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A COMPREHENSIVE MULTI-LEVEL APPROACH TO INCREASING HPV VACCINATION RATES IN RURAL 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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Abstract/Summary

The Graves County Health Department (GCHD) proposes implementation of a multi-level approach to increase Human Papillomavirus (HPV) vaccination rates in Graves County, KY. The approach utilizes multiple evidence-based strategies, including Assessment, Feedback, Incentive, Exchange (AFIX), Vaccines for Children (VFC), Kentucky Immunization Registry (KIR), Comprehensive Clinic Assessment Application (CoCASA), and vaccines per protocol. This proposed project utilizes family medicine and pediatric clinics, pharmacies, and school nurses to deliver the intervention to the target population, which includes 11-12-year-old adolescents residing in Graves County. The objectives of this HPV vaccination-focused intervention align with Healthy People 2020 goals and objectives, the 2012-2013 President’s Cancer Panel report, and the overall mission of GCHD. Implementation of this program will be guided by a local community advisory group (CAG) consisting of physicians, pharmacists, nurses, parents, and religious leaders. The direct, short term goals of this program include increasing county-level HPV vaccination rates. The indirect, long term impact for this program includes sustained collaboration among health care providers, greater public acceptance of the HPV vaccine, greater public acceptance of vaccine administration at pharmacies, and more efficient use of health care resources. Evaluation of the program is integrated into the work plan and results will be disseminated via multiple lay and scientific outlets.
**Target Population**

An estimated 90% of sexually active men and 80% of sexually active women will be infected with Human Papillomavirus (HPV) at some point in their lives. Half of those infected will be infected with a “high-risk” HPV type, such as 16 or 18. Although approximately 90% of cases clear spontaneously, HPV is estimated to cause nearly all cases of cervical cancer (with types 16 and 18 causing approximately 70% of those cases), 95% of anal cancer, 70% of oropharyngeal cancer, 65% of vaginal cancer, 50% of vulvar cancer, and 35% of penile cancer.¹

These cancers are largely preventable by administration of timely HPV vaccines. However, in the United States (US), approximately 17,600 women and 9,300 men are diagnosed with HPV-associated cancer each year, with approximately 11,000 of those diagnoses resulting in cervical cancer.² Prior to HPV vaccine availability, an estimated $8 billion was spent annually in the US for prevention and treatment of HPV-related disease.³ Vaccines against HPV types 16 and 18 have been recommended since 2006 for adolescent and young adult females and 2011 for males of the same age-range.³ Despite a general upward trend in administration of routinely recommended vaccines in 11-12-year-olds, such as tetanus, diphtheria, and acellular pertussis (Tdap) and meningococcal (MCV4), HPV vaccination rates lag behind other adolescent vaccines. Some of the reasons for suboptimal HPV vaccination rates include: lack of knowledge among parents, fear of adverse effects, an attitude that the vaccine is not necessary, misperceptions that the vaccine leads to increased sexual activity among adolescents, lack of school mandate for HPV vaccination, and lack of strong and consistent recommendations made by healthcare providers.⁴

The age-adjusted 5-year incidence rate of cervical cancers per 100,000 women in KY is 8.7 (CI 8.1-9.3) compared to the national rate of 7.6 (CI 7.5-7.7) in the years 2009-2013.⁵ This represents a statistically significant increase in risk of cervical cancer to Kentuckians. A 2015 survey assessing adolescent vaccination rates (boys and girls aged 13-17 years) shows that Kentucky has poor HPV
vaccination rates compared to the national average (Table 1), and well below the Healthy People 2020 objective of 80% coverage.⁶,⁷

Reasons for the disparity between immunization rates for certain adolescent platform vaccines also include physicians’ discomfort providing a strong recommendation for HPV vaccination, which stems from a perception that parents will either not accept or defer HPV vaccination, or the physicians themselves have misconceptions about waning immunity.⁸ Another study found that some providers are uncomfortable discussing sex, and therefore present the HPV vaccine as optional and able to be delayed.⁹

Missed opportunities to vaccinate is an important factor as well. A national survey examining pediatric and family physicians’ practices regarding HPV vaccination found that 27% of physicians give weak recommendations, physicians do not give timely recommendations for 26% of girls and 39% of boys, 59% use a risk-based approach instead of a routine approach, and only 51% recommend same-day vaccination.¹⁰

Disparities in vaccination rates exist between metropolitan areas versus non-metropolitan areas, ethnic/racial groups, males and females, and varying socioeconomic groups. For example, in 2013, national data shows completion of the HPV series for females 13-15 years of age was 34.7% in metropolitan areas vs 23.3% in non-metropolitan areas.⁷ This represents an opportunity for improvement in our more rural areas. Disparities also exist among racial and ethnic populations. White non-Hispanic boys consistently achieve lower rates of HPV series completion by the age of 13-15 years. For example, in 2014, white non-Hispanic boys completed the series at a rate of 16.3% vs Asian boys at 29.3%.⁷ Sex disparities are apparent in both national and state data measuring series completion rates by age 13-17 years, with a national gap between boys and girls of 13.8%, and a gap in Kentucky of 19.1%, both favoring female vaccination (Table 1).⁶
Interestingly, national data shows that falling below the federal poverty level seems to confer a 3.1% - 3.6% advantage in series completion versus those at or above the federal poverty level (Table 2). According to three studies, strong, routine recommendations for HPV vaccination and consistent co-administration of vaccines by clinicians caring for adolescents from lower income households contribute to this advantage. Reagan-Steiner, et al. suggest that provider participation in and patient eligibility for the Vaccines for Children (VFC) program, as well as greater vaccine acceptance among low-income parents may also contribute.

While both cervical cancer incidence and inadequate uptake of HPV vaccination are concerns across Kentucky, Graves County has additional barriers to successfully reaching Healthy People 2020 goals for HPV vaccination. This rural county in western Kentucky, population 38,000 and 552 square miles, has a lower population density at just 67 people per square mile compared to the Kentucky average of 110 people per square mile and is 92.5% white. The town of Mayfield, centrally located in the county, is home to approximately 10,000 of the county’s residents. Figure 1 shows a state map by county.

Data from County Health Rankings and Roadmaps for 2016 shows that several sociodemographic factors may contribute to poor HPV vaccine uptake in Graves County. Access to health care providers is a barrier in this county. The ratio of patients to primary care providers is 2340:1, compared to 1500:1 in Kentucky, overall. Thus, Graves County providers must see 56% more patients than the average provider in Kentucky. In addition, data illustrate a higher proportion of uninsured children in Graves County, where 8% of those under the age of 19 were uninsured, compared to 6% across Kentucky. Just over one-quarter (26%) of children fall below the federal poverty line in both Graves County and Kentucky. The median household income in Graves County is $39,200 versus $42,900 in Kentucky. Children eligible for free lunch is 48% which is the same for Kentucky. Education
data in Graves County shows that 92% of residents achieve high school graduation versus 88% in Kentucky, and 48% of adults have some college education versus 59% in Kentucky.\textsuperscript{12}

The National Cancer Institute’s (NCI) President’s Cancer Panel report from 2012-2013 indicates the need and support from the federal government for a three-pronged approach to urgently accelerating HPV vaccination in the US. Goals include reducing missed opportunities to recommend and administer HPV vaccination, increasing acceptance of HPV vaccination, and maximizing access to HPV vaccine services. The latter promotes and facilitates HPV vaccination in venues outside of the medical home, including pharmacies, by asking states to enact legislation that allows pharmacists to administer the vaccine and be reimbursed by third-party payers.\textsuperscript{13}

Resources available in Graves County to administer the HPV vaccine include two pediatrician groups, two family medicine groups, the Graves County Health Department (GCHD), and six community pharmacies, all of which are in Mayfield. Although there are numerous sources of HPV vaccine-related information such as the Centers for Disease Control and Prevention (CDC), Immunize.org, American Cancer Society (ACS), Kentucky Cabinet for Health and Family Services, National Cancer Institute, Kentucky Immunization Registry (KIR), and Comprehensive Clinic Assessment Software Application (CoCASA), these sources are likely underutilized by health care providers and unknown to the public.

Vaccines for Children (VFC) is a program administered by the CDC that provides free vaccines to providers for administration to children at no charge, and the provider earns an administration fee from Centers for Medicare and Medicaid Services (CMS) for their efforts. Eligibility criteria for VFC as it relates to this program is that the patient must be under 18 years of age, and either enrolled in Medicaid or uninsured.

Finally, the evidence-based CDC program, Assessment, Feedback, Incentives, eXchange (AFIX) is a model that delivers provider-level education, motivation, and collaboration to support their efforts to increase vaccination rates among their patients.
Barriers in addition to access issues may be hindering efforts to increase HPV vaccination, specifically. Primarily, these barriers revolve around adolescent sex. Providers are often hesitant to discuss sex-related topics with preteens or the parents of preteens for fear of alienation. This leads to either weak or no recommendations for the HPV vaccine. Concurrently, some parents don’t understand the need for a vaccine that prevents sexually transmitted infections (STI) if their child is not sexually active. Furthermore, some parents fear that HPV vaccination condones early sexual activity, although this has been refuted.14

For the proposed project in Graves County, a community advisory group (CAG) will be convened comprising key stakeholders from the community. First, healthcare providers will be invited to join the CAG. Local pediatric and family medicine physicians will be included because they are vital in their capacity to champion this program to their colleagues as well as the community in general. Their perspective is needed to determine why HPV vaccine uptake in this specific community is low, so that modifiable barriers can be identified and resolved.

Pharmacists will also be vital in their role because they represent a new, alternative pathway for patients who have either missed the opportunity to be vaccinated with their primary care provider (PCP) or who are seeking a less expensive and more convenient means of obtaining vaccination. Pharmacies can provide immunization at a lower cost because they do not charge an office visit fee to third parties or patients. Pharmacists will provide a unique perspective on technical aspects of the program in their pharmacies and will be relied on to actively seek out patients using patient reminder systems and KIR data. In addition, pharmacies can couple HPV vaccination with influenza vaccination, as pharmacies are becoming more popular for influenza vaccination. This represents an opportunity to give multiple vaccinations, including HPV, during that visit. This method of coupling an under-utilized vaccination with annual influenza vaccination has been shown effective in the Flu-FiT program, which used the influenza vaccination as a vehicle to promote colorectal cancer screening, and successfully screened 59.3% of
patients receiving influenza vaccine at the pharmacy. This study illustrates the receptiveness of patients to receive medical advice from pharmacists.\textsuperscript{15}

Next, school nurses will be invited to join the CAG. Their affiliation with the school system and experience with school-based health initiatives contributes to their in-depth understanding of the community. They will also be able to guide the program identifying the target population and dispersing information to parents of the target group.

Religious leaders, such as youth counselors, may be helpful as well, because they can advise the program on the attitudes of both the children and their parents towards HPV vaccination from the unique relationship they have.

Finally, parents involved in parent teacher associations (PTA) will be invited, because they may be the most active and outspoken parents in the community. Their perspective will provide insight into the attitudes and beliefs of parents, and provide specific threats and opportunities to address during program planning and implementation.

GCHD performed a formal community needs assessment in 2015. The assessment collected data and perspectives at three unique levels: objective, organizational, and individual. The objective perspective used data from national, state, and local sources. The organizational perspective evaluated community health forums, and the individual perspective was given through surveys of individual residents. Notable findings looking objectively at the data showed a disparity in insurance rates and teen pregnancy.\textsuperscript{16}

Assessing the effectiveness of this program is built into the evidence-based AFIX program which is the model for our program in Graves County. The primary measurement for effectiveness will focus on HPV vaccination rates, with the long-term goal of decreasing related cancer incidence. National data are already showing a 64\% decrease in prevalence of HPV positive cervicovaginal specimens in 14-19-year-old females since the vaccines have been available, despite their poor uptake, indicating strong
effectiveness. The vaccination rate will be assessed by utilizing KIR for vaccination data entry along with CoCASA for data analysis.

Additional community assessment methods will include surveying providers’ knowledge, attitude, and practices regarding HPV vaccine. These measures will be important in identifying specific barriers to be targeted during early program planning. Tracking how providers’ behaviors change throughout the program will indicate the sustainability of this program, and allow adjustments to be made during the program to improve sustainability.

US Census data from 2010 shows there are approximately 37,000 people residing in Graves County, and 24.4% of the population is under 18 years of age. Assuming a relatively even number of children in each year of age, there should be approximately 1,000 kids aged 11 or 12 years at any given time. This age group represents the target age group for HPV vaccination in this program. Initially, this means that about 1,000 children will be targeted per year in Graves County, but as the program gains traction the number of kids unvaccinated in this age group will represent only the kids who have turned 11 years of age in the past year (approximately 500), plus remaining children who were not vaccinated in the previous year. This specific age group of 11-12 years is the target of this intervention because this is the age range that the Advisory Committee on Immunization Practices (ACIP) recommends to administer HPV vaccine concurrently with Tdap and MCV4 vaccine. Targeting an age below 15 years of age also increases effectiveness of the vaccine because it is more likely to precede sexual activity, and the HPV series only requires two shots in this age group, reducing the cost to our health care system.

The uninsured rate for children in Graves County is approximately 8%, which means there are 80 children in the 11-12 year old age group who do not have health insurance. Additionally, approximately 5,100 children in Graves County are enrolled in Medicaid, which means there are over 500 kids between the ages 11-12 receiving Medicaid based on population data given above. It is difficult to estimate, but it is likely that there are a number of underinsured children in this age group;
those who have insurance but are unable or unlikely to receive services due to high copays as a percent of family income. Therefore, a conservative estimate is that at least 60% (approximately 600) of children between the ages of 11-12 qualify for free HPV vaccination under the VFC program, which will be used in this program to assist children in obtaining the needed vaccination in a timely manner. Children not qualifying for the VFC program can still obtain vaccination benefit through their insurance.

Regardless of how a child qualifies for vaccination, both physicians and community pharmacists will work together to ensure HPV series completion in the target age group. Legislation has been passed allowing pharmacists to administer all vaccinations “per protocol” to children down to the age of 9 years (SB 101).20

Abid Hussain, MD, pediatrician at the Mayfield Pediatric Clinic will sign a protocol agreement with each community pharmacy authorizing this practice. The protocol agreement will include the stipulation that each dose of HPV must be entered in KIR, and notification must be sent to the child’s primary care provider. This will help to ensure accurate record keeping, but may present a barrier to continued engagement in the program. Therefore, health department resources such as training will be provided to ensure data is collected accurately, and compensation will be provided to pharmacies in lieu of a CMS administration fee.

In addition to the GCHD, three separate groups in the community are required to fully support this program for it to succeed. PCPs are needed because they will often have first contact with the child and their parents through annual visits, can make a strong recommendation for HPV vaccination, and will often administer the first vaccine in the series. Providers will be educated on the current rates of HPV vaccination and their need to involve other health care providers due to their low physician-to-patient ratio to recruit them into participating in this intervention. A selling point to the PCPs is that collaboration with pharmacists will allow them to focus more time on diagnosing and treating acute
illnesses rather than administering vaccinations for only a small administration fee. Their patients will also gain greater access to health care services, which will maintain a higher quality of health care delivery for their reimbursement rates.

Community pharmacists are needed because they are the most accessible health care professional to the public, and can now provide convenient prescription and administration of vaccination without need for an appointment and without an office visit fee. They typically hold longer hours than a physician’s office, allowing patients to receive vaccination outside of normal business hours and during the weekends. As prescription drug sale profit margins shrink, many pharmacies are looking for other sources of revenue, such as vaccination.

Finally, parents or guardians are needed to drive demand for vaccination, or at least be receptive to vaccination when the health care provider makes the recommendation. Education is key for motivating parents. Simple fliers, mailers, or a few minutes of face-to-face time with a health care provider can assist parents in understanding vaccinations and electing to have their child vaccinated. Potential barriers can be avoided when parents are talking about HPV vaccination with health care providers, and not getting erroneous information from the internet, their social networks, or other unreliable sources.

Retention of health care providers to stay engaged in the program will require continuous efforts. One strategy will be to send progress updates of increasing vaccination rates using CoCASA analysis. The movement in healthcare from fee-for-service to quality-based metrics will also help retention by linking payments to star-ratings for preventive care.

Program Approach

Evidence Base
The evidence-based program we propose to implement in Graves County is called, “A Comprehensive Multilevel Approach to Increasing HPV Vaccination Rates in Rural Kentucky”. This program aligns with Healthy People 2020 goals for reaching 80% HPV vaccination rates and using the evidence-based AFIX program to track and improve vaccine administration practices. In addition, the VFC program will be used to expand the reach of this intervention to nearly all children aged 11-12 years in Graves County and KIR will be utilized to track vaccination administrations. The final major component is new legislation allowing Kentucky pharmacists to administer the HPV vaccine to young adolescents per protocol.

The AFIX program is a CDC-funded, evidence-based provider-level intervention program designed to increase vaccination coverage in a sustainable manner. It has success in a wide array of settings and is recommended by The Community Preventive Services Task Force, endorsed by the ACIP, and incorporated in the Healthy People 2020 objectives. AFIX trained staff from GCHD will conduct in-person site visits at each clinic and pharmacy to gain buy-in from practitioners and give initial training. The AFIX program website contains information on how to gain buy-in and train practitioners that GCHD staff will follow.

The Community Preventive Services Task Force recommends the use of assessment and feedback programs based on strong evidence from a systematic review of 20 studies conducted between 1997 and 2012 evaluating the impact of assessment and feedback. These 20 studies are comprised of randomized controlled trials, quasi-experimental studies, prospective cohorts, retrospective cohorts, cross-sectional analyses, post-intervention only studies, and before-after comparisons to assess efficacy. The review found a median vaccine coverage increase of 11% with this intervention alone, and an additional 6% when combined with other interventions. The studies included both children and adults in diverse settings, therefore, good generalizability is expected. None of these studies included HPV vaccination, and none of these studies evaluated adolescent vaccination.
However, based on the generalizability of these results, no difference is expected using HPV vaccination in an adolescent population in terms of the effectiveness of assessment and feedback to providers.

This program will be the first of its kind in Kentucky since legislation passed authorizing pharmacists to enter into protocol agreements with physicians that allow the pharmacist to administer any vaccine to children down to the age of 9 years old. This protocol agreement authorizes pharmacists, to assess a patient’s immunization history, determine appropriate vaccination needs, and administer the necessary vaccine or vaccines without a patient-specific prescription order from a prescriber. Abid Hussain, MD, a pediatrician at the Mayfield Pediatric Clinic, will serve as the authorizing physician for all protocol agreements with community pharmacists in Graves County.

The Community Preventive Services Task Force recommends the use of protocol-driven vaccination efforts by strong evidence gained from a systematic review of 35 studies conducted between 1997 and 2012. These 35 studies are comprised of quasi-experimental studies, prospective cohorts, retrospective cohorts, cross-sectional analyses, post-intervention only studies, and before-after comparisons to assess efficacy. The review shows evidence for effectively increasing vaccination rates among both children and adults. The review estimates that the median increase in vaccination rates is 16% when this intervention is used alone, and 27% when used in combination with other interventions. Sub-group analysis of four studies specific to children found a median absolute increase of 28%. The 35 studies reviewed covered a wide variety of health care settings, provider types, and patient populations, indicating that this intervention is generalizable to other populations. Although none of the 35 studies in the review specifically measured adolescent immunization rates, and did not include HPV vaccination, it is expected that we can gain similar results by adapting our intervention to fit our target population and objectives. No evidence of harm was detected by implementation of protocol-driven vaccination programs. However, there is inherent risk of harm due to improper vaccination technique or unforeseen adverse reactions to vaccination.
Partnership Roles

Implementation of the program will occur in several locations including two pediatrician clinics, two family medicine clinics, six community pharmacies, two middle schools, and GCHD. Each location plays a vital role in the success of this program by complementing the abilities of other locations in the program.

There are two pediatricians, with separate practices located in the town of Mayfield. These include the Mayfield Pediatric Clinic and the Jackson Purchase Medical Center, which are the primary providers of the HPV vaccine in Graves County. In addition, two family medicine clinics, including the Jackson Purchase Medical Center and Western Kentucky Family Healthcare. Their primary roles will be to make a strong recommendation for the HPV vaccine, to provide both verbal and written parent education, administer the vaccine, refer patients to any of the community pharmacies for the next dose, and enter data into KIR.

There are six existing community pharmacies in Graves County. All of them are in the town of Mayfield. Duncan Rx Center, Gibson’s Discount Pharmacy, Stone’s Health Mart, and CVS Pharmacy currently offer vaccination, but do not regularly stock HPV. Whereas the Wal-Mart Pharmacy and Walgreens Pharmacy both offer vaccinations, including HPV. The primary roles of the pharmacies include making a strong recommendation for the HPV vaccine, parent education with both verbal and written materials, vaccine administration, and data entry into KIR to record vaccinations.

There are two public schools in Graves County, including Graves County Middle School and Mayfield Middle School. The school system represents an opportunity to capture a large portion of the target population in Graves County. School nurses will be provided with brief educational materials to distribute by mail to parents of all children at their respective middle schools. The educational material will include information about the safety and efficacy of the vaccine, general cost information, accessibility at local pharmacies, and will address some of the common barriers to HPV vaccination.
GCHD will coordinate the program and provide support in the way of professional training, registration for AFIX, KIR, and VFC, protocol development, parent educational material selection, survey development, data management, planning of all meetings, generation of reports or updates to the CAG, key stakeholders, and CDC. Professional training will include teaching health care professionals why HPV vaccination rates are low and ways they can improve their HPV vaccination practice. Training will also be provided regarding how to use AFIX, VFC, and KIR. Protocol development will include a basic outline that can be modified individually with each community pharmacy to allow pharmacists to initiate and/or complete HPV vaccination. Parent educational material will be collected from tertiary partnership organizations and distributed to PCPs, pharmacists, and school nurses. An electronic survey will be sent to health care professionals. This survey will assess provider attitudes and beliefs toward HPV vaccination. Data generated at each site will be consolidated by GCHD to measure the overall vaccination uptake in our target population. Then, a quarterly report will be generated for the CAG and key stakeholders to assess progress, and an annual report will be delivered to CDC to ensure continued funding.

**Barriers**

Potential barriers to implementation include lack of buy-in from PCPs, pharmacists, and schools/nurses. PCPs may view this program as an additional burden due to the need for documentation in KIR. They may also feel as though pharmacists and GCHD are encroaching into their patient base or medical care responsibilities, possibly taking away business. This intervention will attempt to win over PCPs by providing the necessary training for support staff to document vaccine administration, providing education on local vaccination data, and emphasizing the need for greater vaccination coverage through collaboration. Most of all, it is important to form the intervention as a partnership that supports the PCPs’ efforts, and not one that competes or criticizes them. This program is not expected to take away business from PCPs. In fact, by providing vaccinations in more locations,
PCPs will gain back precious time lost explaining the merits of HPV vaccination, which is one reason many don’t make a strong recommendation for it. It will also give them the option of making a strong recommendation, supporting it with provided literature, and then referring the patient to a pharmacy after the parents have had sufficient time to consider it. This reduces pressure on both parents and PCPs by providing more flexibility in decision making.

Pharmacists may view this program with skepticism for the time it takes for data entry, need for an additional refrigerator for VFC only vaccines, development of a protocol agreement with a physician, inspection requirements, and other related VFC documentation. Therefore, the designated AfiX staff member of the GCHD will train and provide continued support to pharmacies by detailing the legal aspects of the protocol agreement ahead of time, providing training on utilization of KIR, and registering for VFC. Pharmacies will also receive incentive payments from the grant funds to offset their additional labor and equipment costs. The incentive payment will be based on participation in the program and not “per administration” to avoid the issue of unnecessary administration. Participation means pharmacies are registered and compliant with VFC (providing quarterly reports, logging each administration into KIR, proper acquisition and storage), completing each survey from GCHD, and providing at least 10 vaccinations per quarter. Participating pharmacies will be given $1,000 to purchase a VFC-compliant refrigerator and $75 per week they are open and remain compliant to account for 1 hour of time per weekday for a pharmacy technician to enter data, prepare a quarterly report, participate in VFC site inspections, monitor and contact patients who have partially completed the series, and manage any other aspect of the program.

Currently, there is no mechanism to pay pharmacists an administration fee for VFC vaccines, however, Kentucky Medicaid managed care organizations (MCOs) have agreed to make this possible at the same rate as for physicians if pharmacies register for VFC, so this will be handled by GCHD during the program planning period. If this is not resolved in a timely manner, then grant funds will be used to
incentivize pharmacies to provide vaccinations by paying a $20 administration fee. Some commercial insurers pay for HPV vaccination in pharmacies, and some do not. Unfortunately, patients who have commercial insurance from payers who will not reimburse a pharmacy must be referred to their primary care provider, as this would be cost prohibitive for the grant or pharmacy to fund.

The protocol agreement will be drafted by GCHD and signed by Abid Hussain, MD and each pharmacist. Periodic feedback will be provided to help improve processes at each pharmacy. This program will be promoted to pharmacists as an additional revenue stream, an opportunity to build stronger relationships with community members and physicians, and an opportunity to feature other pharmacy products and services. Competition will be used as an incentive for pharmacies to improve their immunization practices by providing CoCASA data that illustrates how they are comparing to their peers. The opportunity for these pharmacies to expand their services to a younger population will also aid in their mission of improving the public health of their community.

All pharmacies in Graves County currently offer vaccination services to the target population, but a one day continuing education conference will be necessary to address improving HPV vaccination rates, updated ACIP recommendations for HPV vaccination, and legal aspects of SB101/protocol agreements. The conference will be given in collaboration with Purchase Area Health Education Center (AHEC), UK College of Pharmacy, and UK College of Public Health to all PCPs and pharmacists in Graves County prior to program implementation.

Schools and school nurses may be hesitant to send information to parents related to a controversial topic, such as the HPV vaccine. Therefore, the materials provided for distribution by school nurses will be mutually agreed upon in terms of content. These materials will focus on the recommendations for HPV vaccination by medical groups, highlight the benefits of vaccination for both boys and girls, discuss the safety of the HPV vaccine, provide information on out-of-pocket costs, and list locations providing the HPV vaccine that can also be used as an informational resource. They will not
focus on aspects of disease transmission, but will provide links to websites that address these concerns if parents choose to seek that information.

The evidence-based interventions, AFIX and protocols, on which this program is built, do not require major adaptation. However, minor adaptations would be needed to address the unique barriers of HPV vaccination among adolescents (and their parents), such as fear of syncope and decreasing the age of onset for sexual activity, as well as provider discomfort with making a strong recommendation for HPV vaccination. Health care providers must be prepared and knowledgeable to speak confidently and convincingly about these issues to be successful. Therefore, specific educational materials will be utilized at both the health care provider and parent levels that debunk these myths of the HPV vaccine and give the provider firm support to make a strong recommendation.

**Fidelity**

Monitoring efforts will include fidelity in data entry into KIR for each administration, requests for parent educational materials, and provider survey response rates. Data entry monitoring will consist of asking the clinics and pharmacies for records of the total number of HPV vaccinations administered and comparing this to the number of data entries into KIR by that provider. Stipulations in the protocol agreements will help to enforce this process at the pharmacy level. A goal rate for any clinic or pharmacy is 90% compliance, and if this goal is not being met GCHD will provide additional training or resources to assist as needed.

Parent educational materials are vital to gaining support and buy-in from the community. Therefore, GCHD will maintain the educational materials for this program and will dispense these materials to each site on request. This will allow GCHD to keep a count of the approximate amount of materials being dispensed at each site. Again, a 90% compliance rate is the goal. Material usage will be compared to expected usage based on patient throughput at the clinics or pharmacies and attendance numbers for the target age group at the schools. Pharmacists are generally familiar with patients’
families, and therefore will be encouraged to pass information to parents known to have children in or around the target age range. Educational materials will be screened by the CAG for medical, cultural, religious, and health literacy appropriateness.

Reach

The intervention is targeted at all pediatric and family medicine clinics, pharmacies, and public middle schools within the county, so it will be inclusive of nearly all the target population. There are three private schools serving the target population that are not included in the intervention, however, these schools account for approximately 15 children in our target population, and it is expected that these children go to local PCPs and/or pharmacies where they too can benefit from this program. Children residing in Graves County who do not see local PCPs are likely to attend public schools where they will benefit from this intervention. There will be some residents who go outside of Graves County for both school and medical care, however, this number is expected to be minimal. Finally, it is important that health care professionals are targeting both boys and girls for this intervention, and educational materials address the potential risks to boys so that the public does not view HPV as only a “female issue”.

Sustainability

Sustainability during the program period will depend on identifying and supporting champions in each setting to maintain and encourage enthusiasm for the initiative. Quarterly reporting of progress toward higher HPV vaccination rates at each site and for Graves County overall will keep sites engaged by seeing their own progress and the overall progress of the partnership. These reports can also be sent to local news media and the Mayfield mayor so that the community itself can take part in pushing for higher vaccination rates by demanding vaccination at the pharmacies.
This project will be self-sustained by the end of the grant period because there is relatively little training required and no major investment must be made for continued operation. Attitudes and knowledge of the HPV vaccine are expected to change in a positive way and prescribers will feel more confident about making strong recommendations for the HPV vaccine. The partnerships formed between PCPs, pharmacists, and schools will go beyond just this program as other opportunities emerge from these partnerships. It is expected that partners will expand the scope of this program to include all vaccinations in all age groups as they recognize the utility of having accurate vaccination data on the populations they serve. They will be able to identify opportunities around them and compete for the business of those who are not yet vaccinated. Ultimately, data from the success of this program will be used to affect change in other problem areas of health care by showing the power of partnerships.

For this project, the goals of sustainability will be maintaining the HPV vaccination rates reached at the end of the program period, and maintaining at least 50% use of the AFIX program and protocol agreements in clinics and pharmacies. Sustainability efforts will be integrated throughout the program by clearly explaining the short and long term goals of this program to health care providers, including the opportunities it will provide in the future.

A challenge to sustainability during the program period will include competing demands of health care professionals for other initiatives. The AFIX program is geared to provide a supportive role, with constructive feedback rather than just requiring clinics and pharmacies to meet an arbitrary goal number. AFIX staff from GCHD will monitor and check back with each site to inquire about ways to support the sites in improving their practice. This partnership will continue throughout the program period.

Challenges to sustainability after the program period are 1) federal government budget cuts or political pressure against prevention efforts that could affect the VFC program, 2) misinformation and
scare tactics from anti-vaccination groups, and 3) complacency with vaccination for uncommon diseases. Budget cuts and political climate cannot be controlled, but aggressive utilization of the VFC program will be needed to remind our government officials of its importance. Defending vaccines from misinformation has not been wildly successful in the past, however, most vaccines are reaching the goal coverage rates due to the strong recommendations that health care professionals provide. Therefore, it is equally important for our health care professionals to become comfortable with these recommendations for the HPV vaccine. After the program period, the culture of health care providers will have changed toward HPV vaccination, and strong recommendations will come easier, even for new clinicians. Complacency with vaccination of, now, rare diseases is difficult to avoid, but reports of other vaccine-preventable disease outbreaks in unvaccinated people such as mumps, measles, and whooping cough, need to be communicated loud and clear to the public as a reminder of the need for continued vaccination. This is no different for HPV vaccine, and will be accomplished again by strong recommendations from health care professionals.

**Dissemination**

Dissemination will target key stakeholders in the community to ensure sustainability and target regional stakeholders to expand the program to neighboring communities, and eventually statewide. Quarterly reports will be sent to local stakeholders, and annual reports sent to neighboring health departments and mayors of county seats. The local news station WPSD 6 will also be contacted to disseminate preliminary results before, during, and after the program period. Following the program period, manuscripts will be sent to journals such as the *American Journal of Public Health*, presentations will be given at the Kentucky Public Health Association annual conference, and both local and statewide newspapers such as the Lexington Herald Leader will be utilized to spread the message throughout the state.
It is important that community members are shown the outcomes in a simple and thoughtful way so that it may affect their attitudes and knowledge of HPV vaccination. Participants should be congratulated for helping to achieve the goal and playing a key role in improving health care delivery. Interest will be sparked in community members that did not participate when they see other members being part of something great. This will result in a change of social norms and will help make HPV vaccination acceptable and mainstream. Media campaigns will be used for this purpose.

Local health care practitioners will be presented statistics in an objective manner so that they can draw their own conclusions and decide on their own to support public health efforts like this. Results will be mailed to their offices and pharmacies along with a letter asking for their continued support for this program and others like it. They will also be thanked for their participation and dedication to improving public health.

Regional mayors will be presented reports emphasizing the ability to gain federal dollars for interventions which improve their communities by increasing HPV vaccination rates and improving partnerships in their communities to handle other issues in the future. Their support will be requested to implement similar programs in their communities so the impact of this program may spread.

Researchers will be targeted by publication of this program into journals and presentations at public health conferences. Results of this program will be added to open source evidence-based public health libraries, such as the National Association of County and City Health Officials (NACCHO), so that others may use our program in their own communities.

The effectiveness of our dissemination efforts will be measured by the impact factor of the journal that the program is published in, the sustainability of vaccination rates in Graves County based on CoCASA data, the regional dissemination and implementation of this program to neighboring communities, the number of invitations to present this program at conferences, and the amount of
correspondence with other public health departments trying to duplicate our program in their communities.

**EVALUATION**

**Formative Evaluation**

Formative evaluation of the program will be performed in consultation with the CAG during the program planning period.

Surveys to professionals will be completed electronically using simple Excel® software. This data will then be analyzed and used to inform decisions made early in the program to ensure successful implementation. It is expected that all professionals working within Graves County will be reached with an electronic survey. An incentive to participating in the survey will be that GCHD will begin assisting the site with VFC registration (if not already registered), protocol agreements, and KIR training so that the site has more time to prepare for program implementation. Quarterly, GCHD will also provide lunch to the clinic staff when surveys are due.

Components of the program that will be evaluated via survey include assessment of the attitudes and knowledge of PCPs, pharmacists, and school nurses toward HPV vaccination, public health efforts, their role in vaccination efforts, capacity of each site to deliver more HPV vaccination and/or materials, estimates of patient throughput at each site, and current practices related to HPV vaccination. The goal of these assessments will be to gauge the potential impact of the program by assessing how much improvement potential exists as well as to identify and gauge barriers to successful implementation from these groups, perhaps identifying means to adjust the program accordingly prior to its implementation.

**Process Evaluation**
Process evaluation will focus on fidelity in data entry related to vaccine administration at providers’ offices and pharmacies, and will also include supply-side factors for obtaining and storing vaccines. Other critical components of this program are dispensation of professional educational materials to provider’s offices and pharmacies, dispensation of parent educational materials from providers’ offices to parents, and dispensation of surveys to provider. Assessment and reporting of these activities will occur quarterly.

Data entry of vaccine administrations and parent reported histories into KIR may be the biggest threat to fidelity of this program because it may be viewed as an additional administrative hurdle with little or no benefit to the performing site. Quarterly, data from vaccine ordering versus administration will be compared to detect the rate at which vaccinations are being logged into KIR. Incentives will likely help in motivating this activity. First, all participants involved in administration or data entry will be educated on the importance of this data collection. Second, the site or sites with the highest percent of data entry per vaccination will receive public praise and free advertisement in the local media for their efforts. This will be assessed on a quarterly basis and the results will be shared across all sites to build competition.

Assessment of providers’ ability to obtain and maintain adequate supply of vaccine will also be crucial to providing administration of vaccine in a convenient, expedient manner and avoiding missed opportunities. Therefore, process evaluation will also include this in the quarterly survey sent to providers to identify any potential ordering or storage issues that might hinder program success.

Dispensation of educational materials will be tracked and assessed by counts of the amount of materials going out to each site. This will provide a rough estimate of use of these materials at each site.
Counts of activities will be compared to expected counts to identify potentially lagging components of the program. The AFIX employee will work to identify sites with less than expected counts, determine the cause of low activity, and implement strategies to improve processes in those specific sites. This will be done in conjunction with quarterly assessments. Expected counts will be based on CAG and/or specific provider input obtained in formative assessment surveys. Pending the results of these assessments, the program will be adjusted to better suit the needs of stakeholders, the sites, and objectives of the program.

**Summative Evaluation**

CoCASA data will be used to estimate the number of HPV vaccinations given by each site, and to measure the change from baseline for vaccinations given at each site. Data from all sites combined will estimate the percentage of the target population completing the HPV vaccine series. This will help to gauge the impact of our program on the primary endpoint.

Survey data will be used to assess impact on attitudes and knowledge toward HPV vaccination in health care providers. This will represent the impact of educational materials and feedback from AFIX reports and visits.

HPV vaccination rates are trending up prior to implementation of this program, therefore, a certain percentage of increased vaccination rates and attitudes/knowledge during this program will be attributable to other efforts impacting vaccination rates. No CoCASA data currently exists to measure the trend in Graves County specifically, so nearby communities with similar attributes where CoCASA data is available before and after the program will be used as a proxy to estimate the increase in vaccination rate that would have likely occurred without this program. Data will be collected regarding sex, race/ethnicity as well as insurance status, for subgroup analysis and to ensure distributive justice.
The long-term goal of this program is to provide another evidence-based program that can be used in other areas of the country to reach the Healthy People 2020 goal of HPV series completion in 80% of both boys and girls 13-15 years old. Milestones along the way will include closing the gap between Tdap/MCV4 versus first dose HPV vaccination rates as these vaccines should be co-administered in the same office visit. Other goals are to improve provider attitudes toward making strong and consistent HPV vaccine recommendations to all parents and to improve parental attitudes toward HPV vaccination in all income and racial/ethnic groups.

Outcomes Evaluation

Outcomes evaluation will assess whether the program has created a lasting impact on attitudes and knowledge of HPV vaccination on providers. This will be assessed by examining CoCASA data to determine the increase in vaccination uptake, and by use of a validated survey (Table 3) which will be given prior to program implementation as well as following the program period. This evaluation will survey whether pharmacies and PCPs continue to implement the new practices when the program has ended and GCHD support is no longer grant funded.

The “before” program survey and estimates will serve as the control period. The “during” and “after” program surveys and CoCASA data will serve as the intervention period. Ideally, each participant would serve as their own control, but realistically this may not be possible depending on response rates, so an average for before and after will be used instead.

The study design will be a quasi-experimental simple interrupted time series design which will assess long term effects of the intervention. This design was chosen because the intervention is community wide in nature and assessment of long term effects is important in determining the lasting impact of this program on the attitudes and knowledge of providers. These attitudes and knowledge will shape the local culture around HPV vaccination moving forward. The challenge with this study
design is that it requires multiple observation points over an extended period, which has the potential limitation of participant fatigue, or in this case the loss of accurate data entry into KIR.

**Capacity of Graves County Health Department**

The Graves County Health Department (GCHD) has prior experience implementing evidence-based programs of similar magnitude, such as the Health Access Nurturing Development Services (HANDS) program provided to expecting families and families of young infants. It aims to assist with education and early family planning. Another service that GCHD has experience in is the Early and Periodic Screening Diagnosis and Treatment Program (EPSDT), which serves children up to 21 years of age with immunizations, screening of disease, health education, and physical exams. GCHD has worked with many partner organizations to complete its mission including organizations relevant to this proposed program such as the Graves County public schools, Jackson Purchase Medical Center, Kentucky Cancer Program, Mayfield Independent Schools, the State Health Insurance Assistance Program, and the YMCA. These strategic relationships are maintained by two-way transparency and critical evaluation of partner activities and missions. These partnerships have resulted in successful provision of services such as the H.A.N.D.S. and EPSDT program.

GCHD conducts a community needs assessment to prevent negative health outcomes and promote positive development in the community. The community needs assessment takes three perspectives including objective data, local organizations, and individuals. Data comes from local, state, and national sources and provides objectivity. Local organizations conduct community health forums and identify strengths and risks within Graves County. Citizens of Graves County provide individual perspectives by participating in surveys to identify the health needs most important to them. The Graves County Board of Health convenes to decide the overall course of actions GCHD will take. This
diverse group of 11 individuals, includes five physicians, one judge, one banker, one attorney, and one lawyer.

GCHD currently has the infrastructure in place to take on a new project countywide. The current staff consists of administrative, financial, nursing, school nurses, school clerks, H.A.N.D.S. staff, nutritionists, environmentalists, and support staff. The organizational chart is found in Figure 2.

The mission statement of GCHD is to “Promote the lifelong physical and emotional well-being of our community through the provisions of preventative health services, health education and environmental services.” The proposed program aligns with this department’s mission of providing preventative health services and health education. In fiscal year 2016, GCHD managed $2,770,258.77, which consisted of $795,890.04 carried over from the previous year and $1,974,368.73 in new funding. Total disbursements for all public health activities and infrastructure totaled $1,767,689.57. Employees of the department are dedicated to the services they provide as indicated by an annual turnover rate of less than 10%, with high levels of employee engagement, productivity, and efficiency.

GCHD is committed to quality improvements and applied for voluntary national accreditation to the Public Health Accreditation Board (PHAB) in 2014. The Accreditation Coordinator and Health Education Director attended the required training in February 2015 and all required documentation was submitted by July of that year. A PHAB site visit took place in January 2016, and an action plan was developed and submitted to PHAB for accreditation review.

GCHD is an equal opportunity employer as stated on its employee application form, “Equal Opportunity Employer”. No question on this form is asked for limiting or excluding any applicant’s consideration because of race, color, sex, national origin, age, marital status, religion, or status regarding public assistance, or disability.” As such, these same ethical principles extend to the services which GCHD provide to community members, partnerships, and collaborators. Any deviation from these
principles is grounds for immediate termination of employment. If partners or collaborators are found to discriminate in provision of their services, those partnerships or collaborations are discontinued.

**Partnerships and Collaboration**

Support for this program comes from key collaborators in the community including, all six retail pharmacies (Duncan Rx Center, Gibson’s Discount Pharmacy, CVS, Wal-Mart, Walgreens, and Stone’s Health Mart) as well as two pediatric clinics (Jackson Purchase Medical Center and Mayfield Pediatric Clinic), two family medicine clinics (Jackson Purchase Medical Center and Western Kentucky Family Healthcare), two middle schools (Graves County Middle School and Mayfield Middle School). Between these 12 locations, plus GCHD, this program will not be limited by scale because it will have no problem reaching the target administration rate of 500 to 1,000 vaccines annually, to reach all children aged 11-12 years in Graves County. Each collaborator is responsible for collecting performance measure data with training and assistance from GCHD.

The pharmacies will play the role of expanding access to HPV vaccine by administering vaccine per protocol. Pharmacists will teach parents the importance of HPV vaccination in both boys and girls, the risks and benefits of vaccination with HPV, and what to expect from vaccination. These pharmacists are already accustomed to providing influenza vaccinations to children down to the age of 9.

The PCP clinics will often give the first dose of the HPV vaccine series, but will also play a role in coordinating with retail pharmacies to ensure the second and third, if needed, doses are administered in an appropriate time following previous vaccination. This will be facilitated by use of CoCASA to track which children have already been vaccinated and at what time. PCP clinics will also provide parent educational resources, developed by the CDC and other organizations, to educate them about the HPV vaccine, and provide additional information about participating pharmacies in Graves County.
The two middle schools in Graves County will be involved by sending information about the HPV vaccine to the parents of children attending those schools. This partnership is crucial to expand the reach of the intervention to children who do not have a relationship with any of the PCP clinics or any of the pharmacies. This information will point children either to the local PCP clinics or pharmacies to receive the initial dose of HPV. Then, they will be referred to any of the pharmacies to administer additional doses, as needed.

Tertiary partnerships with the CDC, ACIP, NCI, ACS, state VFC program, and Immunization Action Coalition (IAC) will provide informational brochures for both providers and parents. These brochures will be used by schools, clinics, and pharmacies to dispense to the public and facilitate question and answer sessions. In addition, CDC and ACIP make annual recommendations for immunizations and the VFC provides vaccines to participating PCPs and pharmacists to administer at no cost to patients who qualify through Medicaid or lack of insurance.

The CAG is composed of a diverse array of 11 community volunteers including the pediatrician at Mayfield Pediatric Clinic, a provider from Western Kentucky Family Healthcare two pharmacists – one from an independent pharmacy and one from a chain pharmacy, one school nurse from either middle school, four parents involved in the PTA – two from each middle school, and two local youth group leaders. Support will be gained by inviting these members to the CAG and expressing the need for their individual perspective of the program to represent their businesses, schools, or congregations.

**Project Management**

**Project Director**

Riley Beth Willett, DrPH, program specialist at GCHD will serve as Project Director and hold overall responsibility for the project. Dr. Willett is a University of Kentucky College of Public Health graduate of 2002, with 15 years of professional experience. She has spent the past 10 years working on
various programs and services such as the HANDS program and immunization services, and has a deep understanding of the needs of a program of this magnitude.

She will make initial contact with all “key personnel” including health care providers, school nurses, CAG members, local VFC staff, and a statistician to establish participation in this program as well as maintain those relationships throughout the program. Identification of key personnel will occur prior to receipt of funding to allow proper planning and organization.

She will provide managerial support for all program activities including the hiring of the Project Coordinator and Project Assistant to start when funding is received. When the program planning period begins, she will begin consulting with CAG members, managing survey development for providers, and providing additional support necessary to program personnel or providers involved with the program. She will provide all initial training for the project coordinator, and along with the project coordinator, provide initial education and training to providers in implementation of this program.

She will coordinate all meetings with the CAG, the Project Coordinator, key personnel, and our Community Providers per the timeline provided in the “program approach” section. This will ensure the program is implemented smoothly and that any additional barriers that are identified prior to or during implementation of the program are handled appropriately.

She will be responsible for disseminating the data obtained from this program to public health workers and researchers in other areas by publishing these findings in journals, presenting the program and its findings in conferences, and participating in efforts to support replication of this program.

Project Coordinator

The Project Coordinator will be hired into the position by the program director prior to funding and will start on day one of funding. This person will be hired based on having at least 5 years of
experience in a similar role and must hold an MPH. The coordinator will be responsible for the daily operations of the program, including responding to the needs of our community providers and supporting them in their efforts by providing provider and parent educational materials, protocol agreements, VFC, AFIX, and KIR registration support, and any other requested support. He or she will also ensure that CMS implements a mechanism to pay pharmacists an administration fee for VFC vaccines during the planning phase.

The Project Coordinator will perform data collection via the identified survey methods, which also includes identification of potentially eligible participants for inclusion into the program; obtain/draft templates for protocol agreements in accordance with state laws and regulations that will allow pharmacists to provide HPV vaccinations to children down to the age of 9; consult with the statistician to ensure all data collection and analysis is done appropriately; and update the CAG on program progress at formal meetings via CoCASA reports.

**Project Assistant**

The project assistant will work under the direction of the project coordinator and perform many of the day to day duties of the project coordinator depending on what tasks need to be performed at any given time. The project assistant will be required to have 2 years of experience in a department of public health and a bachelor’s degree. Much of this position will include data entry of surveys, obtaining and delivering educational materials to each of the sites, and providing technical support for our clinic and pharmacy sites. The project assistant will also perform the project coordinator’s duties when the project coordinator is away for training, sickness, travel, etc.

**Additional Key Personnel**

Dr. Sarah Bush is an Associate Professor in the University of Kentucky Department of Biostatistics. Prior to her appointment, she worked as a senior statistician for a clinical research
organization specializing in Phase IV clinical trials and health registries, where she became interested in methodological issues associated with investigating health outcomes in large, complex databases. She will be consulted during survey development and before data collection begins, then periodically to ensure data collection and analysis are accurate and appropriate for the purposes of this program.
TABLE 1. Estimated vaccination coverage with selected vaccines and doses* among adolescents aged 13–17 years,† by HHS Regions and state, selected local areas, or territories — National Immunization Survey-Teen (NIS-Teen), United States, 2015

<table>
<thead>
<tr>
<th>HHS Region/State/Territory</th>
<th>All adolescents (n = 21,875)</th>
<th>Females (n = 10,508)</th>
<th>Males (n = 11,367)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥1 Tdap§ % (95% CI)¶¶</td>
<td>≥1 MenACWY§ % (95% CI)</td>
<td>≥2 HPV** % (95% CI)</td>
</tr>
<tr>
<td>United States overall</td>
<td>86.4 (±1.0)</td>
<td>81.3 (±1.0)**</td>
<td>62.8 (±1.8)***</td>
</tr>
<tr>
<td>Kentucky</td>
<td>84.0 (±4.7)</td>
<td>79.0 (±5.2)</td>
<td>57.4 (±8.6)</td>
</tr>
</tbody>
</table>

Sarah Reagan-Steiner, MD, et al. MMWR: National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2015 Weekly / August 26, 2016 / 65(33);850–858
**TABLE 2.** Estimated HPV vaccination coverage among adolescents aged 13–17 years,* by race/ethnicity† and poverty level§ — National Immunization Survey–Teen (NIS-Teen), United States, 2015

<table>
<thead>
<tr>
<th>HPV</th>
<th>Race/Ethnicity</th>
<th></th>
<th>Poverty status</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>White, non-Hispanic (n = 12,835) % (95% CI)</td>
<td>Black, non-Hispanic (n = 2,228) % (95% CI)</td>
<td>Hispanic (n = 4,610) % (95% CI)</td>
<td>American Indian/Alaska Native, non-Hispanic (n = 290) % (95% CI)</td>
<td>Asian, non-Hispanic (n = 751) % (95% CI)</td>
</tr>
<tr>
<td>Females ≥3 doses</td>
<td>39.6 (±2.1)</td>
<td>40.8 (±4.6)</td>
<td>46.2 (±4.9)††</td>
<td>38.7 (±12.9)</td>
<td>53.5 (±9.8)††</td>
</tr>
<tr>
<td>Males ≥3 doses</td>
<td>25.2 (±1.7)</td>
<td>26.0 (±3.8)</td>
<td>35.0 (±4.5)††</td>
<td>34.6 (±11.1)</td>
<td>30.7 (±9.9)</td>
</tr>
</tbody>
</table>
Table 3

HPV vaccine recommendation quality indicators

<table>
<thead>
<tr>
<th>Timeliness</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For males: start routinely recommending HPV vaccine...</td>
<td></td>
</tr>
<tr>
<td>Early/on time (≤12 y)</td>
<td>472 (61)</td>
</tr>
<tr>
<td>Late/never (≥13 y)</td>
<td>304 (39)</td>
</tr>
<tr>
<td>For females: start routinely recommending HPV vaccine...</td>
<td></td>
</tr>
<tr>
<td>Early/on time (≤12 y)</td>
<td>573 (74)</td>
</tr>
<tr>
<td>Late/never (≥13 y)</td>
<td>203 (26)</td>
</tr>
</tbody>
</table>

Consistency

Use a risk-based approach to recommending HPV vaccine

| Strongly/somewhat disagree                      | 316 (41) |
| Strongly/somewhat agree/neither agree nor disagree | 460 (59) |

Urgency

Usually recommend 11- to 12-year-olds get HPV vaccine...

| At current visit                                 | 399 (51) |
| At later visit/give a choice/other               | 377 (49) |

Strength of endorsement

Say HPV vaccine for 11- to 12-year-olds is...

| Very/extremely important                         | 568 (73) |
| Not/slightly/moderately important                | 208 (27) |

Reliability: Cronbach’s Alpha = 0.838 (n = 648); Test-Retest = 0.79 (n=226).
Figure 1. County Map of Kentucky
Graves County Health Dept
Organizational Chart

Figure 2 Organizational Chart
Budget Justification

Personnel Salaries  ($225,124)

Staff positions will include Program Director, Program Coordinator, and Program Assistant. Their annual salary rates will start at $80,000, $50,000, and $36,000, respectively, and increase 3% each year. The Program Director will devote 0.2 FTE each year ($49,454 for 3 years). This time commitment is expected to stay the same annually. The Program Coordinator will work 0.5 FTE ($25,000) during the first year, 0.25 FTE ($12,875) during the second year, and 0.5 FTE ($26,523) during the final year, reflecting extra workload on startup, and increased workload as reports and analyses are run during the last 6 months of this program. The Program Assistant will work 1.0 FTE each year of the project ($111,272 for 3 years).

Fringe Benefits  ($103,977)

Fringe benefits were calculated per the table below. Total salary costs for three employees are $225,124, so fringe benefits will total $48,514 (21.55%) for retirement, social security, and other over the three-year program period.

Health insurance is prorated based on FTEs devoted to this program over three years for each employee at the employee + family rate, and increases 3% per year. Annual costs for the program director at 0.2 FTEs annually ($2,213, $2,279, and $2,348) totals $6,840. Annual costs for the program coordinator at 0.5 FTEs, 0.25 FTEs, and 0.5 FTEs annually ($5,532, $2,849, and $5,869) totals $14,250. Annual costs for the program assistant at 1.0 FTEs annually ($11,064, $11,396, and $11,738) totals $34,198. The total for health insurance is $55,288.

Life insurance is prorated based on FTEs devoted to this program over three years for each employee. All employees total 4.85 FTEs (58.2 months) for a total of $175 for the program period.
Graves County Health Dept Fringe Benefits  
Rates Effective Through 7/1/18 Until Amended

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retirement</td>
<td>10%</td>
</tr>
<tr>
<td>Social Security</td>
<td>7.65%</td>
</tr>
<tr>
<td>Other Fringe</td>
<td>3.9%</td>
</tr>
<tr>
<td><strong>Total Percent</strong></td>
<td><strong>21.55%</strong></td>
</tr>
</tbody>
</table>

**PLUS A Prorated Amount of Health and Life Insurance**

Multi-year projects should project a 3% increase in insurance per year. Amounts shown below are for the ‘17-’18 year.

<table>
<thead>
<tr>
<th>Plan</th>
<th>Employee</th>
<th>Employee + Children</th>
<th>Employee + Spouse</th>
<th>Employee + Family</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$495/mo</td>
<td>$649/mo</td>
<td>$783/mo</td>
<td>$922/mo</td>
</tr>
<tr>
<td></td>
<td>$5,940/yr</td>
<td>$7,788/yr</td>
<td>$9,396/yr</td>
<td>$11,064/yr</td>
</tr>
</tbody>
</table>

**Life Insurance**

<table>
<thead>
<tr>
<th>Plan</th>
<th>Employee</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$3/month</td>
</tr>
</tbody>
</table>

**Travel**  

Local travel around Mayfield, KY will be required to train and educate providers at their pharmacies and offices as well as to deliver educational materials to providers and schools. This will be accomplished by use of privately owned vehicles in which drivers will be reimbursed $0.535 per mile in accordance with the 2017 federal reimbursement rate. The average distance to travel roundtrip is 6.2 miles to get to each of the participating sites. Estimating quarterly visits to each of about ten sites results in a total of 248 miles ($139) per year.

Travel to a 3-day annual project director’s meeting in Washington, DC is estimated to cost $1,776 annually, including $250 registration fee, $242 for room for three nights ($726), $500 for roundtrip airfare (including luggage, transportation, and parking), and $75 per diem for 4 days.

Travel to an annual regional training each year will include both the Project Director and Project Coordinator. This training is estimated to cost $1,552 annually including $400 for two registration fees,
$312 for 2 rooms for one night, $632 for two roundtrip airfares (including luggage, transportation, and parking), and $104 per diem for two days.

**Equipment**

($3,000)

Equipment needs include two laptop computers at $1,500 including Windows office software packages for use by the program coordinator and assistant.

**Supplies**

Office supplies will be needed for the three employees of the project. Training materials will need to be printed off for distribution, but many can be sent electronically to reduce costs. The bulk of supply costs will be in the form of patient and provider educational materials. Expenses will include ink, paper, and labor time. These expenses will be included in the “indirect” costs.

**Contractual**

($8,500)

The biostatistician will be consulted to assist in appropriate survey methodology as well as analysis of data on a quarterly basis. Dr. Bush charges $250 per hour. We expect to need eight hours of her time at the beginning of the program period to help with survey development and sixteen hours at the end of the program to help with final reporting of data for publication. In addition, one hour will be needed to help analyze and prepare data for quarterly reporting to the CAG and stakeholders. A total of 34 hours will be needed, resulting in $8,500.

**Incentives**

($60,800)
Each of the six pharmacies will be given $1,000 to cover the cost of a medical grade refrigerator for vaccine storage to comply with VFC regulations ($6,000). This is crucial to help offset the startup cost and gain buy-in for the community pharmacies.

In addition, participating pharmacies will earn $75 per week they are open and remain compliant to account for 1 hour of time per weekday for a pharmacy technician to enter data, prepare a quarterly report, participate in VFC site inspections, track down patients who have partially completed the series, and manage any other aspect of the program. Participation means pharmacies are registered and compliant with VFC (providing quarterly reports, logging each administration into KIR, proper acquisition and storage), completing each survey from GCHD, and providing at least ten vaccinations per quarter. If all six pharmacies remain fully compliant for the entire two years (104 weeks) of actual program implementation, this cost will total $46,800. In addition, a $20 administration fee will be awarded to pharmacies for each HPV immunization in the target population if CMS has not created a way to pay pharmacists this fee in a timely manner. This will also cover administration fees for commercial insurers who do not pay pharmacists an administration fee. This award will be capped at $8,000 for the program period, which is equivalent to 400 vaccinations.

**Indirect costs**  
$(86,729)$

The DHHS-negotiated F&A rate is 21.6% beginning FY17. The indirect cost request is computed on the following direct cost base of $411,524.

- Personnel: $225,124
- Fringe: $103,977
- Travel: $10,123
- Equipment: $3,000
- Contractual: $8,500
Incentives: $60,800
Indirects: $88,889

TOTAL BUDGET ($500,413)
Modified from CDC's example Logic Model for AFIX program grantees\textsuperscript{25}
### Work Plan

#### Goal 1: Set up pre-program initiatives in the first 6 months of the funding period.

**Objective 1:** Gain buy-in among physicians and pharmacists to use the AFIX program  
**Rational:** The AFIX program provides logistic support to providers to help them improve their immunization efforts in an evidence-based, community-wide, approach.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timeline: 2017-2018</th>
<th>Measures</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Train AFIX staff</td>
<td>X</td>
<td>Three GCHD staff trained to implement the AFIX program</td>
<td>GCHD program director, coordinator, and assistant</td>
</tr>
<tr>
<td>2) Set up provider AFIX visits</td>
<td>X X</td>
<td>Make appointments with PCPs, and pharmacists</td>
<td>GCHD program coordinator and assistant Providers</td>
</tr>
<tr>
<td>3) Review provider records, coverage level, and missed opportunities</td>
<td>X X</td>
<td>Obtain coverage and missed opportunity levels for each practice</td>
<td>GCHD program coordinator and assistant</td>
</tr>
</tbody>
</table>

**Objective 2:** Improve provider immunization services effectiveness.  
**Rational:** Greater effectiveness will keep providers interested in vaccination efforts by not simply adding another burden to their already overworked practice.

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</thead>
<tbody>
<tr>
<td>1) Review provider immunization services</td>
<td>X X</td>
<td>AFIX questionnaire</td>
<td>GCHD program coordinator and assistant</td>
</tr>
<tr>
<td>2) Provide feedback and recommend strategies for improvement</td>
<td>X X</td>
<td></td>
<td>GCHD program coordinator and assistant providers</td>
</tr>
<tr>
<td>3) Assist providers with registration and compliance with VFC</td>
<td>X X</td>
<td>Number of VFC registered providers</td>
<td>GCHD program coordinator and assistant providers</td>
</tr>
<tr>
<td>4) Document outcome of visit in CoCASA or AFIX online tool</td>
<td>X X</td>
<td></td>
<td>GCHD program coordinator and assistant</td>
</tr>
</tbody>
</table>
Objective 3: Expand pharmacists’ ability to vaccinate 11-12-year-olds.
Rational: Pharmacists represent an untapped resource for providing better convenience to patients to get their vaccinations.

1) Create protocol agreements with pharmacists
   Number of pharmacists who entered a protocol agreement
   GCHD program coordinator and assistant pharmacists

Objective 4: Improve provider attitudes and knowledge of HPV vaccination practices.
Rational: Improved attitudes and knowledge lead to motivation and sustained change.

1) Provide educational materials to providers
   GCHD program coordinator and assistant

2) Conduct surveys of providers’ attitudes and knowledge
   Survey response rate and assessment of response
   GCHD program coordinator and assistant

Goal 2: Begin and maintain program implementation during middle two years of the funding period.

Objective 1: Build collaboration among physicians, school nurses, and pharmacists, and reward better results.
Rational: Collaboration in the health care community will allow each profession to focus on its strengths, and provide better care for less expense. Rewards will help stimulate collaborative efforts.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timeline: 2018-2020</th>
<th>Measure</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Conduct follow up with providers and recommend additional changes</td>
<td>S  O  N  D  J  F  M  A</td>
<td>Verify VFC, AFIX, KIR use and implementation strategies in place.</td>
<td>GCHD program coordinator/assistant</td>
</tr>
<tr>
<td>2) Promote information exchange</td>
<td>These activities will be performed together quarterly beginning March 2018 – March 2020</td>
<td>Share community wide information among providers to motivate continued improvement</td>
<td>GCHD program director/coordinate</td>
</tr>
<tr>
<td>3) Acknowledge and reward improved performance</td>
<td>CoCASA data media stories</td>
<td></td>
<td>GCHD program director/coordinate</td>
</tr>
</tbody>
</table>
Goal 3: Outcomes evaluations and dissemination of results in the last 6 months.

Objective 1: Measure the impact of the program over time, assess overall success, and disseminate findings. 
Rational: To inform future use of this program or similar approaches, we need to measure the effectiveness and then communicate those results to other health departments in the region for expansion and continued funding in this effort.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timeline 2019-2020</th>
<th>Measure</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S</td>
<td>O</td>
<td>N</td>
</tr>
<tr>
<td>1) Consult with biostatistician for evaluation of CoCASA and survey data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Prepare a manuscript for peer-reviewed journal publication</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3) Disseminate findings at conferences and aid other potential grantees.</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

4) Meet with CAG
References


