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Increasing HPV Vaccination in Elliott and Lawrence Counties

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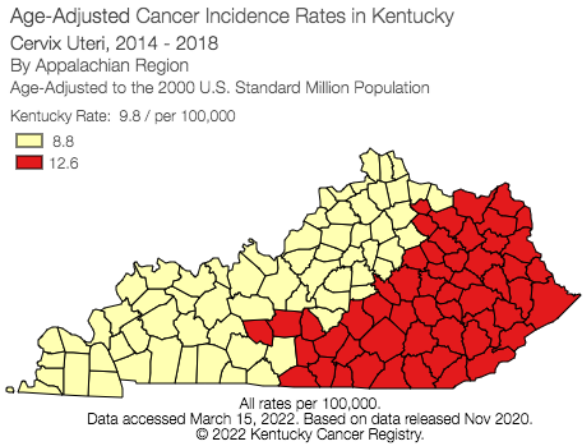
Target Population and Need

Burden of Cervical Cancer

Despite effective measures for prevention and early diagnosis, cervical cancer remains a pervasive disease in certain regions of the United States. In the United States in 2018, cervical cancer was diagnosed in 8 people per 100,000; of all states, Kentucky ranks among the top ten for highest cervical cancer incidence and mortality [1]. In the Commonwealth, there were 8.9 cases per 100,000 and 2.6 deaths per 100,000 due to cervical cancer in 2020 [2]. Within Kentucky, Appalachian regions report even higher rates of cervical cancer diagnosis and mortality. While non-Appalachian regions reported 8.8 diagnoses per 100,000, in Appalachia, there were 12.6 diagnoses per 100,000 [2]. Consequently, there are also more cervical cancer related deaths in Appalachian regions than non-Appalachian regions. In 2018, there were 3.5 cervical cancer deaths in Appalachia, compared to only 2.3 cervical cancer related deaths in non-Appalachian regions [2].



While death is the most serious negative health outcome related to cervical cancer, the disease and treatment can be disruptive. Cervical cancer can be accompanied by abnormal bleeding and pelvic pain [3]. Because cervical cancer may spread to other areas of the body, swift treatment is important. Treatment may include surgery, radiation, chemotherapy, targeted therapy and immunotherapy, which can all cause physical side effects [3]. Additionally, cervical cancer treatment may pose a financial and mental burden on both patients and families [3].

Risk Factors for Cervical Cancer

There are several risk factors that increase the likelihood of cervical cancer diagnosis. These factors include increased age, smoking and tobacco use, giving birth to more than three children, and being on birth control pills for more than five years [4]. Additionally, risk of cervical cancer increases with an increased number of sexual partners[4]. Human Papilloma Virus (HPV) is a sexually transmitted infection that can lead to several different types of cancer. While not all HPV infections will lead to cancer, there are 13 known types of HPV that can lead to cancer [5]. It is estimated that nearly 90% of all cervical and anal cancers are related to HPV infection, but HPV is the most common cancer resulting from HPV infection[5]. By age 50, 4 out of 5 women will have contracted some type of HPV in their lifetime, though not all every HPV type results in cancer [5].

There are currently screenings that can be performed to test for both HPV and cervical cancer. The most recent guidelines from the American Cancer Society (2020) recommends that women are tested for HPV every 5 years along with a Pap test, which examines the presence of cancerous cells in the cervix. These tests should begin at 25 and continue until age 65 (National Institute of Health [NIH], 2020). HPV and Pap tests may be effective in identifying present HPV infection and cancer cells, which can help assessing cancer risk or identifying cancer early, which may improve prognosis, however, HPV and Pap testing do nothing to prevent HPV infection.

HPV Vaccination

HPV vaccination has shown to be effective in preventing cervical cancer rates by protecting from HPV infection. Areas with higher vaccine uptake generally experience lower rates of cervical cancer diagnosis. An 11 year longitudinal study revealed that girls vaccinated

against HPV before the age of 17 had a 90% reduction in cervical cancer rates [7]. The HPV vaccination was first recommended in 2006; since then, the US has seen an 86% decrease in HPV infection in teenaged females and a 71% decrease in HPV infection for females in early 20s [7]. These statistics suggest that with widespread HPV vaccination, cervical cancer rates can be greatly reduced.

Advisory Committee on Immunization Practices (ACIP) has created HPV vaccination guidelines that work to best protect people from contracting HPV. While the vaccine can be administered at as young as 9, it is recommended for both boys and girls at ages 11 or 12 [8]. For individuals receiving the vaccine before his or her fifteenth birthday, a second dose should be administered six to twelve months after dose one, for a total of two doses. Immunocompromised individuals and individuals receiving a first dose after his or her fifteenth birthday should receive a second dose 1-2 months after the first and a third dose 6 months later [8]. By focusing on widespread HPV vaccination in Appalachian communities, cervical cancer can be better controlled, and disparities related to health outcomes can be mitigated.

HPV Vaccine Coverage

Collected data suggests that while HPV vaccination coverage has increased with time through the United States, vaccine distribution is not equitable across all geographic regions, leading to higher rates of associated cancers in some regions. The Healthy People 2030 goal for HPV vaccine coverage is 80% among both boys and girls aged 13-15 [9]. The US is still well behind that goal, with only 54.2% of boys and girls aged 13-17 receiving the HPV vaccine series by 2019 [10]. Vaccine coverage is lower for rural geographic regions, with only 49.2% of boys and girls in rural areas receiving the vaccine [10].

Vaccine coverage in Kentucky is fairly equivalent to the United States as a whole, though some regions are far behind. In 2019, 54.9% of all Kentuckians between 13 and 17 years old were up to date with HPV vaccines [11]. One area development district within the Appalachian region of Kentucky both suffers disproportionately in cervical cancer incidence rates, but also has markedly low HPV vaccine uptake. In the FIVCO region, only 24% individuals up to age 17 were up to date with the HPV vaccine and in 2019, 51 people per 100,000 had cervical cancer [2,11]. Due to high cervical cancer burden and low HPV vaccine coverage, the FIVCO area development district may benefit from an intervention targeted at increasing the uptake of the HPV vaccine.; Elliott and Lawrence counties, with vaccine rates of 38% and 56% are counties within the FIVCO region that lack current vaccine programming and require intervention to ease the cancer burden [12].

Reasons for Low HPV Vaccine Uptake

While no examination of barriers and challenges to HPV vaccination exist for the FIVCO region in particular, published literature reveals reasons that many individuals from rural or Appalachian areas may not vaccinate themselves or children. In semi-structured interviews among adult women in Appalachia, Mills and colleagues (2013) ascertained barriers to HPV vaccination. They found that many women reported a lack of knowledge about cervical cancer, HPV and the HPV vaccine [13]. Additionally, women cited tangible barriers, such as a lack of access, limited transportation to doctor's offices or clinics, and busy schedules as reasons that they and their children were not vaccinated. Women also mentioned misinformation as a reason for avoiding the HPV vaccine [13].

Research on HPV vaccine hesitancy in parents is mainly due to two reasons. [14]. The first of these, as previously mentioned, is misinformation, specifically, misinformation on side effects

from HPV vaccines [15]. One reason that parents might be misinformed about vaccine side effects is because of norms regarding media coverage of opposing views [15]. Despite a lack of evidence that HPV vaccines are unsafe, negative experience with vaccines will still be highlighted by media to show similar coverage of two viewpoints, even if evidence supporting safety of HPV vaccines is much stronger [15]. Social media has been understood as a main driver in vaccine misinformation [16]. Between 2019 and 2020, anti-vaccine groups on various social media sites have increased the number of followers by almost 8 million people [16]. While much of this following has grown due to concerns with the COVID-19 vaccine, it is reasonable to predict that skepticism toward this vaccine might have wider implications for vaccines in general.

Besides misinformation, vaccine hesitancy is also brought on by parent fears that HPV vaccination will lead to teens and pre-teens engaging in sexual activity [14]. Despite this pervasive fear, research suggests that HPV vaccination is not associated with younger sexual debut [17]. Additionally, HPV vaccination is not associated with number of sexual partners, or use of contraceptives [17]. Education on HPV vaccination should stress these points to ease fears about the vaccine encouraging sexual activity in teens.

Appalachian regions also experience more general health disparities that may result in lower HPV vaccine coverage. Appalachian areas suffer from higher poverty rates, and individuals may be more likely to be underinsured, which have been shown to relate to higher all cause premature mortality [18]. Areas within Appalachia often have few healthcare facilities, and people in these areas may have to travel further distances to receive care, creating an issue of healthcare access [18]. Appalachian regions of Kentucky have about 21% less healthcare providers than non-Appalachian regions in the state, which highlights the need for alternate immunization delivery sites [18]. Disparities in Appalachia also have implications for cervical cancer rates and

outcomes, including provider communication, cancer screening, as well as social norms and lack of economic resources [19]. Because of low vaccine uptake and limited healthcare access for many individuals in rural areas, the proposed program will focus on delivering HPV vaccines to middle schoolers while at school, minimizing barriers presented by vaccine delivery at doctor's offices or other clinics.

Program Fit

With regional health disparities in mind, this program will promote health equity by providing access to a cancer-preventing vaccination to middle schoolers within the FIVCO region through schools. Additionally, the proposed program will increase demand for the vaccine within the area by providing information about benefits of the HPV vaccine and risks associated with HPV infection, including cervical cancer. Program activities associated with increasing demand will be tailored to fit community culture. Trusted RNs within the community will be utilized to deliver information, and information will be communicated through community events that maximize reach to parents of the target population, including middle school sponsored events and events occurring in the larger community. Evidence suggests that increasing access and demand are effective ways to increase HPV vaccine coverage; however, some slight adaptations will be made to align community needs and resources with previous vaccine programs.

The proposed program was selected because it both meets a need within the community and because it utilizes currently existing resources within the Elliott and Lawrence Counties. Higher rates of cervical cancer within the area and markedly low HPV vaccine uptake point to a need for intervention. While cervical cancer screening programs may be valuable in this area, screening works as secondary prevention and does little to address underlying inequities;

individuals in this area may still have trouble securing treatment because of lower physician presence. Vaccination should be the target behavior because it works to prevent infections that lead to cancer.

Resources and status of FIVCO area development district

The FIVCO area development district consists of Boyd, Carter, Elliot, Greenup and Lawrence Counties and is located in northeastern Kentucky, bordering Ohio and West Virginia. FIVCO has a population of around 133,000 and is made up of nearly 95% white, non-Hispanic individuals [20]. Twenty one percent of people living in this area development district were living in poverty in 2019 [20]. While 6% of the population has no health insurance, 27% of residents were insured by Medicare in 2019 [20].

Two main resources will be utilized through the program to improve vaccination status in the FIVCO region. One of these is the public-school system within each county. Across the five counties, there are six public middle schools that combine to serve around 1,800 students [21]. Middle schools in Boyd, Carter and Greenup Counties currently benefit from walk-in clinics staffed by nurse practitioners from King's Daughter's Medical Center (KDMC), which can provide immunization services to students in each school. Elliott and Lawrence Counties lack similar services; Elliott County has no school nurses in the 2020-2021 academic year, while Lawrence County had seven school nurses spread across 6 schools, without immunization services [22]. The proposed program aims to expand the KDMC program into middle schools in Lawrence and Elliott Counties.

Working in these middle schools will allow the greatest access to children between 13 and 15 years old, who are at the recommended age to receive the HPV vaccine series as well as their parents, who must consent to their child's vaccination. In Elliott County, there is one

middle school with grades 6-8, Elliot County Middle, in which 230 students are enrolled [21]. Lawrence County contains one middle school that houses grades 6-8 and 430 students, Louisa Middle. Lawrence County also has two elementary schools that serve 6-8 grades, Fallsburg and Blaine Elementary. Fallsburg has 280 students with only 57 in grades 6-8 and Blaine has 200 students, with 57 in grades 6-8 [23]. Between these 4 schools, the program will reach about 800 middle school students in its first year alone [21].

Other resources utilized by this program include Vaccines for Children (VFC), a federally funded program that covers costs of immunizations for uninsured and underinsured individuals. The VFC program will be utilized to help pay for student vaccines. This program is implemented by the Kentucky Cabinet for Health and family services, and provides vaccines free of charge to individuals who are eligible for Medicaid, uninsured, in certain ethnic groups, or eligible for vaccines through local health departments [12]. By utilizing county health departments and VFC, program costs can be reduced.

Program Approach

Community Guide recommendations

The Community Guide to Preventative Services is a trusted source and presents findings on evidence based strategies to improve health behavior; the Community Guide recommends both enhancing access to vaccination services and increasing community demand for vaccines as effective strategies in improving vaccine uptake [24]. The proposed program will incorporate two of these strategies and focus on providing educational materials through the school to both parents and students as a way to increase demand for HPV vaccinations. Additionally, the program will improve access to vaccines by providing vaccines at school, alleviating the need for parents and children to visit clinicians at other sites to receive the HPV vaccine.

Increasing access

One strategy to increase access to vaccinations is providing vaccines in schools. The main activity of the proposed program will be the provision of HPV vaccines to students during school. According to the Guide to Community Preventive Service (2021), school vaccine programs are an effective way to increase access to vaccines as well as decrease the burden of disease in measures of prevalence and mortality[24]. School based vaccine programs reviewed by the Community Preventive Services Task Force (CPSTF) include the administration of vaccines by different healthcare providers, including school nurses and health department employees. Most school-based vaccine programs also increase access to vaccines by reducing or eliminating costs as well as educational components (increasing demand). The CPSTF emphasizes the utility of school-based vaccine programs especially for new vaccines or vaccines with new recommendations. The HPV vaccination has been recommended since 2006, but may still be considered new, especially to parents who were themselves not given the HPV vaccine.

Increasing demand

As previously stated, the Community Guide to Preventative Care supports the use of HPV vaccine programs that increase demand for HPV vaccination. While there is insufficient evidence to suggest that education alone can increase demand for HPV vaccinations, patient education is effective when used in combination with other interventions, including increasing accessibility of HPV vaccinations (The Community Guide, 2019).

The proposed program will utilize previous research on increasing demand for HPV vaccines in order to deliver efficient messaging to middle school students and parents about vaccines. For the proposed program, patient education will be provided by program-hired registered nurses (RNs) and will take place at events that provide access to middle school

parents. A systematic review of HPV vaccine programs reveal that programs promoting HPV vaccination should emphasize the likelihood of HPV infection and the effectiveness of HPV vaccination in reducing HPV risk [25]. Other evidence suggests that educational presentations focused on the Health Belief Model, were effective in improving intentions to vaccinate as well as vaccine initiation after 1-month follow up [26].

In addition to formal education about HPV, vaccines and cancer, the proposed program will utilize other methods to increase demand. Research suggests that parents who have themselves contracted an STD are more likely to vaccinate children; therefore to increase demand for HPV vaccines, personal stories of people who have themselves been diagnosed with HPV and cervical cancer will be asked to share their experiences [27]. This will increase perceived susceptibility, which is a critical construct in increasing likelihood to vaccinate.

Examples of school-based vaccine programs

The proposed program will be implemented to mirror two HPV vaccination programs; one of these took place in rural Kentucky while another took place in rural Texas [28,29]. Both concluded that school-based programs that focus on education and increasing access to vaccines were effective in initiating and completing the HPV vaccine series. School based vaccine programs improve access to vaccines by providing services for students to be given either one or multiple vaccines on school grounds, either during the day or at after school events. While the Kentucky program was implemented in a more similar location to the FIVCO region, the program implemented in Texas is valuable because it utilizes more rigorous research methods to support conclusions.

The current program is supported by a similar school-based vaccine program in south central Kentucky, a rural Appalachian development district conducted by Vanderpool and

colleagues (2015). Instead of using middle schools, this program provided vaccines to adolescents in two area high school. HPV vaccine information and consent forms were sent home with students for parents to review and return to school. Additionally, informational booths staffed by nurses were present at school events, like orientation, open houses and football games. Students were involved in the program by creating slogans and advertisements that would encourage other classmates to receive HPV vaccines, and some incentives were provided for students to be vaccinated. A community advocate, who lost a daughter to cervical cancer, was also invited to speak at a school assembly about the program. A school nurse was employed to give vaccines to students according to ACHIP guidelines.

While complete data is only available for the students who returned consent forms, there is evidence to suggest that providing HPV vaccinations at school increases HPV vaccine uptake. Out of 935 students, only 447 students returned consent forms; of these, 74% of students received all three required vaccines. The vaccine status of individuals not returning consent forms is unknown, so making claims about the overall vaccination rate of the community is not possible. This study is valuable in providing a framework for student involvement and suggests that school vaccine programs increase access for some students.

Another vaccine program in the Rio Grande Valley of Texas provides improved data to evaluate the efficacy of school based programs [29]. This program was implemented at one middle school, while a neighboring middle school was used as a comparison and used education only to improve HPV vaccination rates. This program also included educational events, which were done at both the comparison and intervention school. Educational events included presentations from physicians about HPV, related cancer and the HPV vaccine, along with question and answer sessions and included pediatricians, gynecologists and oncologists. At educational

events, informational materials were available for families to take home. This program also included vaccination events, which took place at the school during special events, like open houses and orientation rather than during the school day.

Findings from this study revealed that the school receiving education and school-based vaccination had higher rates of HPV vaccination than the comparison school at the end of the 33-month program. At the comparison school, 41.56% of students had initiated the HPV vaccine series while 53.67% of students at the intervention school had initiated the vaccine. More students at the intervention school completed the vaccine series as well, with about 28.36% versus 20.53%. Findings from a logistic regression suggested that students at the intervention school were nearly four times as likely to receive the HPV vaccine than students in the comparison school.

The previously mentioned studies and community guide recommendation support the implementation of a school-based vaccine program in the FIVCO area development district as a means to improve HPV vaccination and reduce the burden of cervical cancer on this population. The school-based vaccine program will improve accessibility while also providing education that will help children and parents make more informed decisions about receiving the vaccine.

Potential challenges

Qualitative research by Nodulman and colleagues (2013), highlighted some concerns that community members and stakeholders had in developing a school-based vaccine program. These are important to note as the FIVCO vaccine program will work proactively to address common concerns. One issue that parents had was that school nurses did not seem to be a viable option for vaccine administration [30]. To overcome this, the program plans to form partnerships with local pediatric clinics and health departments so that nurses who work in clinical settings will

administer vaccines. These researchers also noted concern over HPV educational materials and embarrassment for middle schoolers over the subject [30]. To meet this community concern, a community advisory board will meet to discuss and approve of distributed educational materials to make sure they are age appropriate for the middle school audience. Additionally, educational information will be targeted more toward parents, who ultimately make health decisions for children. Infographics and materials for education will outsourced from other trusted groups, like local physicians, so that people are more trusting of the content. Another community concern is that schools and administrators lack resources to provide vaccine services to the school [30]. Besides partnerships with local clinicians, VFC will be valuable in providing vaccine resources to students within the schools.

Proposed program

Much like the previously explained program, this program will utilize school events to both provide vaccines and inform the students, parents and community about the relationship between HPV and cervical cancer, as well as the cancer-fighting HPV vaccination. The program will begin with a partnership-forming phase, which will focus on building relationships with schools and parents and students within each middle school. Information gathered in this first phase will provide guidance on useful settings to deliver information about the program to the community. The second phase of the program consists of delivering informational sessions and vaccine delivery within schools.

Partnership forming

A successful program depends on effective partnerships with both community organizations and community members. As a first step, project managers will meet with county superintendents, school boards and principles at local middle schools. At these meetings, project

managers will brief these key figures on the status of HPV vaccination and HPV related cancers within each county in order to establish the need for action. Project managers will also provide some information about the precedent of school-based vaccine programs in other counties and explain the role of KDMC in providing these vaccinations. Program staff will utilize these meetings for gathering information about current health resources within each school, like current roles of a school health service staff, as well as information about how to run school-based vaccine programs without overburdening school staff, unnecessarily interrupting the school day, identifying spaces within schools that would suite vaccine clinics, and identifying events that would be useful for reaching parents with HPV vaccine information. Program staff will emphasize willingness to work with school staff and administrators to improve vaccine coverage and student health.

The program staff will also form connections with the Kentucky Department for Public Health's Division of Epidemiology and Planning to better understand how the program can best utilize VFC. Program staff will use this information to enroll students at local middle schools into the program and secure HPV vaccines for those who qualify. This resource will also be used to price vaccines for individuals who do not qualify for the state run VFC program.

The partnership forming phase will also take time to develop trust and buy-in from community members, including both students and parents at each middle school. Parents will be contacted through the school email lists and flyers sent home with students, and project coordinator will meet with parents at school parent teacher organization. Interviews and focus groups will be used to better understand specific concerns that Lawrence and Elliott County parents have with HPV vaccines and asked about ideal locations the program can utilize for

educational events. Program staff will utilize these meetings to invite parents onto the Community Advisory Group, which is detailed in a following section.

RNs will be vital to the effective implementation of this program. With this in mind, much care will be dedicated to hiring and training RNs for each of the four middle schools. Though nursing jobs are in high demand, the program staff will recruit to fill these positions in nearby Ashland, Kentucky, where Our lady Bellefonte Hospital recently closed, leaving RNs in this county out of work [31].

Program delivery: educational events

In order to promote trust between parents, students and school health services staff, the same RN that staff school clinics will be responsible for educational events in each school community. These educational events will begin the summer before the start of the in-school vaccine clinic to maximize reach at different community events. RNs will utilize two types of educational events to inform parents about HPV, cancer, HPV vaccines and the school-based vaccine clinic available to students. Formal educational events will consist of scripted presentations while informal education events will be held at a booth or table in a less structured manner.

At formal educational events, RNs will follow scripts and PowerPoint presentations designed by program staff to discuss points of hesitancy identified through both published literature and parent focus groups. Special attention will be paid to identifying misinformation surrounding HPV vaccines because misinformation has shown to be a major source of hesitancy. Messaging from the RN will focus around health belief model constructs and highlight perceived benefits of vaccination and susceptibility and severity of contracting HPV. Formal presentations

will include local data to indicate that vaccine uptake is lower in counties covered by the program compared to the rest of Kentucky.

RNs will also make parents aware of the new partnership with KDMC and the vaccine program in place at the school. Parents that attend these formal meetings will be provided with HPV vaccine infographics from the CDC so that they both have information available and so that they have access to a trusted resource to seek out additional information. Formal educational events will be followed by question and answer sessions, which will allow the RN to answer any remaining questions and build trust with parents. Parents attending these events will be able to sign and return consent forms so students can be vaccinated at the school clinic. Formal vaccine education presentations will be completed twice per semester in either August, September or October in the fall and in January, February or March for the spring. Having these events earlier in the semester will allow time for students to be enrolled in in school vaccine program, and to be vaccinated relatively soon after consent is received.

Informal educational events will occur at school and community events that are not amenable to a formal presentation. These events will include a smaller table setup with marketing materials and CDC infographics about HPV vaccination. In this setting, RNs will explain the program at hand to any parents that inquire at the table. Discussions at informal events will still focus on benefits to HPV vaccination and susceptibility and severity of HPV infection and will also be used to build trust between school RN and the school community. At informal events, parents will be given the same CDC infographic and consent forms available to parents at more formal presentations. These events will occur more frequently than formal events, but timing and targeted groups will depend on demographics of students who have not returned consent forms.

Attempts will be made by RNs at each school to reach parents who are unable to attend community or school events. This will be done through a combination of phone calls to parent phones and through take-home materials given by homeroom teachers to students. School RNs will provide the CDC infographic to homeroom teachers to be delivered home to parents from their children at the beginning of the school year. Predicting that not every infographic will make it to parents, RNs will also use parent phone numbers on file to leave voice messages with parents about the school-based vaccine program. This voice message will inform parents about consent forms and infographics that will be sent home with students. Parents will be left with school RN contact information so that they are able to call a trusted source of information if they have any questions.

RNs will make efforts to contact parents of students who have not returned consent forms. After initial consent forms have been returned to school RNs and the first in-school vaccine day has taken place, the school RN will leave another voicemail with the parents of students who did not return consent forms, informing them of a second upcoming vaccine day and offering to clarify any uncertainties about the vaccine. Parents who return consent forms but indicate that they do not want their child vaccinated will be asked to indicate why they have refused the vaccine. This information will serve to inform program staff about better ways to address parent uncertainties regarding the HPV vaccine.

Formative evaluation: educational materials

Materials, presentations and logos used in marketing and providing HPV vaccine information will go through thorough testing to ensure acceptability, feasibility and relevance to the community. Visual aids and script for the formal presentations will be developed by program staff, including the on-site RN. Once these materials have been reviewed internally, they will be

reviewed by the project CAB. Any suggested changes by this group will be considered and revisions to the visuals and script will be made where appropriate. Program staff aims to provide the formal presentation at least twice per school semester through the duration of this project. After presentations, attending parents will be asked to provide feedback on the presentation by emailing the school RN. Findings from this correspondence will allow program staff to iterate the presentation as needed according to parent feedback.

Program delivery: in-school vaccine clinic

The in-school vaccine clinic will allow students to be vaccinated during the school day with parent knowledge and consent, but without parent presence. Underinsured students will be enrolled in the VFC program, which will reimburse KDMC for HPV vaccines. Data suggests that many students in the 4 target schools will qualify for the VFC program. The table below displays the estimates for low income students in each school [21]. Program staff aims to eliminate stigmatizing groups that rely on free in-school vaccines by also covering costs for some students not qualifying for VFC to utilize in-school services. To this end, the program will purchase vaccines to be given to students who do not qualify for VFC. The proposed program will cover up to 10 vaccines per vaccine event to be spread across all four schools; students who receive a vaccine purchased by the program will also be provided a second dose of the vaccine to complete the series.

School	Percentage of students from low income families	Number of students from low income families
Blaine Elementary	84%	47
Elliott County Middle	67%	154
Fallsburg Elementary	70%	60
Louisa Middle	65%	280

By offering vaccines at school and covering costs, barriers to HPV vaccination are greatly reduced. For RNs to be able to administer vaccines, the chief medical officer of KDMC will need to issue a standing order for HPV vaccination. Standing orders allow other members of healthcare teams, such as RNs, to provide routine care without physician orders [32]. RNs at each school will work under the direction of KDMC Chief Medical Officer of Outpatient Services.

Scheduling and record keeping of consent forms and vaccine delivery will be the job of the school RN. Vaccine events at school will be offered once per month during the school year (October-April). This will allow students to be vaccinated promptly after receipt of consent forms and also allow students to easily be vaccinated with the second dose after six months. Vaccine events may continue from 1-5 school days, depending on the number of students set to receive vaccines.

Vaccine event days will be run in a manner that both minimizes class disruption and encourages further participation from students. Students for whom consent forms have been received will be called out of their classroom in small groups at a designated time, then taken to the in-school clinic. The RN will administer the vaccine according to his or her clinical training, then students will be dismissed to return to class. After the child is vaccinated, students will be sent home with a note to parents that summarizes potential side effects and given a bandage with the project logo to market the program to peers. Though students ultimately cannot make their own medical decisions, marketing the vaccine to students is still important as they may be able to discuss vaccines with parents and indicate wishes to be vaccinated.

The RN will keep track of vaccinated students via Epic, a healthcare software. This software will notify the RN when students are due for the second dose of the vaccine series. Upon this notification, the RN will leave a voice message with the parents to stress the

importance of the second dose of the vaccine and notify parents that consent forms will be sent home with the student. Upon receipt of the consent form, parents will again be called to notify of the scheduled vaccine day. Students leaving the middle school will be contacted when the second dose is due and provided resources about how they may receive that vaccine, either at KDMC, the local health department, or another local physician.

Formative evaluation: in-school vaccine clinic

Program staff desires to keep parents informed with their child's HPV vaccine status and comfortable with in-school vaccine clinic procedures. To do this, program CAB has been including in developing the previously mentioned guidelines. Voice messages sent to parent phones, notes sent home after vaccination, and messaging about upcoming vaccine appointments has been tested with parents in each middle school to ensure that it is clear and provides information that is helpful to parents.

Fidelity:

Program staff will take measures to ensure that the program is implemented with fidelity. This RNs will be responsible for recording date, time, location and type of educational event in an online calendar. They will also record the number of flyers and infographics distributed at educational events to ensure that they were distributed. To ensure that monthly vaccine events are completed, RNs will be asked to record the date(s) that vaccines were distributed in the online calendar and include information on the number of vaccines administered.

Performance Measures and Evaluation

Thorough evaluation will be conducted to ascertain the utility of the program in increasing HPV vaccine coverage. The main outcome measures for this program will be HPV vaccine initiation and HPV vaccine completion. These measures will be valuable in drawing

conclusions about the overall effects of school-based vaccine programs. The Healthy People 2030 goal is for 80% HPV vaccine coverage in people aged 13-15, however, due to marked low vaccine uptake in this region, bringing HPV uptake to US average of 55% coverage would be a considerable improvement for this region [9]. Secondary outcome measures will also be collected from parents of middle school students. Research suggests that constructs of the Health Belief Model (HBM) are have implications on vaccine behavior [25]. In order to affirm previous research, and to ensure that program components are addressing the proper theoretical constructs, parents will be asked about perceived benefits of vaccination, perceived barriers to vaccination, perceived severity of HPV, perceived susceptibility to HPV, self-efficacy and cues to action [25]. HPV knowledge will also be addressed, as knowledge is necessary for informed vaccine decision making for parents [25].

Primary outcome data:

As previously mentioned, the primary outcome data for this program will be HPV vaccination initiation and completion. At the beginning of the school year when consent forms are sent home, parents will be able to indicate how many HPV vaccinations the child has received, either 0, 1 or 2, which will provide a baseline for HPV vaccination in each school. Parents will also be asked if they wish for their child to be vaccinated at the in-school vaccine clinic, to which parents may answer either yes or no. Parents indicating they do not wish for their child to be vaccinated will be asked to provide their reasoning, which can allow program staff to have better targeted information for non-consenting parents in each school. Parents indicating consent to vaccinate will be asked to provide some demographic information on the child, including age, race/ethnicity and biological sex. Consent forms will be sent home twice per semester to students who were not previously vaccinated but will be available for any parent

attending formal or informal educational events. This will both allow second opportunities for non-consenting parents to consent and allow program staff to keep track of students receiving HPV vaccines outside of the school clinic.

Primary data will be updated through KDMC's electronic record keeping software, Epic. Epic will keep track of students vaccinated though the school. KDMC will also keep track of age at vaccination, gender, and race. These measures will allow program staff to determine if certain groups within the school are not receiving vaccines and tailor educational programming to meet vaccine resistant groups.

Secondary outcome data

To collect data related to HBM theoretical constructs and knowledge of HPV, the HPV Knowledge Scale (HPVKS) and the HBM Scale for HPV Virus and its Vaccination (HBMS-HPVV) will be used. The HPV Knowledge scale is a 20-item scale that consists of statements about HPV; participants are asked to judge the statement as true or false. Participants are given a point for each correct answer and no points for incorrect answers, with higher scores indicating more knowledge of HPV than lower scores. Cronbach's alpha for this scale is α=0.88 [33]. The Health Belief questionnaire includes 12 items across subscales for perceived benefits (3 items), perceived susceptibility (2 items), perceived severity (2 items), and perceived barriers (5 items). Response options were recorded on a 4-point Likert scale ranging from "not at all" (1) to "very much" (4). Cronbach's alpha for this scale is α=0.85 [33]. Program staff will add questions about vaccine status of children and intentions to vaccinate children in the future.

Because these surveys are being used to evaluate the utility of the educational programming, these surveys will have to be completed both before and after educational programming. Before education sessions, RNs will share the survey link, QR code or paper

survey with parents and then again after the education sessions. Mean scores on the post-education survey will be compared to the data collected before the education program. If the education sessions are successful, parents will report higher scores on both surveys after the session as well as report a higher likelihood of vaccinating children. Parents will be incentivized to participate in these surveys because participants will be entered in a drawing for a $100 Visa gift card, to be drawn once per school semester.

Process evaluation: educational events

Process evaluation will be completed to better understand strengths and weaknesses of the program. Both formal and informal education events will undergo process evaluation to ensure the program is implemented according to plan. Several methods will be used to gather process data. For informal events, RNs will include the number of parents and community members that attended. For formal education events, an additional program staff member will be in attendance to count number of attendees. RNs will also record the number of consent forms received at each event, as well as the number of consent forms received from students during the school day.

A participant tracking log will help RNs to ensure that each consenting student has received the vaccine and to ensure follow up with parents of non-consenting students. By class, each student name will be printed, and RN will indicate consent form response, completed voice messages to parents, and scheduling/receipt of the vaccine. This log will give insights as to how many or few students have not been reached by the program, which students are still waiting for the vaccine and the number of students with the vaccine initiated and completed.

Semi-structured interviews will also be conducted with school and program staff to better understand the what the program did well and what parts of the program need special attention

for improvement. Two teachers from each school will be interviewed to understand any additional burden that was placed on teachers throughout the program. Each school principal will also be contacted so that any administrative concerns with the program can be addressed. Parent volunteers will also be contacted via telephone to provide feedback on potential improvements for the program. Finally, the school RN will also be interviewed to understand any difficulties experienced throughout the program and to understand what strategies were most effective in communicating and building relationships with parents. Additionally, program staff is interested in learning if any vaccine information was inflammatory versus information that was more likely to lead to thoughtful consideration of HPV vaccine receipt in the RNs communication with parents who are hesitant of the vaccine. Findings from these interviews will be synthesized in a report each year written by program the coordinator and used to inform changes to the remainder of the program.

Capacity and Experience of Applicant Organization:

Kings Daughter's Medical Center is a regional healthcare service organization that is well equipped to implement and evaluate this program. KDMC has a commitment to serving its eastern Kentucky community, and has demonstrated commitment to service through a number of community programs. Currently, KDMC participates in community health fairs, low cost community health screenings and meals on wheels. As a non-profit healthcare organization, KDMC completes a community health needs assessments (CHNA); these reports use both primary and secondary data sources to identify and prioritize community health needs. The most recent CHNA does list cancer prevention as a priority need but focuses only on screening strategies rather than primary prevention measures. This program will work to improve cancer outcomes according to 2020 CHNA identified priority areas.

Most relevant to the program at hand, KMDC provides nurse practitioner walk-in clinics in Boyd, Carter and Greenup County Public Schools. KDMC intends to expand this community service into Elliott and Lawrence County Schools as a way to ensure equity in vaccine coverage and fulfill KDMC's commitment to serving the eastern Kentucky community. Having experience in implementing this type of program in other area schools, KDMC is an ideal organization to provide this service. The hired project coordinator will work with KDMC and be responsible for communication between the larger organization and the walk-in clinics at each of these schools. This includes the distribution and reimbursements of the HPV vaccines.

Being a regional medical center, KDMC already has the infrastructure to implement the proposed program. Being a larger organization, needed employees can more easily be hired, and tools needed to monitor outcomes are already in place. Hired RNs for this program will be hired locally, so that program staff can have a better perspective on needs and resources within the community. This perspective, combined with previous expertise of KDMC staff in other walk-in school clinics, may also help program staff in convening stakeholders and decision makers and building an effective Community Advisory Board. As previously mentioned, KDMC will utilize Epic, a healthcare record software to examine vaccine initiation and completion. This system is already secured and in use at KDMC clinics.

KDMC understands the value in convenient and accessible health care for families and children as well as the need to promote good health within organizations and workplaces, such as schools. By providing this program, KDMC will be able to improve community health by improving community trust in healthcare organizations, equipping community members with good sources for health information, and providing cancer-preventing vaccinations to adolescents to improve cancer incidence rates over time.

Between new hires and existing KDMC staff, the program has needed human resources for a successful program. Full time RNs will be hired to provide educational events and administer vaccines at each school. Additionally, a program coordinator currently works at the KDMC main campus; this person is responsible for communicating with school RNs as well as distributing vaccines and billing for vaccines that can be reimbursed by the state VFC program. Program coordinators will also be in charge of assembling and communicating with the CAB. KDMC currently has a quality improvement officer, who is responsible for tracking vaccine data via Epic to evaluate the efficacy of the program in increasing vaccine uptake. Elliot and Lawrence County schools currently have few hired school nurses; Elliot County has no school nurses while Lawrence County has seven hired nurses across seven schools [22]. When a nurse is present, they will help with tracking participant data, processing consent forms and scheduling vaccines.

Data monitoring will be used to ensure that different population groups within schools are being reached equitably. With this knowledge, school RNs can target certain groups for educational information. Feedback from parents about educational events will also be utilized to improve the program. This feedback will help RNs address specific concerns about vaccination within the community, and to ensure that information is communicated in a way that is culturally appropriate and matches with the interest of parents. Information about vaccine coverage within the area will also be tracked to better understand how these two counties are performing compared to other counties within Kentucky, so that the effectiveness of the program can be better understood.

School based walk-in clinics for vaccinations are built for sustainability because they both provide a service to the community and benefit the applicant organization by establishing

care with a new population of patients. By providing HPV vaccinations to the students, vaccines costs can be reimbursed by VFC, which can be a source of income for school vaccine clinics. The main purpose of the program is to establish in-school vaccine clinics to improve vaccine coverage, but clinics may be used for other student health services, with services billed through insurance which provides additional income and a larger patient population for KDMC.

Partnerships and Collaboration:

KDMC will lean heavily on community partners to implement this vaccine program. As previously mentioned, a working relationship with the middle schools involved in this program are vital to program success. Approval from superintendents from each county will be needed to begin the program, but program staff will interact more closely with school principals to determine best days and times for scheduling vaccines. Within these schools, program staff will make an effort to engage parents in learning about the benefits of vaccines and vaccines through school programs. The program will prioritize engaging parents who have pro-vaccine views, but may not have the means to vaccinate children, or who are generally pro-vaccine, but are uncomfortable with vaccines that prevent sexually transmitted infections. Building these relationships will help spread benefits of this program through informal social networks.

The project manager will be responsible for assembling and communicating with the Community Advisory Board. People invited to the Community Advisory Board include school principals, interested parents and health department representatives. Principals and health department representatives will be contacted directly about membership, while parents will be invited through parent-teacher associations and flyers home from school. Program staff will also invite a member from the Ashland Area Ministerial Association; having pastors from the community involved in the project may ease parent fears about HPV vaccines encouraging

sexual activity in teens. Having these roles represented on the board will ensure that the program is responding to community needs, is transparent with intentions and so that issues with implementation can be resolved with input from several different perspectives and expertise.

KDMC will carry the majority of program responsibilities. These responsibilities include developing and delivering educational presentations as well as administering vaccines. The main role of the schools is to provide a designated space for the hired RN and in school vaccine clinic. Educational events will also occur at school-sponsored events, so schools will need to accommodate some events to allow program RNs to deliver educational programming. Special measures will be taken to ensure that school staff are not overburdened with the proposed program; program RNs will work with principals and teachers to make sure that program activities are minimally invasive to the normal school day.

Project Management:

The proposed program will be managed through several online software programs that will allow for better communication and networking between RNs at each school and program management at KDMC. The program coordinator will upload all needed educational materials to a shared folder, along with reminders on how to best present information on HPV vaccinations. Progress on vaccine initiation and completion will be tracked by the data manager at KDMC through Epic, an electronic health record software. The program manager will send data reports to school RNs following each vaccine event to update RNs about current progress and the portion of the population that remains unreached by the program.

The roles and responsibilities of the program coordinator will be to communicate with individual school vaccine clinics and to ensure they have adequate supplies of vaccines as well as to coordinate billing with the VFC program. Since this program already exists in neighboring

counties, the person already has experience running school-based vaccine programs in Boyd, Carter and Greenup Counties. Hired RNs will be responsible for delivering formal and informal education events, communicating with parents, collecting consent forms and administering vaccines. RNs are trained in vaccine administration and also have skills in providing patient education to patients as well as managing a full schedule of patients. A data manager within the KMDC system will be utilized to gather data from Epic and create reports about the efficacy of the program. The person is this role has experience in creating quality improvement reports that explain the health system's success in meeting certain benchmarks like screenings and vaccines.

The program coordinator will have a standing meeting once per month throughout the school year with the principal and RN at each middle school principle. This will encourage clear communication between these groups so that each party understands expectations and goals for the upcoming month while also clarifying and problem-solving any obstacles from the previous month. At these meetings, the program coordinator will also share data from KDMC about total numbers of vaccine initiation and completion, comparisons to other community populations, and groups within the school that are not receiving vaccines. This will allow a more targeted approach for future educational events and will provide feedback on the current state of the program in relation to its goals. Communication between RNs, principles and program coordinator will also build relationships between these groups to encourage project sustainability.

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Budget Justification:

Project Coordinator (15%): The project coordinator is a staff member of KDMC that is currently oversees the in school walk-in clinic at schools in Boyd, Carter and Greenup Counties. This staff member already has experience with school-based healthcare and coordinating immunizations between suppliers and each school clinic. This position will also be responsible for holding CAG meetings.

	Effort	Salary		Fringe	Total
Year 1	15.00%	$90,000.00	$ 13,500.00	$ 4,725.00	$ 18,225.00
Year 2	15.00%	$92,700.00	$ 13,905.00	$ 4,867.00	$ 18,772.00
Year 3	15.00%	$95,481.00	$ 14,322.00	$ 14,322.00	$ 19,355.00
				3-Year Total:	$ 56,352.00

Registered Nurses: The program also plans to hire one registered nurse (RN) for each school, to be paid on a base salary of $60,000. Percent effort for each of the nursing jobs will be based upon the population of students at the school he or she works in. Percent effort for each nursing position can be seen in the table above Individuals hired for this position will have to be Board Certified and licensed nurses within the regulations of the state of Kentucky. They will be responsible for delivering vaccine education to parents and overseeing the vaccine events in the school each month.

		Effort	Salary		Fringe	Total
Nurse 1	Year 1	75%	$ 60,000.00	$ 45,000.00	$ 15,750.00	$ 60,750.00
	Year 2	75%	$61,800	$ 46,350.00	$ 16,223.00	$ 62,573.00
	Year 3	75%	$ 63,654.00	$ 47,741.00	$ 26,709.00	$ 64,450.00
		Effort	**Salary**		**Fringe**	**Total**
Nurse 2	Year 1	40%	$ 60,000.00	$ 24,000.00	$ 8,400.00	$ 32,400.00
	Year 2	40%	$ 61,800.00	$ 24,720.00	$ 8,652.00	$ 33,372.00
	Year 3	40%	$ 63,654.00	$ 25,462.00	$ 8,912.00	$ 34,373.00
		Effort	**Salary**		**Fringe**	**Total**
Nurse 3	Year 1	10%	$ 60,000.00	$ 6,000.00	$ 2,100.00	$ 8,100.00
	Year 2	10%	$ 61,800.00	$ 6,180.00	$ 2,163.00	$ 8,343.00
	Year 3	10%	$ 63,654.00	$ 6,365.00	$ 2,228.00	$ 8,593.00
		Effort	**Salary**		**Fringe**	**Total**
Nurse 4	Year 1	15%	$ 60,000.00	$ 9,000.00	$ 3,150.00	$ 12,150.00
	Year 2	15%	$ 61,800.00	$ 9,270.00	$ 3,245.00	$ 12,515.00
	Year 3	15%	$ 63,654.00	$ 9,548.00	$ 3,342.00	$ 12,890.00
					3 Year Total	$ 350,509.00

Data Analyst (10%): This program will also provide salary support to an existing data analyst staff member within KDMC This individual will have experience in using Epic to produce data reports about quality measures such as patient vaccination. This individual will utilize Epic software to demonstrate the impact of the program compared to historical rates of vaccination within each county/region and create data reports for the school nurses and program coordinator on a bi-annual basis.

	Effort	Salary		Fringe	Total
Year 1	10%	$70,000.00	$ 7,000.00	$ 2,450.00	$ 9,450.00
Year 2	10%	$72,100.00	$ 7,210.00	$ 2,524.00	$ 9,734.00
Year 3	10%	$74,263.00	$ 7,426.00	$ 2,599.00	$ 10,026.00
				3-Year Total	$29,210

Travel: The program will budget for travel to several training opportunities throughout the three-year program. The program coordinator will travel to a Project Directors Meeting annually. In years 2 and three, the data analyst and project coordinator will travel for a Regional training. Each of these trainings are located in Washington D.C. Costs of travel will be paid to the project manager for the Project Directors Meeting and the project coordinator and data analyst for regional trainings.

	Year 1	Year 2	Year 3
Project Directors Meeting	$ 1,000.00	$ 1,000.00	$ 1,000.00
Regional Training	$ -	$ 1,900.00	$ 1,900.00
		3-Year Total	$ 6,800.00

Research Incentives: Some incentives will be used to encourage parents to complete surveys after delivery of educational events. Each semester, there will be a drawing for a $100 Visa gift card. Over three years, this will total $600.

Equipment: The applicant organization will provide a laptop for each of the school nurses to use within their schools to communicate effectively with KDMC leadership and use Epic to log administered vaccines. These will cost $600 per unit for a 3-year total of $1,200.

Supplies: A large share of the budget will be spent on HPV vaccines. While the federal Vaccines for Children Program will cover a majority of the vaccine costs, the applicant organization will pay for 10 students to receive both the initial and final dose of the vaccine each month. Over three years, this will total 420 vaccines. As of April 1, 2022, HPV vaccines cost $206.50. Other costs related to vaccine administration include needles, gloves, alcohol swabs and bandages.

Supplies needed include printed infographics and consent forms to be distributed at information sessions and sent home with students. This cost is expected to be higher in the first year of the program when there may be more interest and more students and parents are being

reached. In the second and third year of the program, fewer students will be new to the program, so printing costs will be reduced.

Vaccines (140 per year)	$29,127	$29,127	$29,127
Needles ($0.20)	$85	$85	$85
Gloves ($0.12)	$180	$60	$60
Alcohol swabs ($0.16)	$240	$80	$80
Bandages ($0.10)	$150	$50	$50
Printing	$950	$235	$235
		3-Year Total	$90,006

Indirect costs: The facilities and administrative cost rate has been negotiated by the KDMC system at 35%. Over the three-year grant, this will total $167,479.

Logic Model:

Inputs	Activities	Outputs	Outcomes -- Impact		
			Short	*Medium*	*Long*
Partnership forming with schools, principals Partnership forming with health department in enrolling students in VFC Hiring 5 school registered nurses Set-up in school vaccine clinics, physical space Financial resources	Development of educational programming Creation of vaccine programs Meeting with school principals Meeting with parent groups within the school Creation of vaccine schedule/planning educational events	4 formal education sessions per year (2 per semester) Minimum 10 informal education sessions (5 per semester) Distribution of HPV vaccine infographics Distribution/collection of vaccine consent forms Once per month in-school vaccine clinic	Increased knowledge of HPV, cervical cancer and HPV vaccines Increased access to HPV vaccines Increased perceived susceptibility to HPV Increased perceived severity of HPV	Increased rate of HPV vaccine initiation Increased rate of HPV vaccine completion	Decreased rates of HPV infection Lower rates of HPV related cancer, including cervical cancer

Assumptions
Nurses can be hired for program activities
Health Belief Model is useful in addressing vaccine behavior
Parents act in best interest of children

External Factors
Policy affecting RN powers
CDC recommendations to HPV vaccine schedule

Gantt Chart:

	YEAR 1												YEAR 2												YEAR 3											
	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
Development																																				
Recruit/hire RNs																																				
Meet school Principles																																				
Meet with HD																																				
Enroll students in VFC																																				
Recruit CAB																																				
Develop curriculum																																				
Implementation																																				
Informal education events																																				
Formal education events																																				
Consent form distribution																																				
School vaccine events																																				
Evaluation																																				
Parent Interviews																																				
Principal/teacher interviews																																				
Epic data reports																																				
HPV knowledge survey dist/analysis																																				