SCHOOL-BASED HPV9 VACCINATION CLINIC IN THE CUMBERLAND VALLEY AREA DEVELOPMENT DISTRICT OF KENTUCKY

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SCHOOL-BASED HPV9 VACCINATION CLINIC IN THE CUMBERLAND VALLEY AREA DEVELOPMENT DISTRICT OF KENTUCKY

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the requirements for the degree of Master of Public Health in the University of Kentucky College of Public Health

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Lexington, KY
April 11, 2018

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Abstract

Human Papillomavirus (HPV) is a group of more than 150 virus that can cause genital warts and cancers of the oropharynx, cervix, vagina, vulva, penis, and anus. A preventive vaccine currently exists that protects against seven oncogenic HPV strands and two strands that cause genital warts. Current guidelines for HPV9 vaccination consist of a 2-dose series delivered at 0 and 6 months for males and females ages 9-14, and a 3-dose series delivered at 0, 2, and 6 months for those ages 15-26.

While up-to-date (UTD) vaccination rates have increased across the Unites States, in 2017, only about 52.4% of adolescents in central city areas were vaccinated and those outside of a metropolitan area lagged behind at 42.4%. In Kentucky specifically, the Cumberland Valley Area Development Distract (CVADD) has among the highest incidence rates of both cervical and head and neck cancers compared to the other area development districts in the state. As a result, the Cumberland Valley District Health Department has decided to utilize their existing relationships within Clay, Jackson, and Rockcastle County to implement a School-Based HPV9 Vaccination Clinic in the middle schools in the aforementioned counties.

The school-based clinic will begin with recruitment efforts at back-to-school events within the counties involved. The clinics will be deployed in the schools with the first dose of the series offered in August and September for five days each month, and the second dose will be available in March and April. Retention efforts will include paper and text message reminders as well as incentives for initiating and completing the 2-dose series.

Performance evaluation measures will be collected throughout the project; consent forms will be completed by parents or guardians. A process evaluation will consist of clinic logs and parent and guardian surveys to assess barriers to vaccination and their satisfaction with the vaccine clinics. Primary outcome measures will be vaccination initiation and completion rates. Secondary outcomes will focus on existing knowledge of HPV vaccination and biases associated with the HPV vaccine and other immunizations; these will be assessed through the University of North Carolina National Parent Survey. We hope that a School-Based HPV9 Vaccination Clinic will increase UTD vaccination rates among youth in the CVADD, foster a passion that allows us to expand this program to the remaining counties in the CVADD, and decrease HPV-associated cancer rates in this region of Kentucky.
Target Population and Need

Public Health Need

Human Papillomavirus (HPV) is a group of more than 150 related viruses. HPV can be transmitted through skin-to-skin intimate contact. It is most commonly spread through participating in oral, vaginal, or anal sex with someone who carries the virus. The transmission of the virus is common partly because most infected individuals are asymptomatic. Some people will develop symptoms years after being initially infected (i.e., persistent infection), while in others, the virus clears on its own. Nearly all men and women become infected with HPV at some point in their lives.1

When HPV does not clear on its own, it can cause detrimental health effects such as genital warts and cancer. The types of cancers that HPV can cause include cancers of the oropharynx, cervix, vulva, vagina, penis, and anus. Each year, about 39,800 new cancer cases are diagnosed in parts of the body where HPV can be found. Of those cases, HPV is the cause of about 31,500 of the cancers, which equates to nearly 80% of cases. These cancers often have relatively benign symptoms until they are advanced and hard to treat. Cervical cancer is the most common HPV-associated cancer among women, and head and neck cancer is the most common HPV-associated malignancy among men.2

The current Advisory Committee on Immunization Practices (ACIP)-recommended HPV vaccine protects against infection from nine different HPV strands, seven of which cause cervical, head and neck, vaginal, vulvar, or anal cancers and two of which cause genital warts. HPV vaccination is indicated for both males and females who are 9-26 years old. For those aged 9-14, the vaccination is given in a 2-dose schedule wherein the second vaccine is given 6-12 months after the first dose.3 For adolescents and young adults aged 15-26, 3-doses of the HPV
vaccine is recommended; the second immunization is administered 2 months after the first, and the third is given 6 months after the first shot\(^4\). In addition, the Food and Drug Administration approved the use of the HPV9 vaccine for men and women aged 27-45 in October 2018; vaccination guidelines for the older catch-up pool of adults are forthcoming from the ACIP\(^5\). The HPV vaccine is up to 98% efficacious in preventing cervical cancer when the complete vaccination series is administered at the appropriate age. However, barriers exist to receiving the initial HPV vaccine as well as subsequent doses\(^6\). These barriers include, but are not limited to, geographical and socioeconomic barriers to receiving preventive healthcare, absence of a strong and consistent provider recommendation, and limited awareness of the existence of the vaccine and HPV’s link to cancer. Additionally, the vaccine has been encountered with controversy due to moral, religious, political, medical, gendered, and sociocultural beliefs\(^7\).

**Target Population**

Since the introduction of the HPV vaccine in 2006, vaccination rates have increased across the United States (U.S.) over the last 13 years, although they are still suboptimal compared to other adolescent vaccine rates such as Tetanus-Diphtheria-Pertussis (Tdap) and meningococcal conjugate\(^8\). About half of adolescents across the country were up-to-date (UTD) on the HPV vaccine series in 2017 and about two-thirds had received at least the first dose of the vaccine series. This is an increase of about 5 percentage points over the past 5 years\(^9\). However, Kentucky adolescent male and females continue to lag behind the rest of the country when it comes to UTD HPV vaccination rates (Figure 1).
Lower rates of HPV vaccination in Kentucky could be due in part to the rural geography of the state. In the U.S., those that live in a metropolitan statistical area have UTD HPV vaccination rates as high as 52.4% when living in a central city. Those that live outside of a metropolitan statistical area have vaccination rates of 42.4%. Due to this data, the Centers for Disease Control and Prevention (CDC) has prioritized increasing HPV vaccination coverage rates in rural communities\textsuperscript{9}. The Appalachia region of the U.S., comprising 420 counties in 13 states, has higher incidence of all cancer types, including head and neck cancers and cervical cancers, and lower HPV vaccination rates than its non-Appalachian counterparts\textsuperscript{10,11}. As such, we identified the Cumberland Valley Area Development District (CVADD) in Appalachian Kentucky as a rural region in which there was a particular need for a School-Based HPV9 Vaccination Clinic. As mentioned previously, cervical and head and neck cancers are two of the most common complications of HPV, and this district is amongst the highest in the state in both cervical cancer incidence and mortality, as shown in Figure 2 and 3 respectively. The CVADD is also amongst the highest ADD for oropharyngeal cancer rates, as shown in Figure 4\textsuperscript{12}. 

\textbf{Figure 1:} HPV Vaccination Rates in Kentucky versus the U.S., 2017

![HPV Vaccination Rates](image_url)
A high rate of cervical cancer is a sentinel marker for many larger health care issues indicating that there may be broader problems to access to care in these regions\textsuperscript{13}. In addition, CVADD scores lower on many social determinants of health compared to the entire state of Kentucky. For example, from 2012-2016 about 85\% of adults aged 25 or older have graduated high school in Kentucky, while only about 73\% of adults graduated high school within the targeted district. The median household income within the state is $44,811; the median household income within CVADD is more than $14,000 lower at $29,584. There was a higher teen-birth rate in the CVADD than within the state of Kentucky from 2011-2015; 58 per 1,000 women aged 15-19 compared to 37, respectively\textsuperscript{14}. Unfortunately, HPV vaccination data at the county or ADD level is unavailable for Kentucky.

Although we hope to eventually implement our program throughout the entire CVADD, we want to first pilot our program in three counties in the region in order to ensure program
success and establish best practices. We have decided to utilize the existing relationship between the Cumberland Valley District Health Department (CVDHD) and the counties in which it represents – Jackson, Rockcastle, and Clay – in order to complete this pilot. Specifically, our program will target the parents and guardians of middle-school aged children that attend public middle schools within these three counties. Jackson County is home to Jackson County Middle School (JCMS), Rockcastle County contains Rockcastle County Middle School (RCMS), and Clay County has Clay County Middle School (CCMS). CCMS currently has 488 students enrolled within their middle school that is comprised of two grades. We estimate that approximately 250 students will be in the 7th grade each of the three years our program is ongoing. JCMS currently has 448 students and RCMS has 664 students. We estimate that there will be approximately 150 6th graders and 220 6th graders in the respective schools during the length of our program. CCMS will participate in the program for three years, RCMS will participate for 2 years, and JCMS for one. This would equate to 1,340 students with potential participation in our School-Based HPV Vaccination Clinic over the three years. Recruitment initiatives will begin at community Back-to-School events in which information will be provided to parents and students regarding the HPV vaccine series. For more details, see the “Recruitment” section on page 13 of this application. Recruitment and retention efforts will be maintained through regular contact with students while at school.

**Community Resources**

The three counties in which our program will be implemented are served by the Cumberland Valley District Health Department (CVDHD). Based on the success of our pilot project, we hope to foster a relationship between the district health department and the other independent county health departments in the CVADD in order to disseminate our project to
other school settings. The CVDHD clinics offer Tdap, influenza, and Measles-Mumps-Rubella (MMR) immunizations\textsuperscript{15}. While they will need to be trained on HPV vaccination, specifically, there are already staff that are trained to administer routine immunizations. The three counties represented by the CVDHD also have their own local health departments in their respective counties. These local health departments will provide resources, ideas, partners, and personnel to help facilitate our program. Specifically, Healthy Clay, a coalition of organizations and individuals working together to promote policy and community change for Clay County, has a goal to increase school initiatives within their county. The Cumberland Valley District Cancer Council (CVDCC) partners with the Kentucky Cancer Program and the Kentucky Cancer Consortium, managed by the University of Kentucky (UK) Markey Cancer Center (MCC), to discuss strategic planning to address local cancer problems and implement initiatives. The CVDCC meets quarterly and consists of representatives from the county and district health departments, hospitals, government agencies, healthcare providers, universities, businesses, labor unions, schools, tobacco coalitions, and cancer survivors\textsuperscript{16}. Additionally, Clay County Community Hospital and Rockcastle Regional Hospital and Respiratory Care Center exist within Clay and Rockcastle counties respectively\textsuperscript{14}. Somerset Community College is located within this ADD and offers an accelerated Licensed Practical Nurse (LPN) degree. Nurses from these surrounding hospitals and new graduates from the community college can be hired or volunteer to administer vaccinations to adolescents as part of our program.

Our School-Based HPV9 Vaccination Clinic will strengthen current relationships among the health departments and the public middle schools within the counties. The proposed program will enhance the number of adolescents that are reached by making it more convenient and accessible for them to receive the complete vaccine series, and therefore prevent the spread of
HPV and future development of HPV-associated cancers caused by the virus. We will work with the aforementioned parties to assess changing community needs in order to adapt the program as needed throughout the longevity of the grant to provide as many adolescents as possible the HPV vaccine series.

**Program Approach**

**School-Based HPV9 Vaccination Clinic**

This program physically takes place within the school system and consists of collaborations between the school and local health departments, private healthcare providers, and community healthcare services. School-based vaccination programs include a variety of activities, including at least two of the following components: (1) immunization education and promotion, (2) assessment and tracking of vaccination status, (3) referral of under-immunized school or childcare center attendees to vaccination providers, or (4) provision of vaccines\(^\text{17}\). Other activities that have been implemented within these school-based programs are telephone reminder systems, incentives to increase participation, and community advocacy\(^\text{18}\).

The timeline for school-based vaccination interventions vary based on the delivery schedule of the immunizations given and the flexibility of the staff involved. When implemented based on the HPV9 vaccine, those implementing the program would need to follow the standard vaccination series based on the age of the youth (i.e., 2 doses for ages 9-14). Ideally, both doses of the vaccine should be given during the school year in order to avoid a delay in vaccination administration during the summer months. Our program will be based on iterations of school-based HPV vaccination conducted in Guilford, North Carolina and eastern Kentucky. In previous iterations of school-based HPV vaccination programs such as in North Carolina, plans have been implemented in a very fixed timeline, in which the first vaccine of the series would only be
offered to students for one day. Then, the administrators, usually nurses, would come back two and six months later to administer the subsequent doses\textsuperscript{19}. The program has also been previously implemented in a way in which students have the opportunity to receive their first dose over a longer period. For example, as previously implemented in the Lake Cumberland region of eastern Kentucky, the first dose of the vaccine series was offered from August through November\textsuperscript{18}. The second dose of the vaccine would, therefore, be available from March through June.

**Evidence-Base**

Since 2009, vaccination programs in schools and organized childcare centers have been recommended as evidence-based interventions on The Community Guide according to two systematic analyses conducted by the Community Preventive Services Task Force\textsuperscript{17}. Twenty-seven studies were included in these analyses. Based on these analyses, vaccination rates increased by a median of 47 percentage points whenever a school-based program was implemented. The task force considered this to be strong evidence of effectiveness. In 23 of these 27 programs, immunizations were provided on-site and included educational materials, parental notification and consent forms, and additional opportunities to obtain the offered vaccinations (e.g., a “make-up” schedule). Multi-component interventions could potentially show increased effectiveness\textsuperscript{17}.

Positive outcomes have also been discovered when specifically concentrating on the HPV vaccine. The American Academy of Pediatrics conducted a review of 51 studies that shared a focus of increasing HPV vaccination rates. Researchers found environmental interventions, particularly school-based programs, to be the most successful. They stated that school-based vaccination programs had two major advantages that contributed to their success when compared
to other interventions: (1) increased access to the HPV vaccine and (2) that these interventions were able to reach a large, diverse population without regards to individual access to healthcare. In addition, a study in North Carolina was conducted in which six middle schools offered the 3-dose HPV vaccine series to their female students. Of the 181 girls who initiated the vaccine series in the school-based clinics, 80% received all three doses of the vaccine. A similar school-based intervention completed in two high schools in eastern Kentucky, offered the 3-dose vaccine series to both female and male students. The vaccine series was initiated in these school-based clinics by 70% of vaccine-naïve students. Of the 315 students that initiated the vaccine series as part of the clinics, 88% completed all three doses of the vaccine.

**Setting**

When completing our community needs and resource assessment, we identified three counties within the CVADD with elevated HPV-associated cancer rates and a stable public health infrastructure coordinated by the CVDHD. These three counties were Clay County, Jackson County, and Rockcastle County. Each of these counties possess their own public health department that works closely with the CVDHD. In addition, Clay and Rockcastle counties each have a hospital, leading to additional healthcare resources as needed. Therefore, we decided to implement our program within the public middle schools within these three counties: Clay County Middle School (CCMS), Jackson County Middle School (JCMS), and Rockcastle County Middle School (RCMS). Implementation in the middle schools allows us to access the majority of 11-12 year-olds, all of whom are indicated to receive the HPV vaccination series based on age.

**Community Advisory Group**
Assembling an effective Community Advisory Group (CAG) is an essential part to ensuring the success of this intervention. A School-Based HPV9 Vaccination Clinic will be dependent on the school systems in the area as well as local agencies. In order to form this CAG, we have identified key community members who are known in the area and are familiar with the resources within the community. Inviting staff from the CVDHD will be essential in order to expand upon vaccination programs already implemented in the region. Members of the school boards and principals of the middle schools in which the program will be implemented are also integral as these are the locations in which the intervention will take place. Parents will also be invited in order to gauge their perspective on how to best reach most parents with regards to giving consent for the vaccination series. A pediatrician, dentist, and pharmacist will be asked to join the group to give their expertise on the safety, efficacy, and need for vaccines. A nurse will also be in the group as nurses will be the primary staff administering the HPV vaccine. As one of the largest expected barriers to this program is the negative connotation that administering the vaccine will encourage teenagers to engage in risky sexual behavior, a prominent church leader from the area will be recruited for the CAG; he will be beneficial to overcoming negative beliefs about the cancer-preventing vaccine. Additionally, we will recruit two middle school representatives to be a part of the CAG as the students will be the ones participating in the intervention and their opinions and influence are essential to successful program implementation. We will gather interest from the Student Government, Future Farmers of America, and Fellowship of Christian Athletes presidents, captains of various sports teams, and leaders of the drama club and band in order to spread awareness of the program.

The CAG will meet before the Back-to-School event each year and at the beginning of each quarter in order to maintain relationships, provide updates, gain feedback, and assure that
high quality healthcare is provided to both the participants and the community. By meeting this frequently, we also hope to remain up-to-date in information regarding HPV, HPV-associated cancers, and the HPV vaccine. The table below provides a list of the CAG members.

<table>
<thead>
<tr>
<th>Table 1: Community Advisory Group Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lainey Greene, MPH PD, Cumberland Valley Health Department</td>
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<tr>
<td>Megan Wiggins Member, Clay County School Board</td>
</tr>
<tr>
<td>Michael Robin Principal, RCMS</td>
</tr>
<tr>
<td>To Be Named Parent, Jackson County Middle School</td>
</tr>
<tr>
<td>Scott Wees Pastor</td>
</tr>
<tr>
<td>Gabriella Hamilton SGA President, JCMS</td>
</tr>
</tbody>
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**Recruitment**

Before we begin recruiting students to participate in the School-Based HPV9 Vaccination Clinic, it is crucial that we address potential barriers to program implementation. One of the barriers that we will likely face as we begin to recruit individuals is pushback from parents/guardians who do not want their children to receive the vaccination due to negative biases associated with it. This is why we plan to hold an educational event at the schools before the recruitment process begins. This event will take place at community Back-to-School events and be intended for students who are eligible to receive the vaccine series, their parents/guardians, teachers and school administrators, and any other community member that is interested in the information. These events are typically held after school and regular business hours in order to encourage attendance. All of our community stakeholders will be present at the event and are encouraged to invite guests who they know will benefit from HPV-related education. At the event, local healthcare providers will lead a discussion about the safety and
efficacy of the HPV vaccine. This will be followed by an update about the epidemiology of HPV-associated health problems in the region from the director of the CVDHD. Next, a member of the community living with cervical cancer will give her story to the audience. Our portion of the event will end with an open forum in which parents/guardians, in particular, are encouraged to ask any questions they feel need to be answered before giving their consent to HPV vaccine administration in the school. We will also have representatives present at a booth throughout the entirety of the Back-to-School event in order to answer these questions and give parents and guardians the opportunity to fill out consent forms for their children and the pre-vaccination parent survey.

The official recruitment process will begin with consent forms that will be distributed to parents. The forms will be available at the Back-to-School Events and taken home with the students in the 6th grade at RCMS and JCMS and the students in the 7th grade at CCMS on their first day of class. The parents of 6th and 7th graders at the respective schools will also be sent a link via email to complete the consent form online for convenience and to decrease the chance of students losing consent forms either before or after giving them to their parents. Each consent form will gather information on the student’s demographics, past HPV vaccination history, and the form will ask for documentation of vaccine administration, if possible. The form will also ask for both the consent of the parents to administer all doses of the HPV immunization that have not yet been given to the students as well as consent to collect data from parents and guardians in the form of pre- and post-vaccination surveys. If the student is given consent to receive the vaccine series, the parent will be asked to provide the student’s insurance information, if applicable, in order to bill for the vaccine doses. The consent forms will ask information that will assist the nurses in filling out the vaccine administration questionnaire. The HPV9 Vaccine Parent Consent
Form is available as Appendix A. All students who have returned parental consent forms, either over the internet or in-person, will be asked for their assent before participating in our intervention. The parent/guardian and/or student will have the option to discontinue participating in the intervention at any time.

**Implementation of Program**

Our School-Based Clinic will operate with two different cycles available each year. In the first cycle the 2-shot series will be available in August and March; the second cycle will be available in September and April. The first immunization in the HPV vaccine series will be available to the 6th or 7th graders who returned parental consent forms among the three selected middle schools in August. Three nurses, the Program Coordinator (PC), and graduate-level student research assistants will visit each school for a total of 5 days. During those days, students will be able to visit the nurse’s office in order to receive their vaccination. They will be encouraged to do this during either a lunch period, study hall, or any other free periods the student may have so as not to interfere with their academic curriculum. Once they arrive, the nurses will identify the student’s pre-filled vaccine administration questionnaire and be asked if they feel sick that day in order to complete the form. Female students will also be asked if there is any chance they are pregnant. Next, they will be sent to the nurses who will review the questionnaire and administer the vaccination if deemed appropriate. The research assistants will provide them with the current HPV Vaccine Information Statement (VIS), a raffle ticket to be entered into a prize drawing, and a reminder slip for their next vaccination. They will also document the date of the administration or any reasons the vaccine could not be administered. The students will be asked to wait at least 15 minutes before leaving the nurse’s office in order to be observed for syncope or other adverse reactions. If any adverse events do occur, these will be
documented for program research purposes as well as documented officially through the FDA Adverse Event Reporting System (FAERS). The PC will assist with observing the students and overseeing the tasks of the graduate research assistants (GRA) in order to monitor for fidelity and intervene in which the outlined processes are not followed.

All data collected as part of the School-Based Vaccination Clinic will be incorporated into a holistic medical record for each adolescent who participates. This medical record will contain their demographic information, primary care provider or pediatrician, vaccine administration data, allergies, any adverse events that occur due to the HPV9 vaccine, and insurance information. This will allow the implementation team to take a more comprehensive approach to healthcare for the children involved and maintain better tracking records so fewer students are lost to follow-up. Each record will be kept with the intent to share with the pediatrician or healthcare provider who primarily cares for the child.

A similar process will take place six months later during March in order for students to receive the second vaccine in the 2-dose series. Before the second dose is administered, the parents/guardians and students will receive reminders of the upcoming vaccine administration. These reminders are described in more detail under the “Retention” section on page 18. We will repeat the process again with the first vaccination administered in September and the second in April. The first year of the program will be a pilot period in which CCMS will receive the intervention. During this period, the Program Director (PD) and PC will monitor closely for program fidelity, assess areas in which quality improvement measures can be implemented, and determine and mitigate barriers to program implementation. We will also make efforts to assess that all program materials are medically accurate and age, culturally, and linguistically appropriate for our adolescent and parent/guardian populations. In the second year of the grant,
both CCMS and RCMS will have the School-Based HPV9 Vaccination Clinic intervention while JCMS serves as the control. In the final year of program implementation, all three middle schools will receive the intervention in following with the wait-list control method. Appendix B contains calendars depicting when the immunizations will be available at each school.

Training of all members participating in program implementation will be conducted at the beginning of each school year. These trainings will consist of topics such as appropriate ways to interact with adolescents and parents/guardians, sensitivity and inclusivity training, HPV and its associated vaccine education, and program implementation training. A shortened version of these sessions will be conducted before the second semester of each school year for any new members to the implementation team and as a refresher for existing members. Additionally, the nurses administering the vaccine will have a more in-depth training concerning vaccine administration.

Impact

While it is difficult to determine the broader impact of the school-based vaccination intervention for the HPV immunization within Kentucky and the U.S., there have been positive data related to this type of public health intervention in both Canada and Australia. Women who received the HPV vaccine as part of a school-based program in Alberta, Canada had fewer high-grade cervical abnormalities; these cervical abnormalities can often be the first step in identifying a cervical cancer diagnosis. These women also had higher rates of cervical screening, which may indicate that they exhibit a greater overall knowledge about their reproductive health. However, these results only held their significance when all three doses of the vaccination were administered\textsuperscript{21}. In April of 2007, Australia commenced a nationwide vaccination program that targeted 12- and 13-year old girls in schools, a “catch-up program” in schools for girls aged 14-17, and a community-based program for women aged 18-26. A study in Victoria, Australia, in
which they compared cervical abnormalities amongst girls who were eligible for vaccination in the school-based program, found that a lower risk of any histologically confirmed high-grade cervical abnormality was found for women who had received any HPV vaccination compared with unvaccinated women. This effect was observed to be strongest in those that had received the complete vaccination series. Reduced incidence of cervical abnormalities will, hopefully, lead to lower rates of cervical cancer within Australia and Canada. By building upon previous school-based vaccination interventions and adapting for local context, we hope to reproduce this impact in the CVADD in Kentucky.

**Retention**

Retention is crucial for the success of a School-Based Vaccination Clinic for the HPV Vaccine, as to receive maximum effectiveness of the vaccine, both doses have to be given at the indicated interval. Most students participating in the intervention should already be attending school almost every day, so the potential barrier to retention lies outside of not being able to make it to the site of the intervention. However, the students must be reminded to report to the vaccination clinic within the school on the appropriate days 6 months after their first vaccination. One approach in which this will be addressed throughout the program is by sending reminders to the student’s home highlighting the child’s next immunization due date. A paper reminder will be sent home with each student approximately one week before their next vaccine in the series is due. Additionally, parents will receive a text message approximately one day before their child is due to receive their next vaccination. The idea behind both the text message and letter is that the student and parent will each be notified by both reading the letter and receiving the text message or having the message relayed to them. However, if the student never gives their parent/guardian the letter or the parent/guardian forgets to tell their child about their scheduled
vaccination, they each will each be reminded at least once. Although the students will be encouraged to receive their vaccination in the School-Based Clinic, these reminders will also provide information on how to end program participation if they wish to do so.

There will also be incentives in order to increase both participation and completion of the program. If a student completes the entire vaccination series, they will be invited to participate in a pizza party. This will be offered to all students whether they completed the entire series at the School-Based Clinic or finished the series that was already started at a pediatrician’s office or other health center. This is designed so that more students will want to participate in the program through its entirety, rather than just receive one dose in the series. Additionally, students will receive a raffle ticket for every HPV vaccination they receive at school. They will have the opportunity to enter these raffle tickets to receive a basket in a prize drawing held on the day of the pizza party. Some examples of baskets will include a movie basket, a Kentucky sports basket, and a lotion/skin care basket. Our hope is that if peer leaders within the middle schools participate in our program, they will allow other students to be exposed to our intervention through observational modeling. Eventually, we believe that participating in the School-Based HPV9 Vaccination Clinic can become the social norm, and those that did not participate in the clinic initially will be motivated due to fear of missing out on the pizza party and chance to win prize baskets.

While there will be many measures taken, such as text messages and paper reminders and posters created and hung in school, in order to assure that students are reminded to participate and engage in the School-Based Vaccination Clinic, we do foresee that some students may be lost to follow-up. For example, adolescents may transfer schools due to different circumstances. If the child transfers from one school that is participating in the school-based clinic to another,
the child’s medical record will be transferred to his or her new school, and he or she will continue to be followed. However, if the student transfers to a school that is not participating in the intervention, this student will no longer be participating. In this instance, we will transfer the child’s comprehensive medical record to his or her pediatrician if we received consent to do so. This will, hopefully, encourage the pediatrician to complete the HPV vaccination series. If a female student becomes pregnant before the first-dose of the vaccine series she will be ineligible to participate in the program due to the vaccine being contraindicated in pregnant females. She will be encouraged to receive the vaccine if she continues school after delivering her baby. If a student becomes pregnant between the first- and second-dose of the vaccine, she will be encouraged to receive the second vaccination after delivering her baby. The medical record will assist the nursing staff in maintaining contact with these individuals. Finally, if a child experiences a serious adverse reaction to the vaccine, it will be recorded in their medical record and they will be contraindicated from receiving the subsequent dose of the vaccine.

We hope that the relationships built and fostered between the CVDHD, the education provided to and passion instilled in the students, and support from the community due to the School-Based Vaccination Clinics for the HPV9 Vaccine will allow the program to continue after grant funding ends. If this program increases vaccination rates within the participating counties, as we expect, we hope to expand the program to the remaining counties in the CVADD in future years.

Adaptations

Our School-Based HPV9 Vaccination Clinic will consist of two minor adaptations from the original interventions, as executed in Guilford County, North Carolina and the Lake Cumberland region of Kentucky. The first is the way in which consent forms will be delivered to
the students. Although paper forms will still be given to each student, parents will also be sent a link in which they can fill out the form online and have the option to complete the forms during the Back-to-School Events. The additional source of the consent form was added due to low return rates of about 50% in a previous implementation of the program\textsuperscript{18}. We hope to reach more parents with the consent forms than in the original model. For example, if a student is given a consent form at school but forgets or neglects to give it to their parent once they get home, this new method of consent may help to increase consent rates. Secondly, we hope to eliminate the barrier of turning the consent form in given a child may lose it or forget to turn it in at school.

The second adaptation that will be made to this program is that it will be offered to both female and male students in a 2-dose series. This will be done in order to reflect the current ACIP recommendations. By offering the vaccine to all students within the designated grades, we hope to decrease the incidences of both cervical cancers and head and neck cancers, as well as provide students with the additional benefits that the vaccine series has to offer. Moreover, we hope to eliminate any gender biases that may have been associated with the HPV vaccine previously.

\textit{Performance Measures and Evaluation}

\textbf{Process Evaluation}

The program will utilize a process evaluation as recommended by the CDC in order to determine if the program is being implemented as planned, determine any barriers to implementation, and identify who is being reached by the program. The process evaluation will also consist of a financial analysis to ensure that the cost of implementing the program remains within the budget set forth in Appendix I. The data collected as part of the process evaluation will be utilized to adapt the program as warranted.
The consent forms that are sent to parents both electronically and in paper format will contain basic demographic information that will be valuable to the study. In addition to asking for vaccination consent, the form will ask for information regarding the adolescent’s sex, age, insurance status (either insured, Medicaid/KCHIP, or no insurance), and prior doses of the HPV vaccine\textsuperscript{18}. Collecting information on these measures will allow the Evaluation Team to determine groups of children that are being missed by the implementation strategy and identify ways to include these groups of individuals in future semesters of the program and studies.

In order to ensure that the School-Based HPV9 Vaccination Clinics are implemented as planned, both the Program Coordinator and the Assistant Coordinator will be present on all clinic days. They will be well-trained in the program implementation process and ways to course-correct to guarantee fidelity of the program. In addition, the nurses will complete study logs during and immediately following their experiences on clinic days. These logs will be used to document clinic processes as they have been implemented rather than intended\textsuperscript{17}. The Evaluation Team will review these logs after each semester and compare their outputs to the intended processes. The leadership team will plan additional training sessions if warranted based on the results from the nurses’ logs.

After the School-Based Vaccination Clinics, two different post-surveys will be given to parents and guardians of adolescents who returned consent forms. For those who gave consent for their children to be vaccinated, the Post-Vaccination Parent/Guardian Survey will characterize the reasons for which parents gave consent, prior barriers to vaccination, and evaluation of the School-Based Vaccination Clinic. This survey is shown in Appendix C. Parents will be encouraged to choose as many answers as they feel reasonable rather than limit themselves to one answer choice. For those parents that declined to give vaccination consent, a
separate Declined Consent Parent/Guardian Survey will be sent in order to determine barriers to obtaining this consent\textsuperscript{19}. This survey will consist of one question and is presented in Appendix D. Again, parents will be encouraged to choose multiple answers if they feel it is necessary to comprehensively answer the question. If there are a large number of parents who show displeasure with the evaluation of the School-Based Vaccination Clinic or who decline consent for vaccination, focus groups will be formed in order to further discuss this displeasure or barriers to consent. The outcomes of these focus groups will be used to make adaptation to the program and determine ways to overcome barriers to consent in future semesters.

**Outcome Evaluation**

In order to accurately assess the impact of the School-Based HPV9 Vaccination Clinic on immunization rates and other outcomes, our study will operate as a cluster wait-list controlled trial with a pilot period. Each school will serve as its own cluster. One school, CCMS, will serve as the pilot and will be the only school participating in the program during the first year. One additional school will be added to the study in each year thereafter, so that all schools will be participating in the intervention in the final year of the study period.

The primary outcomes assessed during this study will be HPV9 vaccination initiation and completion rates. These analyses will be conducted in two different manners. In the first analysis of each, only those who returned consent forms will be assessed in order to provide a straightforward interpretation of those choosing to participate in the program. A second analysis will be conducted in which school-wide vaccination rates will be considered. If an adequate amount of consent forms are returned to the schools with vaccination records, these materials will be used in order to determine the baseline vaccination initiation and completion rates. If not enough are returned, unfortunately, state-level data will have to be used as an estimate for these
three counties. Each time a vaccine is given or a series is completed throughout the study, it will be noted by the researchers. The post-program vaccination completion rates will be computed based on baseline data and those given as part of the program. Additionally, at the end of program implementation, we will assess our data at the CVDHD and contact local health departments and pediatrician offices to determine if more parents/guardians decided to have their children vaccinated during the study period, but outside of our School-Based Vaccination Clinic.

Secondary outcomes assessed will include parents/guardians’ existing knowledge of HPV vaccination and biases associated with the HPV vaccination and vaccinations in general. In order to assess these measures an adaptation of the UNC National Parents Survey regarding questions and concerns about HPV vaccination will be used. This survey was originally available online and intended to compare communication methods about HPV9 vaccination; however, it includes topics such as vaccination history, general vaccine attitudes, and HPV vaccine attitudes that would be beneficial to assess as a part of our School-Based Vaccination Clinics. Our iteration of the parent/guardian survey is available in Appendix E.

The original survey items have been previously validated in studies of parents, adolescents, and healthcare providers. Some items were adapted from other sources. The fully developed survey was cognitively tested with a convenience sample of 16 parents/guardians of adolescents who were aged 9 to 17 to confirm that participants understood items as intended. Additionally, the instrument was pre-tested with 31 parents from the national panel.

The measure will be available to the parents/guardians before vaccination at the Back-to-School Events, as well as, with the consent packets both in paper format and electronically. The clusters that are not receiving the intervention will serve as the baseline knowledge and control for this portion of the study as they will not be present at Back-to-School Events yet. These
parents/guardians will receive the survey as part of their adolescent’s packet at the beginning of the school year. All parents/guardians who complete the survey will receive a $5 Walmart gift card. The results of the surveys will be assessed for patterns and compared between the two groups.

A logic model detailing our anticipated inputs, activities, and short- and long-term outcomes is provided in Appendix G. Our leadership team formulated this model based on the Health Belief Model, the theory we hope to follow during program implementation. We believe we will address students’ and parents/guardians’ perceived susceptibility and severity of HPV and perceived benefits of receiving a preventive HPV vaccine through education delivered during back-to-school events. We anticipate decreasing perceived barriers to action by bringing the clinic directly into the middle schools and assessing and intervening on additional barriers. These factors will cue parents and guardians to action, and their children will participate in our School-Based HPV9 Vaccination Clinic.

**Capacity and Experience of the Applicant Organization**

The mission of the Cumberland Valley District Health Department (CVDHD) is “to improve and protect the health of individuals, families, and the public by implementing preventative health services that focus on individual and population-based health promotion to prevent disease, injury, and disability”15. This district health department has served the following counties for 46 years: Bell, Clay, Harlan, Jackson, Knox, Laurel, Rockcastle, and Whitley. We have long-standing coalitions with the Clay, Jackson, and Rockcastle County Health Departments. We have existing school health initiatives in the aforementioned counties’ schools that include having a health department nurse present to assist in preventive services such as well-child screening and immunizations, in addition to referral services and assessment and
treatment under physician collaborations and protocols. We confidently believe that the proposed School-Based HPV9 Vaccination Clinic aligns with our vision to become a healthy community in which the members have complete access to high quality care.

The department and its staff have experience implementing multiple programs within the CVADD including the following: partnership with the Health Access Nurturing Development Services (HANDS) program, syringe exchange programs, diabetes prevention and awareness programs for children and adults, and preventive cancer screenings. More specifically, within the Clay County, Jackson County, and Rockcastle County schools, they have hosted educational events detailing physical activity, healthy eating, and hand hygiene and have, most recently, provided filtered water-bottle filling stations. Most closely related to the Vaccination Clinic, we provide Td, Tdap, influenza, MMR, and Hepatitis A vaccinations on-site.

We also have strong partnerships with the county health departments in which we serve and have been actively involved in the training, implementation, and evaluation of multiple programs with them. Healthy Clay is comprised of goals in which they hope to meet by 2022. We have worked closely with them on these initiatives, one of them being to integrate healthy living and wellness into the school curriculum. Our collaboration has built gardens at Clay County schools to provide food and knowledge of healthy eating patterns. We have partnered with Jackson County Healthy Communities to develop and enhance access to walking and biking paths within the community. These paths include access to all Jackson County schools. We have collaborated with the Rockcastle County Health Department to establish greenhouses in all county schools and participate in Farm to Table programs. In addition, we partnered with them to enroll students in RocketReader programs to increase reading speed and scores. These prior
initiatives and collaborations including the target population will encourage adolescents and parents to participate in the CAG and foster support that may not have existed otherwise.

The CVDHD is led by Public Health Director Lainey Greene. Ms. Greene has experience implementing programs in her current role such as the syringe exchange program and was the lead in implementing the diabetes prevention program for children. In past roles, she has implemented mentorship programs for children from grade school through high school. She prides herself on having strong communication, education, and leadership skills and her past experiences are evidence of her commitment to improving the health of children in Appalachia Kentucky. For the past 4 years, Ms. Greene has managed the CVDHD budget of over $1,150,000 and serves as the supervisor of 38 committed employees.

In 2016, Rockcastle Regional Hospital and Respiratory Care Center performed a Community Health Needs Assessment (CHNA) in accordance with the National Association of County and City Health Officials’ recommendations of Rockcastle County and 14 surrounding counties. As part of this assessment, CVDHD assisted in evaluating the 2013 strategic priorities and developed the following 3 strategic priorities for the 2017-2019 fiscal years: cancer care and prevention, health education, and mental health and substance abuse. A School-Based HPV Vaccination Clinic will effectively fill a previous gap in the cancer care and prevention strategic priority. Our program can partially be evaluated as part of the 2021 CHNA.

Additionally, the CVDHD does not and shall not discriminate on the basis of age, disability, sex, race, color, national origin, religion, sexual orientation, gender identity, or reprisal or retaliation for prior civil rights activity in any of its activities or operations. These activities include hiring and firing of staff, selection of volunteers, and delivery of services. If administration of CVDHD discovers that any member or collaborator on a project is in violation
of this policy, that member shall be permanently terminated from the organization and banned from the project.

**Partnerships and Collaborations**

The CVDHD has a long-lasting history of foundational partnerships, and the collaboration on the proposed School-Based HP9V Vaccination Clinics will be no different. As the program will physically take place within the middle schools in the region, one of the most integral partnerships has already been developed with the middle schools in the area. The principles of each middle school participating in this program have voiced their support of the program through a letter of commitment. These letters of commitment are available in Appendix H. In addition to providing the vaccination clinic services, representation from the CVDHD has agreed to meet with the principals of each school to determine any additional services that can be provided through them to increase the health of the students in the region.

However, the School-Based Vaccination Clinic will rely on many other partnerships. Fortunately, many individuals and organizations have already voiced support and commitment to collaboration with the CVDHD for implementation of the proposed program. The following table illustrates those who have already given support and roles in implementation of the School-Based HPV9 Vaccination Clinic.

<table>
<thead>
<tr>
<th>Collaborative Organization</th>
<th>Representative/Liaison</th>
<th>Role</th>
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<tbody>
<tr>
<td>MCC Affiliate Networks</td>
<td>Dr. Jacob Wilkins; Oncologist at Rockcastle Regional Hospital and Respiratory Care Center</td>
<td>MCC will assist with determining baseline data for HPV-associated cancer rates. In addition, they are responsible for ensuring that all education regarding HPV-associated cancers provided to students and...</td>
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<tr>
<td>Organization</td>
<td>Contact Person</td>
<td>Role</td>
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<tr>
<td>Kentucky Health Departments Association (KHDA)</td>
<td>Eryne Wiethorn, MPH; Member, PC, and CAG member</td>
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<tr>
<td>American Academy of Pediatrics (AAP)</td>
<td>Dr. Margaret Roberts; Pediatrician at Baptist Health Corbin Primary Care and CAG member</td>
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<tr>
<td>American Nurses Association (ANA)</td>
<td>Michaela Sherman; RN, BSN, AC, and CAG member</td>
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<tr>
<td>Kentucky Cancer Consortium (KCC)</td>
<td>Brooke Dean; Cumberland Valley District Cancer</td>
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<tr>
<td>Organization</td>
<td>Contact Person</td>
<td>Description</td>
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<tr>
<td>Student Government Association</td>
<td>Gabriella Hamilton; SGA President at Jackson County Middle School, CAG member, and student</td>
<td>SGA at each school will be responsible for designing posters and determining appropriate engagement activities and times to foster student participation in the School-Based Vaccination Clinics.</td>
</tr>
<tr>
<td>UK College of Public Health</td>
<td>Nicholas West, PhD; Associate Professor in the Department of Health, Behavior &amp; Society</td>
<td>UK College of Public Health will assist in recruitment efforts of two graduate-level students who are interested in and capable of becoming research assistants for this project.</td>
</tr>
<tr>
<td>Kentucky Rural Health Association (KRHA)</td>
<td>Dr. Christopher Jones; Member and Primary Care Physician at White House Clinic in McKee, KY</td>
<td>KRHA will ensure that all materials are culturally appropriate for our rural population of both adolescents and parents/guardians. They will partner with us to provide contact information to adolescents without a Primary Care Provider or pediatrician.</td>
</tr>
<tr>
<td>Clay, Jackson, and Rockcastle County School Boards</td>
<td>Megan Wiggins; Clay County School Board Vice President, mother, and CAG member</td>
<td>The school boards will assist with assessing and overcoming barriers to program implementation and negative connotations associated with the HPV vaccine.</td>
</tr>
</tbody>
</table>

**Project Management**

**Leadership**
To meet the goals set forth above, the School-Based HPV9 Vaccination Clinic will be directed by a set of three leaders. The leaders of the program will consist of the Program Director, Program Coordinator, and Assistant Coordinator. They will have a presence at all of the school-based clinics and ensure that the program is implemented and evaluated as planned. They will also make any decisions in regard to program implementation and evaluation in order to accurately represent our CAG.

*Program Director*

Lainey Greene, MPH, will serve as the Program Director (PD) of the School-Based HPV9 Vaccination Clinic. Ms. Lainey Greene earned her Master of Public Health (MPH) Degree from Eastern Kentucky University in 2011. She currently serves as the Public Health Director for the CVDHD and has over 10 years of experience working at the Madison County Health Department in various capacities. Her primary responsibilities will include program design, implementation, and evaluation. Additionally, she will be accountable for financial supervision of the program.

*Program Coordinator*

Eryne Wiethorn, MPH, will serve as the Program Coordinator (PC) for our clinics. She received her MPH from UK and serves as the current Program Analyst of the CVDHD. She has previous experience in implementing and analyzing the district health department’s current initiatives in school health and clinical services, including immunizations. Ms. Wiethorn will assist the PD in the design, implementation, and evaluation of the program. Her primary responsibilities will include (1) day-to-day oversight of the program, (2) training of the assistant coordinator and additional staff, (3) data collection, (4) maintaining a relationship with the key stakeholders in the region, and (5) organizing quarterly update meetings with the CAG.
Assistant Coordinator

Michaela Sherman, RN, BSN, will operate as the Assistant Coordinator (AC) for our program. She earned her Bachelor of Science in Nursing at UK and has three years of experience working as a nurse at MCC. Currently, she serves as a nurse at the CVDHD. In this role, she oversees the school health program in which local health department nurses are available for students to assist with acute illnesses and long-term management of special healthcare needs. Ms. Sherman will assist the PC in the day-to-day oversight of the program. Primary responsibilities will include (1) training of all nurses involved with vaccine administration, (2) administration of vaccines during clinic hours, and (3) coordination of recruitment and retention activities.

Staff

Graduate Research Assistants (GRA)

The School-Based HPV9 Vaccination Clinic will not be possible without additional support staff members. Two MPH GRAs will be hired to help implement the program. They will be present during the clinics and provide students with the VIS, raffle tickets, and reminder slips, as well as, document vaccine administration information. They will assist with data collection of the consent forms and vaccine administration. These MPH students will be recruited through recommendations with our partners at the UK College of Public Health. Before implementation of the School-Based HPV9 Vaccination Clinics, they will receive data collection training and complete required human subjects protection training. After each clinic, or once per semester, these students will meet individually with the PC and one of their professors to assess any learning needs and areas for professional development.

Nurses
Additionally, the local health department nurses, whom already have a relationship with the schools, will be recruited to facilitate the HPV vaccination clinics before program implementation. Their purpose will be to review the vaccine questionnaires for appropriateness of administration and administer vaccinations to the students. They will also assist the AC with retention activities. As these nurses will have the primary responsibility for administering vaccinations, they will receive extensive training before program implementation. This training will be facilitated by the AC. Various healthcare professionals will conduct the training to educate them on HPV, HPV vaccination, and program implementation. They will also receive sensitivity training for the specific patient population. At the end of their training, they will be required to pass a short test in order to ensure safe administration procedures.

_Biostatistician_

A biostatistician will be hired to serve as the primary data analyst during the month of July before data collection. He or she will be responsible for analyzing data collected from the vaccine consent forms and communicating the interpretations of the data with the PD and PC. Once the program begins, the PD will conduct biweekly phone conferences with the statistician to assure that he or she is on task and to obtain any updates.

All leadership and staff members will complete appropriate training in order to comply with HIPAA regulations and to facilitate appropriate interactions with students. The PD will ensure that all leadership and staff members of the program are adequately compensated for their time and efforts to ensure minimal staff turnover throughout the duration of our project. The figure below shows the project management structure for the School-Based HPV9 Vaccination Clinics.

*Figure 5: Project Management Structure*
References


5. FDA Approved Expanded Use of Gardasil 9 to Include Individuals 27 through 45 Years Old (2018, October 5). Retrieved February 02, 2019, from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622715.htm


7. Vanderpool, RC, Stradtman, LR, and Brandt, HM (2019, January 04). Policy Opportunities to Increase HPV Vaccination in Rural Communities. Human Vaccines and
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24. Sears Owens, K and Harris, D (2016). Rockcastle Regional Hospital and Respiratory Care:
Community Health Needs Assessment. Retrieved February 06, 2019 from

25. Mahan, Dee (September 2017). The Children’s Health Insurance Program (CHIP). Families
USA. Retrieved October 28, 2018, from https://familiesusa.org/product/children-health-
insurance-program-chip
Appendices

Appendix A: HPV9 Vaccine Parental Consent Form

<table>
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<tr>
<th>Human Papillomavirus (HPV) Vaccine Consent Form</th>
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<tr>
<td>Student’s Name ______________________________ Age_____ Gender_______</td>
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<tr>
<td>Child Identifies as: ____ White ____ African American/Black ____ American Indian</td>
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<tr>
<td>____ Asian ____ Latino/Hispanic ____ Other: ____________</td>
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Please complete the appropriate section.

ACCEPT VACCINATION

_____ My child has not received the HPV vaccine. Yes, I consent to my child being fully protected by receiving the entire two (2) dose series. I understand this will be administered at no cost to me or my child.

_____ My child has already received the HPV vaccine but has not completed the recommended two (2) doses. I understand 2 doses are required for full protection. Yes, I consent for the remaining dose. I understand this will be administered at no cost to me or my child. The dates of the previous dose is: __________

Does your child have an allergy to medications, foods, or latex? ____ Yes ____ No
If yes, please specify: ____________________________

Does your child have an allergy or hypersensitivity to yeast? ____ Yes ____ No

Has your child had a serious reaction to a vaccination in the past? ____ Yes ____ No

(For Females) Is your child pregnant or is there a chance she could become pregnant within the next month? ____ Yes ____ No

My child: ____ does not have insurance ____ has private insurance that covers vaccinations ____ is enrolled in Kentucky Medicaid ____ is underinsured

By signing this, I am consenting to my child receiving the recommended three doses or the remaining doses required for full protection. I have read or had read to me information about the HPV vaccine. I have been given the Vaccine Information Statement for the vaccine. I had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and the risk of the vaccine to be administered and ask that the vaccine be given to my child. I also consent to care which may include, assessments, treatment, first-aid, over the counter medicine, and any other health service given to me/my child by staff or agents of the Cumberland Valley District Health Department. I understand no guarantees are being made as to the effect of any exam or treatment on me/my child. I likewise release the staff from any liability related to the administering of the above vaccine to my child so long as the responsibility is discharged according to the manufacturer’s instructions. I authorize the school health clinic to release medical information about my child, as permitted by the Health Insurance and Portability and Accountability Act of 1996 (HIPAA), to his/her primary care provider and to share pertinent medical information (history of allergies or significant medical history) with school staff who may need to provide care to my child in an emergency or in order to meet school...
reporting requirements. I understand that the sharing of this information is on a need to know basis only. If my child has Medicaid or KCHIP or private insurance, I also authorize the school clinic to release this information to these parties so that they can be billed for visits to the school clinic. This permission can be revoked at any time, and will expire one year from the date signed.

Signed (Parent/Guardian)_________________  Printed ___________________  Date__________

DECLINE VACCINATION

_____ My child has already completed the recommended two (2) dose series and is fully protected. No, I do not consent my child to participate in the vaccination clinic.

Signed (Parent/Guardian)_________________  Printed ___________________  Date__________

_____ No, I do not consent my child to receive the HPV vaccination series as part of the vaccination clinic.

By signing this, I admit that I have read the Vaccine Information Sheet from the Centers for Disease Control and Prevention explaining the vaccine and the disease it prevents. I have had the opportunity to discuss this with my child’s school nurse and Program Coordinator, who have answered all of my questions regarding the recommended vaccine. I understand the purpose and the need for and the risks and benefits of the recommended vaccine. I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others with which my child might come in contact. I know that I can change my mind and accept the vaccination for my child in the future.

Signed (Parent/Guardian) _________________  Printed _________________  Date __________

If you require additional information before giving consent, please contact Eryne Wiethorn, the Program Coordinator at eryne.wiethorn@cvhdh.gov or (606)779-3373.
Appendix B: Program Calendars

AUG 2019

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SEP 2019

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APR 2020

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<tr>
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<td>SUN MON TUE WED THU FRI SAT</td>
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<td></td>
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|   |   |   |   |   | 01 | 01  
| 02 | 03 | 04 | 05 | 06 | 02 | 02  
| 07 | 08 | 09 | 10 | 11 | 12 | 03  
| 17 | 18 | 19 | 20 | 21 | 22 | 04  
| 23 | 24 | 25 | 26 | 27 | 28 | 05  
| 29 |   |   |   |   |   |   |

Clay County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School

<table>
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<td>SUN MON TUE WED THU FRI SAT</td>
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</table>
|   |   |   |   |   | 01 | 01  
| 02 | 03 | 04 | 05 | 06 | 02 | 02  
| 07 | 08 | 09 | 10 | 11 | 12 | 03  
| 13 | 14 | 15 | 16 | 17 | 18 | 04  
| 19 | 20 | 21 | 22 | 23 | 24 | 05  
| 25 | 26 | 27 | 28 | 29 | 30 | 06  

Labor Day (No School)  
Spring Break (No School)  
Spring Break (No School)  
Spring Break (No School)  
Spring Break (No School)

Clay County Middle School  
Clay County Middle School  
Clay County Middle School  
Clay County Middle School  
Clay County Middle School

Clay County Middle School  
Clay County Middle School  
Clay County Middle School  
Clay County Middle School  
Clay County Middle School

Rockcastle County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School  
Rockcastle County Middle School
Appendix C: Post-Vaccination Parent Survey
### School-Based HPV9 Vaccination Clinic Post-Vaccination Parent/Guardian Survey

Why did you decide to allow your child to be vaccinated for HPV? (check all that apply)

- [ ] It is the best way to prevent HPV infection
- [ ] The potential health consequences of HPV infection could be serious.
- [ ] My child’s healthcare provider recommended it.
- [ ] My child is, or will be, at risk of acquiring HPV.

Why did you decide to not get your child HPV vaccinated previously? (check all that apply)

- [ ] HPV vaccine is too expensive.
- [ ] I didn’t know enough about HPV.
- [ ] It was inconvenient to make two appointments to receive all the shots.
- [ ] I didn’t know enough about HPV vaccine.
- [ ] HPV vaccine is not mandatory for school entry.

Feedback about the School-Based HPV9 Vaccination Clinic. (check all the apply)

- [ ] I was pleased with the overall experience.
- [ ] I would like to see more partnerships between the school system and district health department in the future.
- [ ] I would recommend School-Based Vaccination Clinics to family and friends.
- [ ] I felt that the information and consent packet was sufficient to make an informed decision.
- [ ] The other information I received from this project helped me to make an informed decision.

---

### Appendix D: Declined Consent Parent Survey
School-Based HPV Vaccination Clinic Declined Consent Parent/Guardian Survey

Why did you choose not to have your child participate in the School-Based HPV Vaccination Clinic? (check all that apply)

_____ My child already received all three doses of the HPV vaccine.
_____ I am not sure the HPV vaccine is safe and effective.
_____ I am worried about potential side effects of the HPV vaccine.
_____ I do not believe my child needs the HPV vaccine.
_____ I need more information before making a decision about the HPV vaccine.
_____ Other: ________________________________________________________________

Appendix E: UNC National Parent Survey – Adapted

Parent/Guardian HPV Vaccination Survey

Please mark one option for each answer.

1. How many children do you have between the ages of 9-17 in your household? _____

2. How many shots of the HPV vaccine has your youngest child between the ages of 9-17 had?
   _____ None _____ 1 _____ 2 _____ 3

3. What age did your youngest child between the ages of 9-17 receive the HPV vaccine?
   _____ 9 _____ 10 _____ 11 _____ 12
   _____ 13 _____ 14 _____ 15 _____ 16 _____ 17

4. Vaccines are necessary to protect the health of middle school children.
   _____ Strongly agree _____ Somewhat disagree
   _____ Somewhat agree _____ Strongly disagree
   _____ Neither agree nor disagree

5. Vaccines do a good job in preventing the diseases they are intended to prevent.
   _____ Strongly agree _____ Somewhat disagree
   _____ Somewhat agree _____ Strongly disagree
6. If I do not vaccinate my child, he or she may get a disease such as meningitis and cause others to get the disease.

   ____ Neither agree nor disagree
   ____ Strongly agree
   ____ Somewhat agree
   ____ Somewhat disagree
   ____ Strongly disagree

7. The HPV Vaccine may cause lasting health problems.

   ____ Neither agree nor disagree
   ____ Strongly agree
   ____ Somewhat agree
   ____ Somewhat disagree
   ____ Strongly disagree

8. I do not have enough information about the HPV vaccine to decide whether to give it to my child.

   ____ Neither agree nor disagree
   ____ Strongly agree
   ____ Somewhat agree
   ____ Somewhat disagree
   ____ Strongly disagree

9. The HPV vaccine is effective in preventing several cancers.

   ____ Neither agree nor disagree
   ____ Strongly agree
   ____ Somewhat agree
   ____ Somewhat disagree
   ____ Strongly disagree

10. It would be hard to find a provider or clinic where I can afford the HPV vaccine for my child.

    ____ Neither agree nor disagree
    ____ Strongly agree
    ____ Somewhat agree
    ____ Somewhat disagree
    ____ Strongly disagree

11. Other parents in my community are getting their children the HPV vaccine.

    ____ Neither agree nor disagree
    ____ Strongly agree
    ____ Somewhat agree
    ____ Somewhat disagree
    ____ Strongly disagree
<table>
<thead>
<tr>
<th></th>
<th>Somewhat agree</th>
<th></th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neither agree nor disagree</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. Most people who are important to me would support getting the HPV vaccine for my child.

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th></th>
<th>Somewhat disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Somewhat agree</td>
<td></td>
<td>Strongly disagree</td>
</tr>
<tr>
<td></td>
<td>Neither agree nor disagree</td>
<td></td>
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13. How many vaccines do you think would be safe for a one-year old to get at a single check-up?

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th></th>
<th>3 vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 vaccine</td>
<td></td>
<td>4 vaccines</td>
</tr>
<tr>
<td></td>
<td>2 vaccine</td>
<td></td>
<td>5 or more vaccines</td>
</tr>
</tbody>
</table>

14. How many vaccines do you think would be safe for an eleven-year old to get at a single check-up?

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th></th>
<th>3 vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 vaccine</td>
<td></td>
<td>4 vaccines</td>
</tr>
<tr>
<td></td>
<td>2 vaccine</td>
<td></td>
<td>5 or more vaccines</td>
</tr>
</tbody>
</table>

15. Imagine you agree to get your child the three vaccines they are due for: meningitis, HPV vaccine, Tdap vaccine. Would you prefer…

<table>
<thead>
<tr>
<th></th>
<th>Get all 3 vaccine at one visit</th>
<th></th>
<th>Spread the vaccines across multiple visits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Get whatever the doctor or healthcare provider recommends</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. Imagine your child gets the first dose of HPV vaccine today. When would you prefer he or she get the next dose?

|   | As soon as is recommended |   | At their next check-up |

---

Appendix F: Gantt Chart
### Appendix G: Logic Model

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Activities</th>
<th>Short-Term Outputs</th>
<th>Long-Term Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preparation</td>
<td>Increase student and parent knowledge about HPV and the vaccine</td>
<td>Increase the initiation and completion rates of HPV-9 vaccination</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>Reduce barriers to the HPV vaccine</td>
<td>Reduce the incidence and mortality of genital warts and HPV-related cancers</td>
</tr>
</tbody>
</table>
| Partners | - Train school nurses and intervention staff  
- Hold Back-to-School Event  
- Provide student education | |
| Budget | - Consent packets and student surveys  
- Conduct vaccination clinics  
- Collect data and send reminders  
- Send post-vaccination surveys | |
| Resources | KCR  
MMWR  
CDC  
Immunization records | |

**Contextual Conditions** (e.g. national recommendations, media reports)

---

### Appendix H: Letters of Commitment for the Proposed Program

- **Task:** Obtain IRB approval  
  Contract biostatistician  
  Attend Back-to-School fairs and recruit  
  Data collection for parent consent forms/pre-vaccination survey  
  Conduct vaccination administration training for nurses  
  Conduct program training for all researchers  
  Develop promotional posters with students  
  School-Based HPV Vaccination Clinic: Pilot  
  Retention Efforts: Send text message and paper reminders  
  Distribute and Collect Post-Vaccination Parent/Guardian Surveys  
  Host pizza party and prize drawing  
  Conduct analyses and determine adaptations  
  School-Based HPV Vaccination Clinic: With Control  
  School-Based HPV Vaccination Clinic: All Schools  
  Perform final analyses  
  Presentations at national conferences  
  Preparation of manuscript

Q1: July-September; Q2: October-December; Q3: January-March; Q4: April-June
A. Letter of Commitment from Mr. Steven Diamond, Clay County Middle School Principal

B. Letter of Commitment from Dr. Adam Kirby, Jackson County Middle School Principal

C. Letter of Commitment from Mr. Michael Robin, Rockcastle County Middle School Principal

Appendix I: Budget and Justification

The Grant budget is proposed for July 1, 2019-June 30, 2022.

Anticipated Enrollment

As outlined in the “Target Population and Need” section on page 3, our program has the potential to reach approximately 1,340 students over the three-year course of this grant. However, we assume that 40% of our students will be UTD on their HPV vaccination before implementation and that many students will not return consent forms. Therefore, we anticipate that 50% of eligible students will enroll in the program, or about 670 students. On average, we estimate that about 225 students will enroll in our School-Based HPV9 Vaccination Clinic each year. More specifically, we estimate that 125 students will be enrolled in Year 1, 235 students will be enrolled in Year 2, and 310 will be enrolled in Year 3. This will allow us to utilize $250,000 per year, or $750,000 total over the duration of the grant.

Personnel

Table 3: Personnel Budget Year 1

<table>
<thead>
<tr>
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<th>Year 1</th>
<th>Effort</th>
<th>Salary</th>
<th>Fringe</th>
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<tr>
<td>Program Director</td>
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<td>$5,486</td>
<td>$25,486</td>
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<tr>
<td>Program Coordinator</td>
<td>70.00%</td>
<td>$80,000</td>
<td>$56,000</td>
<td>$16,226</td>
<td>$72,226</td>
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<tr>
<td>Assistant Coordinator</td>
<td>50.00%</td>
<td>$60,000</td>
<td>$30,000</td>
<td>$9,465</td>
<td>$39,465</td>
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<tr>
<td>MPH GRA 1</td>
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<td>$32,000</td>
<td>$10,560</td>
<td>$4,283</td>
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### Table 4: Personnel Budget Year 2

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<tr>
<td>Program Director</td>
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<tr>
<td>Program Coordinator</td>
<td>80.00%</td>
<td>$82,400</td>
<td>$65,920</td>
<td>$85,020</td>
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<tr>
<td>Assistant Coordinator</td>
<td>50.00%</td>
<td>$61,800</td>
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<tr>
<td>MPH GRA 1</td>
<td>33.00%</td>
<td>$32,960</td>
<td>$10,877</td>
<td>$15,289</td>
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<tr>
<td>MPH GRA 2</td>
<td>33.00%</td>
<td>$32,960</td>
<td>$10,877</td>
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<tr>
<td>CCMS Nurse</td>
<td>6.00%</td>
<td>$41,200</td>
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<tr>
<td>RCMS Nurse</td>
<td>6.00%</td>
<td>$41,200</td>
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### Table 5: Personnel Budget Year 3

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<td>$10,609</td>
<td>$13,519</td>
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</table>

Wiethorn  50
The majority of the budget for the School-Based HPV9 Vaccination Clinic will be dedicated to the salaries and other benefits of the personnel implementing the program. While the PD will be charged with overseeing the design, implementation, and evaluation of the program, as well as have all financial responsibilities, she will have few hands-on responsibilities of implementation. We expect her to spend only 20% of her time on our project in Year 1 and 10% of her time in the two subsequent years. The PC will have the direct oversight, data collection, and training responsibilities. Therefore, we expect her to spend the majority of her time on our project. The AC will be expected to be present on all clinic days and will assist in the retention process by contacting students and their parents to remind them to complete the second dose of the vaccine series. She will also be responsible for training all other nurses involved in the program. Therefore, we expect the AC to spend 100% of her time on this program for 6 months out of each year.
The MPH GRAs will be hired for 20 hours per week. These assistants will be present at the clinics in order to distribute VIS, incentive tickets, and reminder slips and document vaccine administration. They will also aid in data collection and interpretation year-round. The local health department nurses that are already affiliated with each of the schools included participate in the program by administering vaccines to appropriate students. The clinics will be at each school for 20 days out of the year. By including time for training, we will reimburse them for almost one-month’s salary. We expect the additional nurse to be present during all clinic days at each school to assist in the previously mentioned activities. Additionally, he/she will assist the AC with reminders for second doses. We will also hire a biostatistician to assist in analyzing our data. We will expect this person to spend approximately 5% of their time on our project during Years 1 and 2. However, we would like the statistician to spend more time during Year 3 in order for us to draw final conclusions for our project.

*Equipment*

The only equipment that we plan on purchasing for our intervention is two School-Based HPV9 Vaccination Clinic laptops that are to be used solely for the purpose of our project. We will purchase two MacBook Airs, priced at $1,100 each for a total of $2,200.

*Supplies*

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<td>Needles</td>
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<td>250 (Y1); 470 (Y2); 620 (Y3)</td>
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<td>Gloves</td>
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<td>500 (Y1); 940 (Y2); 1,240 (Y3)</td>
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</tr>
<tr>
<td>Bandages</td>
</tr>
<tr>
<td>Alcohol Swabs</td>
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**INCENTIVES**

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<th>Year 3 Cost</th>
<th>Total Cost</th>
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<td>Gift Cards for Parents</td>
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<td>$3,100</td>
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<td>Basket Materials</td>
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<td>$150</td>
<td>$300</td>
<td>$450</td>
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<tr>
<td>Pizza Party Materials</td>
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<td>$200</td>
<td>$200</td>
<td>$400</td>
<td>$600</td>
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</table>

**RECRUITMENT SUPPLIES**

<table>
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<tr>
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<th>Year 1 Cost</th>
<th>Year 2 Cost</th>
<th>Year 3 Cost</th>
<th>Total Cost</th>
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<tr>
<td>Totals</td>
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<td>$47,387</td>
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<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>$105,885</td>
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</table>

A substantial portion of the funds needed for this program will be used in order to acquire the HPV9 vaccines themselves. While we are estimating that 125 students will utilize our clinics in Year 1, 235 in Year 2, and 310 in Year 3, we estimate that at least 39% of these students will be enrolled in Kentucky Children’s Health Insurance Program (KCHIP), as this is the current national coverage rate. We will bill KCHIP for our services and estimate the ability to bill for approximately 20% of additional vaccines through private insurance companies. Therefore, we
only estimate to accrue the cost of about 100 vaccines in Year 1, 190 vaccines in Year 2, and 250 vaccines in Year 3. We will also need to purchase all other medical supplies (gloves, bandages, needles, etc.) needed to administer the vaccines. While we will not have to purchase a printer, we will supply our own paper and ink in order to print the VIS, reminder cards, consent forms, and surveys. Additionally, we will budget a set amount of money for raffle tickets, prize baskets, and pizza parties each year for incentive purposes. We will budget $3,100 per year to put towards $5 Walmart gift cards for parents or guardians who return both the pre-clinic survey and post-clinic survey in addition to the consent form. We will also reserve money to be used for recruitment activities. We expect to spend about double the funds on recruitment during the first year compared to the two subsequent years.

*Travel*

*Table 7: Travel Budget*

<table>
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<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td>Local Travel</td>
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<td>$300</td>
<td>$300</td>
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<tr>
<td>APHA Meeting Registration</td>
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<td>$1,000</td>
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<tr>
<td>Airfare</td>
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</tr>
<tr>
<td>Overnight</td>
<td>$1,000</td>
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<tr>
<td>Total</td>
<td>$3,300</td>
<td>$3,300</td>
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</tbody>
</table>

The leadership and staff members of our program will be required to travel locally to the schools in order to implement the program and attend trainings. The schools furthest from each other are Rockcastle County Middle School and Clay County Middle School with a distance of 44 miles. The MPH GRAs will also be required to travel from UK to the CVADD, totaling about
96 miles, in order to participate about 5 times per year. We will reimburse mileage based on the standard mileage rates of 54.5 cents per mile. We will reserve $3,000 per year in our budget for these purposes.

Additionally, we plan to have two leadership members attend the American Public Health Association annual conference. We will budget for the members’ registration, travel, and lodging fees. We are estimating that the registration fees will be about $500 each, airfare will be $500 each, and each room will cost about $250 per night for two nights.

**Training**

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fee for service</td>
<td>$1,500</td>
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<td>$1,500</td>
</tr>
<tr>
<td>Room</td>
<td>$400</td>
<td>$400</td>
<td>$400</td>
</tr>
<tr>
<td>Nurse-specific training</td>
<td>$750</td>
<td>$750</td>
<td>$750</td>
</tr>
<tr>
<td>Food</td>
<td>$300</td>
<td>$300</td>
<td>$300</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$2,950</td>
<td>$2,950</td>
<td>$2,950</td>
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</table>

In order to ensure that those implementing the program are educated on the program in its entirety, we will hold a 4-hour training event before the recruitment process for the program begins. We anticipate spending $50/hour in order to rent a room to host this event. We will also provide a meal for all who attend as well as reimburse them for their time. We will hold a similar 2-hour abbreviated training event before the school year starts in order to ensure fidelity of the program over time. Additionally, we will hold a nurse-specific hour-long training session at the
beginning of each school year. This training will cover what the nurses should be reviewing from the vaccination questionnaires and proper administration techniques.

Other Expenses

In addition, tuition is requested for the two GRAs in agreement with UK’s policy. Tuition estimates have been calculated based on current in-state rates and are projected to increase by approximately 10% each year. Quarterly, we will meet with the CAG in order to discuss our progress and share ideas, thoughts, and concerns regarding HPV, HPV9 vaccination, and our School-Based Clinic. We will budget $15/person for meals at each of these meetings.

Final Budget Sheet

<table>
<thead>
<tr>
<th>Category</th>
<th>Year 1</th>
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<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel</td>
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<td>$749,856</td>
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</table>