)
Characteristic	n	%	n	%
Gender				
Male	4	50	10	55.6
Female	4	50	8	44.4
Age				

#### Data from Chart Audit Tool

9	0	0	1	5.6	
10	0	0	3	16.7	
11	0	0	1	5.6	
12	1	12.5	5	27.8	
13	4	50	4	22.2	
14	2	25	1	5.6	
15	1	12.5	3	12.7	
Insurance					
State Funded	8	100	17	94.4	
Private	0	0	1	5.6	
Race					
White/Caucasian	6	75	14	77.8	
Black/African American	0	0	2	11.1	
2 or more races	2	25	2	11.1	
Guardianship					
Parental	1	12.5	11	61.1	
State	6	75	6	33.3	
Relative	1	12.5	1	5.6	
County Size					
Rural	4	50	4	22.2	
Micropolitan	0	0	5	27.8	
Metropolitan	4	50	9	50	
Vaccine Status on Admission					
Complete	2	25	7	38.9	
Partially Received	5	62.5	3	16.7	
Naive	1	12.5	8	44.4	
*Consented to HPV Vaccine					
Yes	4	66.67	9	81.8	
No	2	33.33	2	18.2	
*Did not include children who had completed the HPV vaccine series previously					

\*Did not include children who had completed the HPV vaccine series previously

# Table 4

Age Demographic Descriptive Statistics

Age Demographics	Pre-Intervention (years)	Post-Intervention (years)
Mean	13.38	12.28
Median	13	12
Mode	13	12
Range	3	6
Minimum Age	12	9
Maximum Age	15	15

**Educational Session Pre- and Post-Test Results** 

The CDC post-test for You Are the Key to HPV Cancer Prevention was utilized as a preand post-test to determine if there was any change in HPV and HPV vaccine knowledge. Although a modified version of the educational session was utilized, the key points from the test were still discussed. The mean score increased from 68% to 82% post-educational session (see Table 5). A paired sample t-test was performed between the mean scores of the pre-and post-test which yielded a p-value of 0.052 (t=-2.75).

### Table 5

Frequencies of Pre-and Post-Test Scores	Pre-Test	Post-Test
Mean	68%	82%
Median	60%	80%
Mode	60%	80%
Range	50-90%	70-100%
Score Frequencies		
50	1	0
60	2	0
70	0	1
80	1	3
90	1	0
100	0	1

Frequencies of Pre-and Post-Test Scores

# Post-Intervention Demographic, Consent, and Vaccination Rates

For the post-intervention data, there were a total of 18 participants (see Table 3). The mean age of the post-intervention participants was 12.28, with the median and most common age being 12 years of age (see Table 4). Both demographic sets had similar average ages, with the post-intervention participants being slightly younger. Seven of the 18 children were already fully vaccinated (38.9% of the population); therefore, their guardians were not eligible to consent to the HPV vaccine and these children were not followed through to completion of this project. Of the 11 children who needed to complete or initiate the HPV vaccine series, nine guardians

consented to the vaccine for a post-intervention consent rate of 81.8% for newly admitted children. There was no relationship between the children's county of residence and whether their guardians consented to the HPV vaccine (n=13; p=0.90). There was also no relationship between the children's county of residence and whether they were vaccinated within 30 days of admission (n=13; p=0.21).

To calculate the percent change, previously vaccinated children were not included in this rate. There was an increase of 22.69% in the consent rates for this population. Of the nine children who were consented and could receive the vaccine, only four received the HPV vaccine within the month policy indicating that there was a 44.4% post-intervention vaccination rate; this resulted in a decrease of 11.2% in HPV vaccination rates post-intervention rates.

#### Table 6

#### Pre-and Post-Intervention Consent and Vaccination Rate

	Pre-Intervention	Post-Intervention	Percentage of Change
Consent Rates	66.67%	81.8%	+22.69%
Vaccination Rates	50%	44.4%	-11.2%

#### Discussion

The goal of this project was to have more than 90% of newly admitted children and adolescents consented and vaccinated for the HPV vaccine. This project aimed to increase staff HPV and HPV vaccine knowledge by increasing pre-and post-test scores and implementing an updated evidence-based consent form. Increasing the HPV and HPV vaccine knowledge and consent rates were both a success. However, the final aim was to increase vaccination rates as evidenced by an overall increase in post-intervention rates when compared to pre-intervention rates. While it was a success in that the consent rates were increased, the overall vaccination rates did not increase but rather decreased.
### **Interpretation of Results**

### **Educational Session**

Regarding the educational session, it was concluded that the p-value of 0.05 approached statistical significance; however, clinical significance is very apparent in the increase in the mean scores of the exams. At the four- and eight-week check-in, the staff stated they had no questions regarding the vaccine and that there were no questions the guardians asked that they could not answer.

#### **Change in Consent and Vaccination Rates**

During the eight-week check-in, the program director's assistant was asked how the new consent process was working as she is often the sole healthcare team member obtaining consent for all vaccines. The program director's assistant stated there were no current issues with the new consent, and the guardians seemed genuinely very receptive to the one consent form versus the previous four consent forms. After the new consent and evidence-based education, there was an increase in consent rates. However, while the assumption could be made that if consent rates increase, vaccination rates should also increase, this was not the case. There was a negative percent change in the vaccination rates potentially due to various factors. Four of the five children who needed to get vaccinated in the post-intervention group were unable to get vaccinated due to a shortage of appropriate needle sizes and gauges at the facility. One child was unable to get vaccinated due to having dual insurance policies of state and private insurance. These children have still not been vaccinated over a month later suggesting that there are still challenges in getting the children vaccinated. Once the opportunity was missed for the children to get vaccinated, there were no built-in solutions to troubleshoot these problems and get them

vaccinated within the policy window. The clinical significance was that there was a system failure and once the system failed, there was not a built-in way for it to improve.

#### **Project Outcomes**

This project impacted the staff's perception of the HPV vaccine via the educational session, which matriculates down to the parents who have questions regarding the vaccine during admission. The increase in consent rates would expectantly increase vaccination rates, but this was not the case. Consent rates did increase, but vaccination rates declined due to factors outside the control of this student and the project. Ultimately, the goal of having at least 90% of children consented and vaccinated for HPV was not met.

#### **Comparison to the Literature**

When compared to the literature, this QI project confirmed the findings previously discussed. The evidence claimed that a multi-method intervention that included education on a strong healthcare staff recommendation, general HPV and HPV vaccine knowledge, motivational interviewing, and cancer prevention verbiage along with a new evidence-based consent form would increase consent rates, which would consequently increase vaccination rates. While this project addressed the issues regarding the admission process, it did not address the actual administration of the vaccine, which slowly was uncovered to have some complications.

#### **Costs/Trade-Offs to the Project**

Ultimately, there were no costs or trade-offs necessary for this project. There was one child who had both private and state insurance, which did prove to be a hindrance to that child becoming vaccinated. Staff were to verify with this child's insurance to determine which policy would cover the cost of the vaccination, but this has not yet been completed.

#### Limitations

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The first unanticipated limitation of this project was the provider recommendation letter and video, which provided an equal and strong recommendation for all vaccines, were unable to be implemented at this time due to changes in staffing. Without this evidence-based portion of the intervention, the guardians may not have open communication with the provider which could have made them feel more at ease with the HPV vaccination. This is an intervention that should be re-evaluated for future QI projects once staffing changes have stabilized.

Another limitation was that not all identified staff members were able to attend the educational session. The RN was unable to attend due to simultaneously occurring work duties, therefore, only five of the six proposed staff members were in attendance. All staff members needed to attend the educational session as this was not only where the HPV information was presented, but also where the new consent was introduced. While this session itself could not be recorded due to needing consent from all participants, the pre-recorded CDC version of You Are the Key to HPV Cancer Prevention was available online for the staff member who could not attend.

The third limitation of the project was that the consent was unable to be simultaneously implemented with the educational session due to the delay in the approval process. The consent was approved and implemented four weeks after the educational session. This could skew the data as the legal guardians of children admitted the first month after the educational session did not have access to this new consent.

The fourth limitation is the generalizability to the general population. This population is very specific to children with high ACE scores and who have various psychiatric comorbidities. There was a sample size of 26 children within this project, which with a maximum population of 160 children, this sample size might not be representative of this entire population. The final unanticipated limitation was that despite the policy of requiring all children to become vaccinated or at least initiate a vaccine series within 30 days of admission, this was not occurring in all cases. While the NP was placing the orders for each child to receive their vaccine, there was a delay in administering the vaccine during clinic days. In the month of April, many children were unable to become vaccinated during the vaccine clinic due to the clinic running out of the correct gauges and lengths of needles needed.

#### Conclusion

#### **Implications for Practice**

This quality improvement project showed an increase in consent rates; however, it did illuminate a decrease in vaccination rates of the pre-intervention data when compared to the post-intervention data. This project targeted the healthcare staff and the parents via the multi-method interventions of the educational program and the change in the consent form. However, it was discovered that there also lies an issue within the administration of the vaccine due to shortages of supplies. The educational session approached statistical significance (p=0.05) with an increase in overall mean scores on the pre-and post-tests.

It is recommended that the staff continue to use the new consent form as well as the information learned from the CDC presentation. With this knowledge and the new evidence-based consent form, the HPV vaccine is recommended in the same manner and importance as all other vaccines, and with the increase in consent rates, this project helped further provide evidence for these recommendations.

#### Sustainability and Usefulness of this Project

This project has remained sustainable for the entirety of the intervention timeframe. The consent is still being utilized in practice and the staff obtaining consent have expressed their

satisfaction with the new consent. The staff also indicated there have not been any questions asked by the parents that they could not answer after the educational session. The facility received all statistical data from pre- and post-test scores and vaccination rate changes. It is feasible for other facilities that have similar barriers to their vaccination consent process to adopt the new consent form in this project as well as the educational session for their staff members who might lack formal education regarding the HPV vaccine. This project could be easily replicated and modified for other facilities.

#### **Suggested Next Steps**

In the final step of the PDSA cycle, Act, modifications for future QI projects or interventions were determined. While the consent rates increased with the multi-method interventions, it illuminated an area for concern for possible future QI projects. The provider recommendation letter and video were unable to be implemented due to staffing changes, so this could be utilized in the future to help solidify the increase in consent rates. While the consent will be utilized for future admissions, the modified educational session was not recorded, therefore, a future project could identify a plan for future healthcare staff education sessions. Future QI projects could address the barriers to the administration of vaccines within the 30-day policy as well as needle supply issues. Possible ways to overcome this issue would be supply verification before the vaccine clinic days, more vaccine clinic days per month, or if there is a severe miscalculation like in the past, have the flexibility to add another vaccine clinic day to catch up. While this project illuminated consent and administration issues, it did not address the guardians who declined the vaccine.

Another possible QI project could be to create a process to follow up with guardians who declined the vaccine originally. This could be via telephone or email through an electronic

reminder system. Some of the children who are admitted reside at this facility for almost a year, therefore there is ample time to follow up with the guardians and provide some additional education. Emerging literature is focusing on technological uses in helping educate and remind guardians about their child's HPV vaccine. Regular reminders via various electronic media regarding doctors' visits, providing educational resources via social media, and awareness campaigns provided convincing evidence for increasing vaccination rates (Khalid et al., 2023). However, there is conflicting evidence regarding electronic media improving vaccine uptake behaviors. Mobile interventions assisted parents and adolescents in becoming more confident in discussing the HPV/HPV vaccine with healthcare staff, nevertheless, alone these interventions were not sufficient to cause a behavior change and increase in vaccine consent behaviors (Choi et al., 2023).

#### Summary

This QI project's findings showed an increase in staff's knowledge about HPV and the HPV vaccine. There was an average increase of 14% in the pre-versus post-test scores, with a p-value of 0.05, which approached statistical significance. As well, this project also showed an increase in the HPV vaccine consent rates, however, due to limitations previously discussed, it highlighted an overall decrease in HPV vaccination rates. Vaccine consent rates had a 22.69% percentage of change increase, while the actual vaccination rates had an 11.2% percentage of change decrease.

A multi-method intervention was needed as evidenced by the extensive literature provided (Beck et al., 2021; Efua Sackey et al., 2022; Holloway, 2019; Perkins et al., 2020; Vollrath et al., 2018). While this intervention targeted primarily the healthcare staff members and parents, it did not address any possible clinic administration issues. To continue the PDSA cycle and hopefully increase HPV vaccination rates, any future QI projects should address clinic-

specific issues to continue quality improvement.

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### Appendix A

You Are the Key to HPV Cancer Prevention PowerPoint Presentation and Script

Rosenblum, H. G., & Wodi, A. P. (2022). *You are the key to HPV cancer prevention*. Centers for Disease Control and Prevention. <u>https://www2.cdc.gov/vaccines/ed/hpv\_key/yatk.asp</u>



# Disclosures

- CDC, our planners, our content experts, and their spouses/partners wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias.
- Content will not include any discussion of the unlabeled use of a product or a product under investigational use.
- CDC did not accept commercial support for this continuing education activity.



These are the disclosures of the CDC.

### Objectives

- 1. Describe the burden of HPV infection and disease in the United States.
- 2. Define the importance of HPV vaccination in cancer prevention.
- 3. Describe recommendations for HPV vaccination for adolescents and adults.
- 4. Describe the rationale for the routine HPV vaccination at age 11 or 12 years.
- 5. List two components of an effective HPV vaccine recommendation.
- 6. Identify relevant and compelling information to share with parents about HPV vaccine to help inform their decision to vaccinate their child.
- 7. Locate current immunization resources to increase knowledge of the team's role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.



Today we will discuss these objectives listed on the slide. The focus will be on how to recommend the vaccine and answer guardians questions.







We will start with Understanding the Burden of HPV and its related cancer and illnesses.

### **HPV Types Differ in Their Disease Associations**



There are over 120 different types of HPV in the mucosa and skin. The high-risk types of HPV 16 and 18 can lead to cancer. The HPV vaccine can prevent against HPV prevalence, genital warts, and cervical lesions.

### **HPV Infection**

- Most females and males will be infected with at least one type of mucosal HPV at some point in their lives
  - Estimated 42 million Americans currently infected
  - 13 million persons with a new infection/year in the US
  - HPV infection is most common in people in their teens and early 20s
- Most people will never know that they have been infected

vis et al. Sex Trans Dis 2021



HPV will affect both males and females and is most common in teens and early 20s. An estimated 42 million Americans are currently infected with HPV and unfortunately most people will never know that they were infected.

## Number of HPV-Associated and HPV-Attributable Cancer Cases Per Year, U.S., 2014–2018



ides anal and rectal squamous cell carcinomas

ach cancer type, we estimated HPV-attributable cancers by multiplying the number of cancer cases by the percentage attributable to HPV based on a genotyping study. We estimated that 36,500 cancers (79%) attributable to HPV each year during 2014–2018. Of these, we estimated that 33,700 cancers could have been prevented by the 9-valent HPV vaccine, including 29,500 caused by HPV types 16 and 18 and 4,200 ed by HPV types 31/33/45/52/58. HPV-negative cancers are not shown in the graph; it is estimated that about 10% of cervical and anal cancers, 30% of oropharyngeal, vaginal, and vulva cancers and 40% of penile ers are HPV-negative. YOU ARE THE KEY T CANCER PREVENTIO

es: Data are from cancer registries participating in CDC's National Program of Cancer Registries and/or NCI's Survellance, Epidemiology, and End Results program that lata quality criteria for 2011–2015, covering 100% of the U.S. population. The analysis and methods were based on: Viens, et al. MNWR Morb Mortal Wily Rep. 2016 //www.cdc.gov/cancer/uss2/pdf/USCS-DataBrief-No26-December 2021-h.pdf

This visual lists the various types of cancer that HPV can cause and its burden on males and females. From the graph we can see that it is essential for males to get vaccinated as their prevalence of oropharynx cancer is even higher than women's cervical cancer.



# HPV-Associated Cancer Rates by Sex, Race, and Ethnicity, United States, 2014–2018

It is also important to understand the disease burden across sex, race, and ethnicity. Women hold a slightly higher incidence in each race and ethnicity, however, both sexes are almost equally affected now. These HPV related cancers occur in all races and ethnicities.



Now we will discuss the HPV vaccine and how to recommend it.

### **HPV Vaccines**

- Recombinant L1 capsid proteins that form "virus-like" particles (VLP)
- Non-infectious and non-oncogenic
- Produce higher levels of neutralizing antibody than natural infection



**HPV Virus-Like Particle** 



When the vaccine is introduced to the body, the body stimulates antibody production and when those antibodies encounter HPV in the future, the antibodies will bind to the virus and prevent it from infecting cells. It is also important to highlight that the vaccine produces a larger number of antibodies than the natural HPV infection does. This vaccine does not contain a live infection or anything that causes cancer itself.

### **HPV Vaccine Comparison**



This diagram shows how the vaccines have evolved over the years from originally protecting against 2 types of HPV and now currently the vaccine protects against 9 strains. The most recent vaccine protects against genital warts, 2 strains that cause 73% of cervical cancers and 81% of all HPV attributable cancers, as well as 5 strains that accounts for 11% of HPV attributable cancers. Again, the most recent vaccine accounts for 9 different strains of the HPV vaccine.

### **HPV Vaccine Recommendations**

### CDC recommends routine vaccination at age 11 or 12 years to prevent HPV cancers

- The vaccination series can be started at age 9 years.
- Two doses of the vaccine are recommended if the series is started before the 15<sup>th</sup> birthday.
- The second dose of the vaccine should be administered 6 to 12 months after the first dose.

ites, et al. MMWR Morb Mortal Wkly Rep. 2016



HPV Vaccine Recommendations

The CDC recommends HPV vaccination to begin at age 11 or 12 to prevent HPV related cancers. The vaccination series can be started at age 9. Two doses of the vaccine are recommended if the series is started before the 15<sup>th</sup> birthday. The second dose of the vaccine should be administered 6-12 month after the first dose.

### HPV Vaccine Recommendations: Catch-Up/Late

- Vaccination for everyone through age 26 years if not previously adequately vaccinated.
- Vaccination is not recommended for everyone older than 26 years.
  - However, some adults ages 27 through 45 years may decide to get the HPV vaccine based on discussion with their clinician, if they were not adequately vaccinated when they were younger.
  - HPV vaccination of people in this age range provides less benefit, as more have already been exposed to HPV.

ites, et al. MMWR Morb Mortal Wkly Rep. 2019



HPV Vaccine Recommendations: Catch up/Late Vaccination is for everyone through age 26 if not previously vaccinated. Vaccination is not recommended for everyone older than 26 years of age, however some adults aged 27-45 may decide to get the HPV vaccine after discussion with their clinician. HPV vaccination in this age range provides less benefit, as they have more than likely already been exposed to HPV.

### **HPV Vaccine Dosing Schedule, United States**

Population	Number of vaccine doses	Interval between doses
Persons initiating vaccination at <b>9 through 14</b> years, except persons with immunocompromising conditions	2	0, 6–12 months*
Persons initiating vaccination at <b>15 through 26</b> years and persons with immunocompromising conditions initiating vaccination at 9 through 26 years	3	0, 1−2, 6 months+

\* In a 2-dose schedule of HPV vaccine, the minimum interval between first and second doses is 5 months.

+ In a 3-dose schedule of HPV vaccine, the minimum intervals are 4 weeks between the first and second doses, 12 weeks between the second and third doses, and 5 months between the first and third doses

 Persons are considered adequately vaccinated if they completed a recommended schedule with 9vHPV, 4vHPV, or 2vHPV vaccine.

tes, et al. MMWR Morb Mortal Wkly Rep. 2016



The HPV Dosing Schedule

Persons aged 9 to 14 who initiate the vaccine (except for people who are immunocompromised) will receive 2 vaccine doses. There should be 6 to 12 months between the doses.

Persons aged 15 to 26 and people who are immunocompromised starting the vaccination aged 9 to 26 years will receive 3 doses of the vaccine. In a 3 dose schedule, the minimum intervals are 4 weeks between the first and second doses. 12 weeks or 3 months should be between the second and third doses, and 5 months between the first and third doses.

It is important to also point out that if children vaccinate before 15, then they only have to receive two vaccines instead of three. No child wants to have to get another shot.

### **HPV Vaccine: Contraindications and Precautions**

- HPV vaccines should not be given to anyone who has had a severe allergic reaction to a previous dose or to a vaccine component, including yeast
- HPV vaccination is not recommended for women who are known to be pregnant; wait until after pregnancy to vaccinate
- HPV vaccination may be delayed in persons with moderate or severe acute illness with or without fever

s://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html



HPV Vaccine: Contraindications and Precautions HPV vaccines should not be given to anyone who has had a severe allergic reaction to a previous dose or to a vaccine component, including yeast. HPV vaccination is not recommended for women who are pregnant. The HPV vaccine may be delayed for anyone who currently is experiencing an acute illness with or without fever.



We will now discuss HPV vaccine safety.

# **CDC Vaccine Safety Monitoring Systems**

System	Collaborators	Description	
Vaccine Adverse Event Reporting System (VAERS)	CDC and FDA	Frontline, spontaneous reporting system to detect potential vaccine safety issues	
Vaccine Safety Datalink (VSD)	CDC and 9 integrated health care systems	Large, linked database system used for active surveillance and research ~13 million members (~4% of US pop)	
Clinical Immunization Safety Assessment (CISA) Project	CDC and 7 academic centers	Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research	



These are three safety monitoring systems that monitor HPV vaccine safety in the US.

# **Evaluating and Monitoring:** HPV Vaccine Safety in the United States

#### Monitoring of VAERS reports

- Clinical review of serious reports and other prespecified adverse events
- Premature ovarian insufficiency, postural orthostatic tachycardia syndrome, pregnant persor
- Data mining to identify disproportional reporting
- Vaccine Safety Datalink
  - Near real-time monitoring of prespecified outcomes
  - Evaluation of specific adverse events
    - Venous thromboembolism, Guillain-Barre Syndrome, primary ovarian insufficiency, long-terr risk of developing type-1 diabetes, spontaneous abortion
- Manufacturer post-marketing commitments
  - Observational study to further characterize the safety and long-term studies
  - Pregnancy registry

s://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html



This is a further in-depth description of what each of the three vaccine safety monitoring systems are. You would report an adverse reactions to these systems.

### **HPV Vaccine Safety in the United States**

- We have more than 15 years of HPV vaccine safety data.
- With more than 135 million doses of HPV vaccines distributed in the United States, there are robust data showing that HPV vaccines are safe.
- As with all vaccines, CDC and FDA continue to monitor and evaluate the safety of HPV vaccines.
- Clinicians can reassure parents who may have concerns about HPV vaccination.

s://www.cdc.gov/hpv/hcp/vaccine-safety-data.html



HPV vaccine safety in the US: We have more than 15 years of HPV vaccine safety data More than 135 million doses of the HPV vaccine have been given in the US As with all vaccines, the CDC and FDA recommend continuing to monitor and evaluate the safety of the vaccine. Clinicians can reassure parents who may have concerns about the HPV vaccination.

### **HPV Vaccine Adverse Reactions**

- Reactions after vaccination can include:
  - Injection site reactions: pain, redness, and/or swelling in the arm where the shot was given
  - Systemic: fever, headaches, nausea, muscle or joint pain
- Life threatening allergic reaction can occur after any vaccine, including HPV vaccines
- Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
  - Patients should be seated (or lying down) during vaccination and remain in that position for 15 minutes

Vaccine Safety and Effectiveness Data | CDC s://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html , et al. Hum Vaccine Immunother. 2016



We also need to discuss the possible adverse reactions to the vaccine. Reactions after vaccination can include: injection site reactions such as pain, redness, and swelling in the arm where the shot was given. Systemic reactions include fever, headaches, nausea, muscle or joint pain.

Life threatening allergic reactions can occur after any vaccine, including the  $\ensuremath{\mathsf{HPV}}$  vaccine

Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including the HPV vaccine.

Position the patient in a seated or lying down position during the vaccination and remain in that position for 15 minutes. People most often pass out because they don't stay in this position for the full 15 minutes.







We will now discuss the impact of the HPV vaccination program for immediate and future outcomes for the children
## Impact of HPV Vaccination Programs



- Post-licensure evaluations are important to assess real-world effectiveness of vaccines
- Population impact against early and mid outcomes has been reported in many countries

; cervical intraepithelial neoplasia

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Impact of HPV Vaccination Programs:

It is important to understand the immediate and prolonged benefits of this vaccine. By protecting the child from these HPV strains this protects the child from contracting the virus as well as prevents the virus from becoming precancerous and ultimately cancer. The HPV vaccine prevents against the original HPV infection which could cause genital warts or eventually cancer.



## Vaccine-Type HPV Prevalence Among Females, NHANES

This chart shows how the prevalence of the strains the HPV Vaccine protects against has declined over the years.



## Cervical Precancer Incidence Rates among Screened Women, HPV IMPACT Project, 2008-2015

The vaccine was introduced in 2006 and this chart starts at 2008 so people were becoming vaccinated prior to this. It is easy to see the decrease in cervical precancer incidence rates over time. After 5-8 years of vaccination, among 13-to-19-year-old females HPV 16/18 (which if we remember is the most common cancer-causing strains) decreased by 83%.

## **HPV Vaccine Duration of Protection**

- Studies suggest that vaccine protection is long-lasting
- No evidence of waning protection
  - Available evidence indicates protection for at least 12 years
  - Multiple studies are in progress to monitor

CIP. Summary Report. June 22-23, 2016; Ferris, et al. *Pediatrics*. 2017; oldstone, et al. *Lancet*. 2021; Kjaer, et al. EClinicalMedicine. 2020



HPV Vaccine Duration of Protection If a parent asks how long this vaccine will protect their child, you can educate that studies have suggested that the vaccine protection is long-lasting. There is no evidence of waning protection and some evidence indicated protection for at least 12 years.

## HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

#### **HPV Vaccine Is SAFE**

- Benefits far outweigh any potential risks
- Safety studies findings for HPV vaccination are reassuring and similar to MenACWY and Tdap vaccine safety reviews

#### **HPV Vaccine WORKS**

 Population impact against early and mid outcomes has been reported in multiple countries

#### **HPV Vaccine Protection LASTS**

- Studies suggest that vaccine protection is long-lasting
- No evidence of waning protection



The HPV vaccination is safe, and the benefits far outweigh any potential risks. The HPV vaccination works, and the HPV vaccine protection lasts



We will now discuss HPV vaccination coverage from around the US over various time periods.

## HPV Vaccination Coverage among Adolescents Aged 13-17 Years, NIS-Teen, United States, 2006-2020



surce: Pingali C, Yankey D, Elam-Evans LD, et al. National, Regional, State, and Selected Local Area Vaccination sverage Among Adolescents Aged 13–17 Years — United States, 2020. MMWR Morb Mortal Wkly Rep. 2021



This graph shows that adolescents are receiving other vaccines such as the TDAP and Meningococcal vaccines but are slower and less likely to receive the HPV vaccine which is concerning. This can be due to several factors which we will discuss later in the presentation.



## Vaccination Coverage Higher among Those Reporting a Recommendation

This graphic illustrates that when parents received a strong recommendation for the vaccine, they were more likely to vaccinate their child when compared to those whose clinician did not recommend the vaccine.

## **Top Reasons for Not Vaccinating against HPV**



This slide illustrates the top reasons for parents not vaccinating against HPV and the most common reasons include safety concern/side effects, the vaccine was viewed as not needed or necessary, and the vaccine was not appropriately recommended by the clinician. All of these reasons why parents are not vaccinating are areas we can intervene and help educate the parents.



## **Parents Place Similar Value on Vaccines**

This graph shows us that parents place similar value on all vaccines.



## Clinicians Underestimate the Value Parents Place on HPV Vaccine

Clinicians in general underestimate the value parents place on the HPV vaccine as evident by the graph.. These clinicians may not recommend the HPV vaccine as they should since they believe parents do not believe the HPV vaccine to be as important as other vaccines.







Now we will move on to talking about the HPV vaccination with parents and how to frame the conversations.

# Strong Evidence Base Supports the Importance of an Effective Recommendation

- HPV vaccination coverage was higher among patients whose parents reported receiving a recommendation.
  - An effective recommendation from you is the main reason parents decide to vaccinate
- Many mothers in focus groups stated they trust their child's clinician and would get the vaccine for their child as long as they received a recommendation from the clinician.

ilker, et al. MMWR. 2019; Smith et al. Vaccine. 2016; Unpublished CDC data, 2013



There is a strong evidence base that support the importance of an effective recommendation HPV vaccination coverage is higher among patients whose parents reported receiving a recommendation. An effective recommendation from you is the main reason parents decide to vaccinate.

## Make an Effective Recommendation: SAME WAY, SAME DAY

#### Group all the adolescent vaccines

 Recommend HPV vaccination the same way you recommend Tdap and meningococcal vaccines

#### **Recommend HPV vaccine TODAY**

 Recommend HPV vaccination the same day you recommend Tdap and meningococcal vaccines

wer, et al. Pediatrics. 2017



Even though the child will not receive their vaccines on the day of admission, you should recommend the HPV vaccine in the same way as other vaccines to make an effective recommendation. Already, you recommend the vaccine the same day as the other vaccines since you obtain consent for all the vaccines at once.

## **Bundled Recommendation**

Your preteen needs three vaccines **today** to protect against meningitis, HPV cancers, and pertussis.



ewer et al. Pediatrics. 2017



This is an example of how you bundle the recommendation for all vaccines. Your preteen needs three vaccines to protect against meningitis, HPV cancers, and pertussis.

## **Bundled Recommendation – Example 1**

Now that Sophia is 11, she is **due** for **three vaccines**. These will help protect her from the infections that can cause meningitis, HPV cancers, and pertussis.

We'll give those shots today.



Bundled Recommendation- Example #1

Now that Sophia is 11, she is due for three vaccines. These will help protect her from the infections that can cause meningitis, HPV cancers, and pertussis. Many parents accept the bundled recommendation. When a parent asks you a question about the vaccine, it is probably because they need reassurance from you.

Q: Why does my child need HPV vaccine?

HPV vaccination is important because it **prevents cancer**.

That's why I'm recommending that your child start the HPV vaccine series today.



Q: Why does my child need the HPV vaccine? The HPV vaccine prevents cancer.

## Q: What cancers are caused by HPV infection?

Persistent HPV infection can cause cancer of the cervix, vagina, and vulva in females, cancer of the penis in males, and cancers of the anus and the throat in both.

We can help prevent infection with the HPV types that cause these cancers by starting the HPV vaccine series today.



Q: What cancers are caused by the HPV infection?

HPV can cause all these cancers listed on the slide and we can prevent infection with the strains of HPV that can cause these cancers by getting the children consented for the vaccine.

## Q: Is my child really at risk for HPV?

HPV is a very common virus that infects both women and men.

We can help protect your child from the cancers and diseases caused by the virus by starting HPV vaccination today.



Q: Is my child really at risk for HPV? HPV is a very common virus that infects both women and men. We can help protect the children from cancers and diseases caused by the virus by getting them consented for the HPV vaccine.

## Q: Why at 11 or 12 years old?

#### When should the bike helmet go on?

- A. Before they get on their bike
- B. When they are riding their bike in the street
- C. When they see the car heading directly at them
- D. After the car hits them



Q: Parents may ask why start vaccinating at 11 or 12 years old?

- The same question could be asked when should the bike helmet go on?
- A. Before they get on their bike
- B. This slide provides an adjacent example of why there is a need to vaccinate children early against HPV and before their first exposure to HPV, just like you wear a helmet before the child crashes and becomes hurt.

## Q: Why at 11-12 years old? Video with Dr. Margot Savoy



ting to Parents Who Think Their Kids Don't Need HPV vaccine at Age 11 or 12: Dr. Savoy - YouTube



This clinician speaks about how to address parents who don't think their kids need the HPV vaccine starting at age 11 or 12.

Q: I'm just worried that my child will perceive this as a green light to have sex.

Studies tell us that getting HPV vaccine doesn't make kids more likely to start having sex.

I made sure my child (or grandchild, etc.) got HPV vaccine, and I recommend we give your child her/his first shot today.



Q: I'm just worried that my child will perceive this as a green light to have sex. Studies tell us that getting the HPV vaccine doesn't make kids more likely to start having sex.

### Q: How long can we wait and still give just two doses?

The two-dose schedule is recommended if the series is started before the 15th birthday.

However, I don't recommend waiting to give this cancerpreventing vaccine. Older teens have busier schedules and it becomes more difficult to schedule an appointment.

It's best to start the series today so your child is protected as soon as possible.



Q: How long can we wait and still give just two doses? If you start the vaccine series before the child's 15<sup>th</sup> birthday, then two doses of the vaccine can be given. However, I don't recommend waiting to give this cancer preventing vaccine. Older teens often have busier schedules, and it becomes more difficult to schedule an appointment. Its best to start the series as soon as possible. Q: I'm concerned about the safety of the vaccine. I read online that HPV vaccine isn't safe. Do you really know if it's safe?

> As of 2021, more than 135 million doses of HPV vaccines have been distributed in the United States since they were licensed. Data continue to show the vaccines are safe and effective.



Q: I'm concerned about the safety of the vaccine. I read online that the HPV vaccine isn't safe. Do you really know if it's safe? More than 135 million doses of the vaccine have been given in the US. Data continues to show the vaccine is safe and effective.

## Is HPV Vaccine Safe? Video with Dr. Alix Casler



This video addresses the vaccine safety.

## Q: Can HPV vaccine cause future fertility problems?

There is no evidence to suggest that getting HPV vaccine will affect future fertility.

However, women who develop an HPV precancer or cancer might need treatment that could limit their ability to have children.



Q: Can the HPV vaccine cause future fertility problems? There is no evidence to suggest that getting the HPV vaccine will affect future fertility. However, women who develop an HPV precancerous lesion or cancer, might need treatment that could limit their ability to have children.

## Q: Why should I get my child the HPV vaccine if it's not required?

School-entry requirements don't always reflect the current recommendations to keep your child healthy and often focus on prevention of highly contagious diseases.

HPV vaccine, along with other adolescent vaccines, will provide your child with the best protection.



Q: Why should I get my child the HPV vaccine if it's not required? School requirements for vaccines does not always reflect the current recommendations. The CDC recommends the HPV vaccine just as much as the other "school required" vaccines. Again, as we know, the HPV Vaccine can prevent a highly contagious disease and ultimately cancer.

### If a Parent Has Questions After Your Recommendation

- Listen to and respond to parents' questions.
  - Sometimes parents simply want your answers to their questions.
  - Your willingness to listen to parents' concerns will play a major role in building trust in you and your recommendation.
- If you encounter questions you do not know the answer to or information from sources you are unfamiliar with, it is best to acknowledge the parent's concerns and share what you *do* know.

bs://www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html



If a parent has a question after your recommendation, it is often due to the parents wanting to know your answers to their questions. Your willingness to listen to parents' concerns will play a major role in building trust in you and your recommendation. If you encounter questions you do not know the answer to, acknowledge the parents' concerns and share what you do know.

## If a Parent Declines Today...

- End the conversation with at least one action you both agree on.
- Refusal today may not be final. Revisit the conversation at the next opportunity.
- Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a declination form.



If parents decline the HPV vaccine today, it's okay to end the conversation and know that refusal today may not be final. If the opportunity arises at another interaction, the vaccine can be reintroduced.



The HPV vaccine is cancer prevention, and you all are the key!

#### Appendix B

Previous Facility HPV Vaccine Consent



Resident Name:

#### Consent or Declination Form for HPV (Gardasil) Vaccine

Human Papllomaxicus (HPV) is a common virus. HPV is so common that nearly all sexually active men and women get it at some point in their lives. There are many different types of HPV. Getting vaccinated early can stop these health problems from happening in our communities.

The HPV vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control (CDC) for boys and girls, as early as age 9. HPV vaccines are safe and effective. They can protect boys and girls against diseases (including cancers) caused by HPV when given in the recommended age groups. The HPV vaccine works by preventing the most common types of HPV that cause cervical cancer and genital warts.

It is given as a 3-dose vaccine over a 6-month period. Boys and girls aged 9 and above can start the vaccination series to protect them from the diseases and health problems HPV causes. If you have started the vaccine series we can assess which dose on the series you should get. If you have never received the vaccine, we can start the series now.

Please read the enclosed Vaccine Information Sheet (VIS) and indicate below whether or not you give permission for medical personnel to administer the vaccine.

\_\_\_\_\_ I have reviewed the enclosed VIS and have had the opportunity to ask questions. In signing this form, I acknowledge that I understand the information provide and have given permission for the HPV vaccine to be administered.

I have reviewed the VIS and decline permission for the HPV vaccine to be administered.

Signature of Parent/Guardian

Date

Signature of

Personnel

Date

#### Appendix C

#### New Consent Form



Resident's Full Name:	Parent/Guardian Name:
Date of Birth:	Relationship to Resident:

The vaccines to be received if not up to date include

0	IPV (Polio)*	0	Meningococcal*	0	Hepatitis B*
0	MMR (Measles,	0	Rotavirus *	0	Prevnar 13*
	Mumps and	0	Tdap (Tetanus,	0	HPV
	Rubella) *		Diphtheria and	0	Influenza
0	Varicella		Pertussis) *	0	COVID-19
	(Chickenpox) *	0	HIB (Haemophiles		(Moderna)
0	Hepatitis A*		Influenza B) *		

\*Required vaccinations by the state of Kentucky

#### Acknowledgement:

I have been provided with the Vaccine Information Statements (VIS), which includes information about the recommended and required vaccines, including their potential risks and benefits. I have had the opportunity to ask questions, which were answered to my satisfaction. I understand that vaccines are essential for prevention of serious and potentially life-threating disease.

I understand that vaccines are not without risks, but the benefits outweigh the risks. I understand that vaccines play a vital role in public health and help protect myself and those around me. **Consent:** 

I hereby consent to the administration of the vaccines listed above. I understand that I have the right to refuse any vaccination. It is my responsibility to inform the healthcare team of any prior adverse reactions to vaccines, known allergies, or other medical conditions that may hinder the patient's ability to safely receive vaccines.

#### Please check one of the boxes below:

- □ I consent and give my permission to all recommended CDC vaccines for my child.
- I consent to all recommended CDC vaccines except for \_
- □ I consent for only vaccines required by the state of Kentucky. Your child will not receive the HPV, Influenza, or COVID-19 Moderna vaccinations.

#### **Release of Information:**

I authorize and release the healthcare team to administer the above vaccines to the resident and to share immunization records with appropriate facilities and institutions to maintain a record of the vaccinations in compliance with state and federal laws.

Parent/Guardian Signature	Printed Name of Above Signature	Date
Staff	Title	Date

#### Appendix D

#### Proposed Provider Recommendation Letter/Video

Bellewood and Brooklawn Letterhead

Hello Parents and Guardians!

My name is Dr. Ashley Defamette. Doctor of Nursing Practice, APRN and I am the primary care provider for Seven Counties at Brooklawn and Bellewood. Any primary care needs your child has will occur on-site at Brooklawn and within 2 weeks of admission, your child will receive a full physical assessment and will have the opportunity to discuss any physical health issues they are experiencing. Common primary care issues that can be addressed at the clinic include addressing medication side effects, monitoring routine laboratory values, treating, but not limited to, common illness such as ear infections, sore throats, urinary infections, and injuries from sports or other physical activities. Immunization certificates are reviewed at this appointment and any child not up to date on their vaccines are identified.

Immunizations are a very important part of ensuring your child's health and wellbeing. Children living in a residential facility are at higher risk for communicable diseases. Being up to date on all vaccines helps protect your child from most preventable diseases. We follow the Centers for Disease Control vaccine schedule and administration guidelines and recommend all vaccinations available to your child.

During the admission meeting, you and your child will receive and review vaccine information sheets required by the Vaccines for Children Program. During the admission process, you will be presented with a vaccine consent form, and I encourage you to review this thoroughly. If your child is not up to date on their vaccines and qualifies for administration, vaccines are conveniently available on-site and will be given within 30 days of your child's admission. If you have questions or concerns about any of the medical services provided on-site, please contact our medical staff directly. Any of the medical staff will be happy to assist you.

Thank you,

Dr. Ashley DeJamette DNP, APRN Contact Information

Please scan the QR code below to see the message above from **Ashee** 

#### Appendix E

CDC Post-test to You Are the Key to HPV Cancer Prevention-2022 (Web on Demand)

1. For an 11 year old patient, what is the currently recommended, routine dosing schedule?
A)3 doses at 0, 6, 12 months
B)3 doses at 0, 1-2, 6 months
C)2 doses at 0, 4 months
D)2 doses at 0, 6-12 months

Rationale: For persons initiating vaccination before the 15th birthday, the recommended immunization schedule is 2 doses of HPV vaccine. The second dose should be administered 6–12 months after the first dose (for a 0, 6–12-month schedule).

**2.** For a 15-year-old patient receiving a three dose HPV vaccine series, what is the minimum interval between dose one and dose three?

A)3 months B)5 months C)6 months D)1 year

Rationale: For persons initiating vaccination on or after the 15th birthday, the recommended immunization schedule is 3 doses of HPV vaccine. The second dose should be administered 1–2 months after the first dose, and the third dose should be administered 6 months after the first dose (0, 1–2, 6-month schedule). The minimum interval between dose one and dose three in a 3-dose schedule is 5 months.

3. What is the main reason parents decide to vaccinate?
A) Recommendation by clinician
B) Advice from family
C)Suggestions from friends
D)Opinions on social media

Rationale: A clinician's recommendation is the number one reason parents decide to protect their children with vaccination. Regardless of the perceived or real concerns of a parent about HPV vaccination, an effective recommendation for all adolescent vaccines needs to be given. There is a strong evidence base to support the importance of an effective recommendation in improving parental acceptance of HPV vaccination.

4. What is the most common cancer caused by HPV diagnosed annually in women in the United States?A) AnalB) Cervical

C)Vaginal D)Vulvar

Rationale: HPV causes 11,100 cervical cancers, 4,500 anal cancers, 2,900 vulvar cancers, and 600 vaginal cancers diagnosed annually in women in the United States.

**5.** What is the most common cancer caused by HPV diagnosed annually in men in the United States?

A) AnalB) OropharyngealC)PenileD)Rectal

Rationale: HPV causes 12,100 oropharyngeal cancers, 2,100 anal cancers, and 900 penile cancers diagnosed annually in men in the United States.

6. HPV vaccination impact has been demonstrated by decreases in which of the following?A) HPV PrevalenceB) Genital WartsC)Cervical LesionsD)All of the above

Rationale: HPV vaccination impact can be monitored through post-licensure evaluations of the various outcomes of HPV infection, including HPV prevalence, genital warts, and precancerous cervical lesions. Reduction in each of these outcomes have been reported in the United States and other countries.

7. When providers were asked to estimate how much value parents placed on HPV vaccination, they incorrectly \_\_\_\_\_.

A) Rated it as equal to the other recommended adolescent vaccinations

B) Rated it as higher than the other recommended adolescent vaccinations

C)Rated it as lower than the other recommended adolescent vaccinations.

D)Did not rate it all.

Rationale: Research conducted by Dr. Mary Healy and colleagues in Houston, Texas revealed that the way that providers think parents feel about HPV vaccine influences how providers talk about the vaccine, which in turn influences whether or not parents get the vaccine for their child. This perception that parents value HPV vaccine less than other adolescent vaccines changes the conversation between the clinician and the parents regarding HPV vaccine.

8. A question from a parent about HPV vaccine means they are refusing or delaying.A) TrueB) False

Rationale: Many parents with questions about HPV vaccine are looking for additional reassurance from their child's doctor. Taking the time to listen to parents' questions helps clinicians save time and give an effective response. A clinician's recommendation is the number one reason parents decide to protect their children with vaccination.

**9.** Which of the following is an example of an effective recommendation? A) "Your preteen needs three vaccines today to protect against meningitis, HPV cancers, and pertussis." B) "Now that your child is 11, she is due for three vaccines today. These will help protect her from the infections that can cause meningitis, HPV cancers, and pertussis. We'll give those shots at the end of the visit."

C) "Now that your child is 12, he is due today for three important vaccines. The first is to help prevent an infection that can cause meningitis, which is very rare, but potentially deadly. The second is to prevent a very common infection, HPV, which can cause several kinds of cancer. The third is the tetanus booster that also protects against pertussis, so she doesn't get whooping cough. We'll give those shots at the end of the visit. Do you have any questions for me?" D)All of the above

## **Rationale:** The most effective recommendation for HPV vaccination bundles all of the vaccines recommended for preteens into one simple and effective presumptive statement.

**10.** An effective recommendation for HPV vaccination is given in the same way and on the same day as the other vaccines recommended for preteens.

A) True

B) False

Rationale: Successful recommendations group all of the adolescent vaccines. The HPV vaccine series should be recommended the exact same way the other adolescent vaccines are recommended.

Centers for Disease Control and Prevention. (2023, October 2). *Course summary*. Centers for Disease Control and Prevention. https://tceols.cdc.gov/Course/Detail2/8540?previousPage=search
# Appendix F

### Auditing Tool for Vaccination Status and Demographics

Participant #	
Current Vaccination Status	<ul> <li>None/Naive</li> </ul>
	• Partially Received
	• Series completed
If not up to date on the vaccine, did the	• Consented on/
guardian consent or decline the HPV	• Declined on/
vaccine	
Date of vaccine administration after	//2024
consent	
	• Was the vaccine received within 30 days
	of admission? Circle Yes or No
	• Or has not received HPV vaccine yet
	• Reason why not administered?
Age	years old
Race	• White/Caucasian
	• African American or Black
	<ul> <li>2 races reported</li> </ul>
Gender	• Male
	• Female
Geographic Location/County of	
Residence via Zip Codes	
Insurance	• Private Insurance
	• State Funded
Guardianship	• State Worker
	• Parent
	• Relative

# Appendix G

# Legend for Auditing Tool

Participant #	
Current Vaccine Status on Admission	$\circ$ None/Naïve (0)
	$\circ$ Partially Received (1)
	• Complete (2)
Consented to vaccine	• Yes (1)
	$\circ$ No (0)
Was the vaccine administered after the	• Yes (1)
child was consented	• No (0)
Was the vaccine administered within 30	• Yes (1)
days of admission	• No (0)
Age	• # years old
Race	$\circ$ White/Caucasian (0)
	$\circ$ African American or Black (2)
	$\circ$ 2 races reported (1)
Gender	$\circ$ Male (1)
	$\circ$ Female (0)
	<b>``</b>
Insurance	• Private Insurance (0)
	$\circ$ State Funded (1)
Guardianship	• State Worker (1)
	$\circ$ Parent (0)
	$\circ$ Relative (2)
County Size	$\circ$ Rural (0)
	• Micropolitan (1)
	• Metropolitan (2)
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### Appendix H

Preamble for Consent to Participate in the Intervention

#### Implementation of an Evidence-Based Intervention to Improve Human Papillomavirus (HPV)

#### Vaccination Rates of Children Newly Admitted to a Residential Facility

Dear Participant:

You are being invited to participate in a quality improvement project. The purpose of this project is to implement an evidence-based multi-modal intervention to increase HPV vaccination rates and evaluate its effectiveness. This project is conducted by Dr. Mollie Aleshire, DNP, Dr. Sally Martens, PhD, and Krista Fitzgerald, DNP Student at the University of Louisville.

Your participation in the project will involve taking a pretest of your HPV/HPV vaccine knowledge, participating in an educational session, taking a posttest, and being educated on the new consent and provider recommendation letter/video. The project will take approximately one hour to complete. There are no known risks for your participation in this quality improvement project. The information you provide will be used to assess knowledge before and after the educational session. Your information will be stored on CardBox and be de-identified. The information collected may not benefit you directly. The information learned in this project may be helpful to others.

Individuals from the University of Louisville School of Nursing, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPO), and other regulatory agencies may inspect these records. In all other respects, however, the data will be held in confidence to the extent permitted by law. Should the data be published, your identity will not be disclosed.

Taking part in this quality improvement project is voluntary. By answering test questions, you agree to take part in this quality improvement project. You do not have to answer any questions that make you uncomfortable. You may choose not to take part at all. If you decide to be in this project, you may stop taking part at any time. You will not lose any benefits for which you may qualify.

If you have any questions, concerns, or complaints about the quality improvement project, please contact: Krista Fitzgerald, phone number: (502)475-5372.

If you have any questions about your rights as a participant in a quality improvement project, you may call the Human Subjects Protection Program Office at (502) 852-5188. You can discuss any questions about your rights as a participant in a quality improvement project, in private, with a member of the Institutional Review Board (IRB). The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this quality improvement project.

If you have concerns or complaints about the quality improvement project or project staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24-hour hot line answered by people who do not work at the University of Louisville.

Sincerely, Krista Fitzgerald DNP Student, BSN, RN

Version Date: Version 1; 12/04/2023

### **Appendix I**

### Permission to Use Post-Test and CDC PowerPoint

