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Madeline Brown, Student

Dr. Jerod Stapleton, Committee Chair

Dr. Richard Ingram, Director of Graduate Studies

**Implementing a Mobile Saliva Rinse Screening for P16 Markers for HPV (Human Papillomavirus)
Positive Head and Neck Cancers in Central Kentucky**

University of Kentucky College of Public Health

By Madeline Franklin

Lexington, Kentucky

Target Population and Need

HPV and HPV-positive Head and Neck Cancers

HPV is a sexually transmitted infection. It is spread through skin-to-skin contact during oral, vaginal, or anal sex. About 10% of men and 3.6% of women are positive for oral HPV (10). Some strands of HPV are low-risk and can cause little to no symptoms. The high-risk strands can cause cancers to the site where it was transmitted. More than half of all sexually active people contract one or more types of this virus at one time, making it the most common sexually transmitted disease in the U.S and making it extremely prevalent (11).

Unfortunately, HPV can lead to cancers years, even decades, after the person contracts it. One of the primary cancers it causes is oropharyngeal cancer, which includes the back of the throat, base of the tongue and tonsils. About 70% of OPSCC (oropharyngeal squamous cell carcinoma) cases in the United States are caused by HPV. Oral squamous cell carcinoma (OSCC) and oropharyngeal squamous cell carcinoma (OPSCC) are the most common types of head and neck squamous cell carcinoma (HNSCC), accounting for 263,900 new cases and 128,000 deaths worldwide. Overall, the lifetime risk of developing HPV-positive oral cavity and oropharyngeal cancer is about 1 in 60 (1.7%) for men and 1 in 140 (0.71%) for women. Every year the rate of HPV positive OPSCC is rising across the US. (10) Normally tobacco and alcohol use are the main causes of this type of cancer, but in recent years there has been a decline in tobacco and alcohol linked cases and a rise in cases caused by HPV. Recent data shows “(10). CDC (Centers for Disease Control) data shows that men are much more likely to be diagnosed with HPV-positive HNC. For every 3,500 new cases diagnosed in women yearly, 16,200 men (about the seating capacity of Madison Square Garden) are diagnosed yearly. (11)

HPV-positive Head and Neck Cancer risk in Kentucky

Rates of HPV-related head and neck cancers are increasing across the nation and more specifically, there has been a significant increase in the state of Kentucky. From 2002 to 2012, there

were 149,301 cases of HNC recorded in the SEER database. The HNC rate decreased by 0.22% per year and the rate of laryngeal cancer decreased by 1.9% per year. The rate of oropharyngeal (HPV-related) cancer increased by 2.5% per year. Kentucky has some of the highest cancer rates in the nation overall and Kentucky also has one of the highest incidences of head and neck cancer in the United States. Rates nationwide are increasing at less than half of a percent a year, while rates in the Commonwealth have increased by more than 2 percent since 2001(4). From 2002 to 2012, there were 149,301 cases of HNC. The rate of oropharyngeal (HPV-related) cancer increased by 2.5% per year. (7)

According to the American Cancer Society 26,5000 new cancer cases are estimated this year alone in Kentucky. Nationally, Kentucky ranks as one of the highest states many risk factors for cancer.

Kentucky has one of the highest rates of obesity in all stages of life. When looking at middle-aged men nationally the obesity percentage is 36%. In Kentucky however it is 43.8%. This is just one of the many risk factors we see in this middle-aged population in Kentucky. Other issues that Kentucky faces are disparities in nutrition, access to care, and education.

In rural communities, like Appalachia, it is even more difficult to get access to many of the resources that are available in the bigger cities in Kentucky. These health-related resources that are hard to find include cancer screenings. Kentucky ranks among the lowest in cancer screening rates. Nationally, with pap/ HPV cervical cancer testing in women 21-65 the state is ranked 22nd. For rankings when it comes to HPV Vaccination in children 13-17 the state ranks 47th with girls and 42nd with boys. Although these populations are not middle-aged men, the population we are focused on, they serve as a foundation so that we can better understand the community ideas and beliefs surrounding HPV vaccination and HPV screening in the state of Kentucky. Current HPV vaccination rates in KY fall well below national health goals established by Healthy People 2020 and although county-level HPV vaccination data in KY is not readily available, several published articles and state health department reports are available, detailing low HPV vaccination rates in MCC's catchment area." (6) If we look at the

five-year invasive cancer incidence rates of HPV- related Oral and Pharynx Cancer in Kentucky versus the United States we see that the Kentucky and Non-Appalachian Kentucky sit at 13.6 and 13.5, much higher than the United States rates of 11.0.

Central Kentucky Community Risk factors- sociodemographic and behavioral

In most of Kentucky disparities are high, obesity rates are high, and tobacco use is high. When we look at the percentages. of Kentucky is 17.3% obese compared to the nation’s 13.4%. If we look at the percentage of people in Lexington/ Fayette County living below poverty, we see that the number is still high at 16.8% for Fayette County and 15.8% for Lexington MSA. We know that poverty contributes to lack of access to good health care and can be a barrier when finding and establishing care. When you combine all these factors it creates the perfect storm for a high cancer burden.

Another risk factor is our low cancer screening and vaccination rates across Kentucky. Below are the vaccination rates for HPV-positive cancers in Kentucky among girls and boys 13-17. Kentucky consistently ranks in the 10 lowest in the country. Kentucky is doing a poor job as a state of vaccinating children for it when they are in the window for prevention and therefore, we are seeing these cancers form more frequently in our state in adults who no longer have that preventative option.

HPV Screening and Vaccine Rates in Kentucky			
Screening/ Vaccine	KY	Rank	US
Pap HPV test, Women 21-85 years	86%	22	85%
HPV vaccination coverage, Boys 13-17 years	40%	42	49%
HPV vaccination coverage, Girls 13-17 years	45%	47	54%

This intervention will be focused on men ages 45-65 in Central Kentucky. The evidence-based intervention focuses on this specific population to meet many gaps that are currently present. Not only

does this specific group (middle-aged men) have a higher incidence of HPV positive SCC of the head and neck, but also this specific group is less likely than their female counterparts and of males in other age groups to attend annual checkups or doctor's appointments including dental check-ups where the dentist may do a quick physical exam of the oral cavity for signs of head and neck cancers. According to the Head and Neck Cancer Alliance this cancer occurs much more frequently in men. The ratio between men with this and women is about six or seven to one. The average age of a patient with this is 40-55, a decade younger than the traditional "smoker/drinker" patient with head and neck cancer. (2) When it comes to men in the Central Kentucky Area the Community Health Assessment and Improvement Plan released in 2017 by the Lexington Fayette County Health Department showed that two out of the top 10 health concerns among men were access to primary care providers and access to dental care (3). These providers are key in detecting and diagnosing early stages of head and neck cancers and missing regular appointments with them can cause important symptoms and other warning signs to be missed.

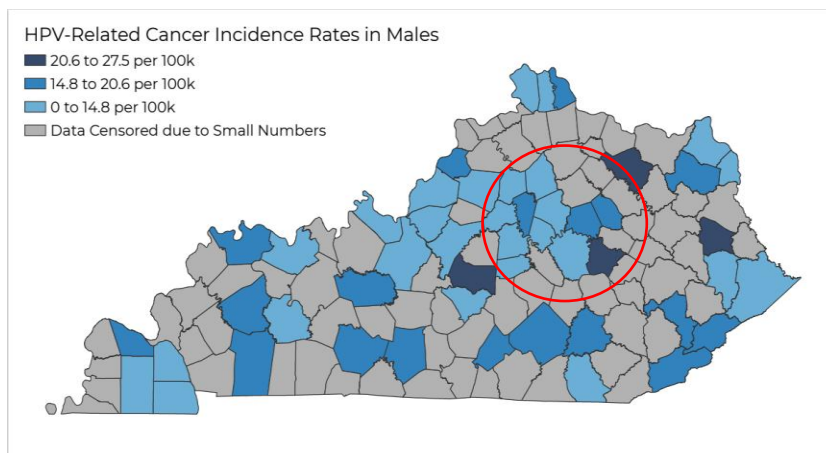


Figure 2- HPV Related Cancer Incidence Rates in Males in Kentucky

*The circled area, Central Kentucky is the targeted location.

The map above shows the highest risk areas in Kentucky for HPV-related cancers in men. As you will notice, most of central Kentucky falls in the darker blue tones and is a high-incidence area. (Figure 2)

According to the KY CNA's Cancer-related outcomes the HPV-related cancer incidence rate per 100k people is 11.7 in the US, 16.5 in KY, 15.8 in urban and non-Appalachian KY areas including central Kentucky and rates are higher in black and white Kentuckians both in comparison to the nation's rates.

Why is it so important for this population of men to get screened for and catch this specific type of cancer early? Because the stage and time that it is diagnosed can make a significant difference in whether the patient lives or dies. HPV-positive head and neck cancers have a higher rate of survival post diagnosis in comparison to those with HPV- negative head and neck cancers. Yet another reason we should work to catch this cancer early before metastasis local or distant. More than half of these tumors are diagnosed at an advanced stage and only 50% of HPV-negative patients and 66% HPV-positive patients survive up to 5 years post diagnosis. In addition, approximately 30% of HPV-positive patients develop recurrences within 2 years of initial diagnosis, whilst HPV-negative HNSCC patients show recurrences within a year (4).

Available Community Resources

The Lexington, Kentucky location of Markey Cancer Center (MCC) will be where the program's "home base" is and this intervention will serve middle-aged men in the Lexington/ Fayette County community in its primary phase and has the possibility to move on to being implemented to middle-aged men in counties across Kentucky where MCC has affiliate locations in the later phases which would foster program sustainability. These locations reach over 21 counties (See figure 1.2) across Kentucky and bring cancer care and screenings from a designated NCI (National Cancer Institute) cancer center to communities who would otherwise not have access to this kind of care.

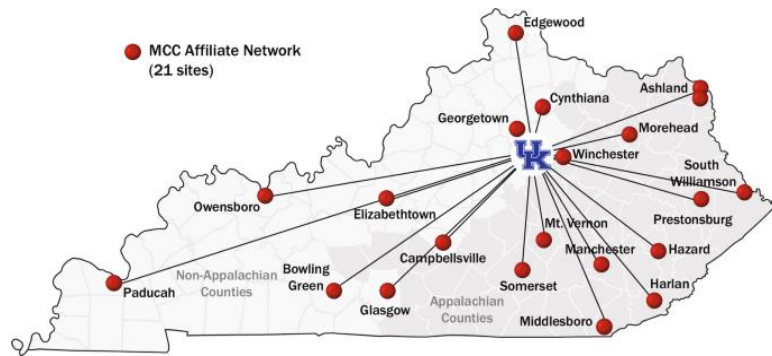


Figure 4- Markey Cancer Center and Affiliate Locations

When it comes to resources

related to cancer screening, prevention, and care there are some quality choices for care in the Central Kentucky geographical area. Lexington is home to a few large hospitals and healthcare centers that can provide wonderful cancer care and can also provide more regular access to screening. Markey Cancer Center, the state's only NCI designated cancer center is in Lexington at the heart of Central Kentucky and offers a screening program with exams for: Breast, Cervical, Colorectal, Lung, Ovarian, and Prostate cancers. This program offers free screening for many individuals who meet the requirements. Markey Cancer Center is focused on community-based research and does a lot specifically for HPV vaccination with their HPV- Vaccine Quality Improvement project. This model is based on those at existing partnering centers like the Vanderbilt-Ingram Cancer Center. Those in surrounding counties and even in rural areas sometimes have the choice to receive care at Markey affiliate locations throughout Kentucky, as seen in figure 1.2. These locations are scattered throughout Eastern Kentucky, in Appalachia, Southwestern Kentucky, and other rural areas marked with disparities.

There is a plethora of oncology related screening resources available at MCC, but there is a bottleneck in resources when it comes to those related to HPV-positive head and neck cancers because there is currently no strongly supported evidence-based screening technique for HPV- related head and neck cancers and therefore they are often caught in the late stages. The screening program that will be introduced is one that takes a commonly used mobile screening clinic, modeled after others at Markey Cancer Center, and modifies it in order to reach middle-aged males, the population most at risk for this

type of cancer. This screening program holds a lot of promise, and I am hopeful that it will become best practice in the future.

We can do better than just trying to catch this cancer once it has metastasized or intensified. Instead of focusing all our resources on late-stage treatment let us take a close look at the impact we may be able to have on this specific population with screening of HPV positive head and neck cancers.

A mobile HPV- positive head and neck cancer screening program will help connect individuals in the community who may be at risk for HPV-positive head and neck cancers with screening opportunities by bringing the screening to them and reaches the specific population it is targeting by meeting them where they are. This program enhances the existing screening programs that UK Healthcare and Markey Cancer Center offer by taking a cancer that is rapidly becoming more common and targeting the most at-risk population with educational and easily accessible screening tools.

Implementation Strategy:

To successfully implement this screening program to scale in the Central Kentucky community, we will use the implementation strategy of adapting it to the specific community we are trying to reach. First, as mentioned earlier, all the advertising and the placement of these mobile events are specifically tailored to capture the interest of the demographic we are focusing on. Because these aspects of recruitment and the actual mobile clinic and screening itself are tailored to this population it is more likely we will be able to implement it better in this specific community and among our specific demographics.

Program Approach

The Elements of HPV Positive Head and Neck Screening Program:

- Recruitment at mobile clinic location
- Gathering of demographic information

- Brief introduction to the screening process
- Saliva rinse test screening (2-3 minutes)
- Post- survey submitted via email invitation using REDCap tool within 5 days of initial screening-
Program Assessment (5-10 minutes depending on speed of participant)
- Follow-up with participants whose screening results showed the presence of HPV-16 markers
and referral of follow-up care at MCC or MCC network locations.

HPV-Positive Head and Neck Cancer Screening Program

The focus of this program is the saliva-rinse test screening tool. The Central Kentucky community needs a non-invasive and predictive screening tool for HPV positive head and neck cancers and a saliva rinse test has been tested and is looked at as the best screening tool to fit this criterion. This screening tool will be implemented in our program and will be the cause of an increase in screenings in the community and a decrease in late-stage diagnosis of HPV head and neck cancers.

Evidence-base

For this evidence-based part of our program the existing practice of saliva- rinse screening will be implemented in a mobile clinic setting in the Central Kentucky Community to screen for HPV-16 and other HPV positive markers which can help to diagnose HPV positive head and neck cancers at an early stage. HPV is a virus that can only live in certain cells, which are squamous epithelial cells. These cells are present in the inner lining of the nose, mouth, and throat. This last one is what this program is focusing on HPV positive squamous cell cancer cells in the lining of the mouth and throat, also known as the oral cavity. The program will use an evidence-based saliva rinse screening test. This test can detect the presence of HPV-16 and other HPV positive markers in the oral cavity (see figure 1.3) which can lead to an early diagnosis of HPV positive head and neck cancer in participants. We will quickly (2-3 minutes) collect a small vial of saliva from the participant. This vial will be put on ice in coolers at the mobile clinic

and at the end of the day when the CRA's are returning to the MCC campus they will drop the specimens off at MCC BPTP for processing.

How the saliva-rinse screening test works:

This saliva rinse test is a non-invasive predictive biomarker used to detect HPV-16 markers and the presence of HPV-positive Head and Neck cancer DNA in a participant's oral cavity. Participants will swish around about 200 mL of water around their mouth from the small water bottles provided to participants and will then swallow this to cleanse the mouth of any food or debris. Then an oral rinse (drool) saliva sample will immediately be collected in a small vial, the participant will drool until the 2 mL vial is filled to the top. (9) These saliva samples are stored on ice and then examined by the BPTP team where they undergo examination of the tumor p16 expression using immunohistochemical (IHC) analysis. (9) The qPCR method will be used on these same samples to determine HPV-16 genotyping and viral load (9). This combination of analysis will give us and MCC BPTP all the important pieces to fully examine and determine screening test results. According to a recent study on the potential of saliva-based testing to detect HPV-16-Oropharyngeal and oral cancers good inter-rater agreement ($k = 0.612$) was found between tumor p16 expression and oral HPV-16 infection in OPC. (9)

Evidence Basis:

To begin we would like to acknowledge, this saliva rinse screening program, while backed by many journal articles that support it and acknowledge its value, has yet to be widely implemented in the United States due to a lack of overall knowledge about the screening and the necessity of it. There is promise that it will be more widely used and become an actual evidence-based screening in the near future. This screening does have immense value in the oncology world as an early identifier of these HPV-16 cancer markers, which can help to diagnose HPV positive head and neck cancers in initial stages, instead of later when it has worsened and spread. On this basis, we propose using this screening tool in

hopes that it will increase screening for the population of focus and raise awareness about this specific type of cancer.

In a meta-analysis done on the association of Salivary HPV infection and Oral and Oropharyngeal Cancer it was found that there was a significant association between the presence of salivary HPV and oral and oropharyngeal cancers and proved the value of HPV detected in saliva as a strong predictive indicator. (6) In a study done evaluating HPV status in oral exfoliated cells, oral rinses were collected from 93 patients and 205 controls. It found that there was a significantly increased risk (OR= 3.70) of cancer in positive oral HPV patients regardless of any alcohol or tobacco use (7). Oncogenic oral HPV infection has recently been shown to be a precursor to malignancy and as such could potentially be used as a biomarker to diagnose, monitor disease progression, and tumor recurrence of squamous cell carcinoma of the head and neck.(8) This screening test will likely be well accepted by our target population as “the detection of HPV in oral exfoliated cells from saliva (with oral rinses) represents a quick and easy non-invasive alternative for oral and oropharyngeal cancer screening in high-risk populations” (6) Finally, accumulating evidence indicates a strong association between persistent high-risk HPV infections and the development of HPV-driven malignancies. (12) This is further supported by further research that prospectively demonstrated a positive association between HPV infection and oropharyngeal malignancies. (13) Moreover, it has been reported that presence of HPV-specific antibodies were detected well before the development of oropharyngeal squamous cell cancer of the head and neck (15) thus further supporting the role of persistent infections in the development of oropharyngeal malignancies. Previous studies have also reported that the HPV DNA in both saliva and tumor tissue samples was positively correlated (16). Together this evidence shows strong support for a saliva-based rinse test to be used as a screening tool to detect HPV-16 markers and thus HPV positive head and neck cancer patients in participants.

The overall study design is cross-sectional as we assess the outcome's prevalence in a broad population during 2023-2026.

Adaptations:

The screening tool, a saliva test widely used to screen for different markers, would not have to be adapted for this intervention. As evidence has shown above, the saliva-based test has been proven to be able to detect P-16 markers that show the presence of HPV. The test itself is non-invasive, as noted above, and low-cost; a producer of the test has each individual unit listed between 2 and 3 dollars. The test will be a quick gathering of saliva from those being screened, a small vial worth. The saliva-rinse screening test will be administered to the population in focus, men ages 45-60 in the Central Kentucky Area. This age group was administered to account for any outliers although any men who may approach mobile clinics and wish to sign up are outside of this age group. They will still be welcomed and their access to screening will not be denied. They will be factored into the data separately as outliers.

This saliva rinse test intervention will be implemented in a mobile clinic setting. This mobile clinic would be set up in specific locations where our target population, not normally able to be as easily reached (men ages 45-60) could be more easily approached. These free screenings will be well publicized through a key partnership with UK Athletics and Local Media (see partnerships and collaboration section) so that the community is well informed about it and their interest is piqued. These mobile clinics would be set up once a month from August to March or April. This leaves most of the summer months (May, June, and July) for training and reevaluations of the program yearly, at midpoint. This also leaves a few months for replenishing staff, supplies, and educational resources if needed.

Implementing this saliva-rinse screening at the mobile clinic will be possible by working with MCC. MCC currently houses multiple screening programs and will be the "headquarters" for this program intervention. Because MCC has years of experience implementing screening programs their existing network will be the primary resource for obtaining and training staff for our program. MCC will

also have resources available for the screening, including existing educational materials and pamphlets about Head and Neck cancers and HPV positive cancers that we will adapt to this specific screening program while maintaining the core information. MCC also houses an array of expertly trained staff of health care and research professionals who know about the science and preparation behind administering oncology screenings and research. Once staff, training, and resources are obtained within Markey it will be time for the implementation staff to take the mobile clinic into the community to recruit participants.

Saliva-rinse mobile screening program Logic Model:

Inputs	Activities	Audience	Outputs	Short-Term Outcomes	Long-Term Outcomes
-Staff -Staff Training -Funding -Printed Materials -Saliva- rinse Screening kits	-Advertising -Participant Recruitment -Saliva-rinse screening test -Post-survey -Follow-up from Nurse or Social Worker on staff (if needed) -Follow-up appointment or establishing care for more screening and or biopsies if needed	-Men in the Central Kentucky Community ages 45-60	-At least 500 individuals a year participating and getting screened for HPV –positive Head and Neck Cancers - More early-stage diagnoses -More discussions and awareness around HPV related HNC	-Higher HPV-related cancer screening rates among the target population in central Kentucky	-Higher screening rates among partners of HPV- positive individuals who were screened -Lower mortality rates among those with HPV positive head and neck cancers

Formative Planning and Readiness

The first 6 months prior to program start-up will be for initial planning and readiness and for a piloting period. The first half of that six-month period will be focused on planning and preparation to roll

out this evidence-based intervention in the Central Kentucky Community. All program staff will go through all required training. Training includes diversity and inclusion training, CITI Training, HIPAA (Health Insurance Portability and Accountability) Training, and REDCap Training. We will also have all staff take a quality improvement course through the MCC CIO office and we will have a training unique to this program where we look at other successful screening programs and campaigns UK and MCC host and apply what has worked in terms of recruitments and maintaining follow-up and referrals to our program. It will be a lunch and learn setting where we are learning from those who have successfully implemented screening programs in the community. We want to take advantage of the plethora of resources available when working under the MCC umbrella. During this time, we will establish a Community Advisory Board (CAB) which will include members from a diverse selection of groups in the Central Kentucky community who can provide a wide range of information and feedback in their areas of expertise. We will ask them to review and give feedback on the adaptations we make to advertisements, program pamphlets and materials that we will adapt to this screening program. This feedback will help us choose words, images, and graphics used and information included in all materials. CAB members will also be asked to hear the screening intro that workers at the mobile clinic will give to participants, and they will also be asked to take the post-test and give feedback on the questions, the number of questions, and the layout. We will have representatives from the community and from cancer screening and prevention programs, and community impact and outreach in cancer care all represented, among others. I will discuss more specific details about the CAB in the Partnerships and Collaboration section. During this planning period, all materials and supplies for the mobile clinic will be obtained, and we will develop the questions set for the post-survey given to participants within 5 days of completing the screening.

Piloting Period

The piloting period will occur in year one. We want to make sure that this Saliva Rinse Screening for HPV-16 markers for HPV Positive Head and Neck Cancers is implemented well, addresses community needs, and is implemented to scale. We will first pilot the intervention three months before its official start in the Lexington community. We will pilot it at the Blue and White scrimmage and at a few smaller-scale UK athletics events such as the women's basketball games and UK baseball or soccer scrimmages. These will serve as a great setting to still reach the same target population, but to also pilot and prepare for real implementation. This pilot period will help us to make sure all gaps are met and to see if any issues arise that we need to troubleshoot.

During the piloting period feedback from participants will be gathered, which is important to make sure this screening program is being implemented well in the community of focus. Those who complete the screening test will receive a post-survey link via email, this is done through the REDCap platform. This post-survey asks specific questions to gather feedback on the setting, staff, and implementation of the intervention. An example of these questions included in the survey is in the appendix. The survey will include a comment box for any comments or concerns they may have. This feedback from real participants in the piloting period will help us make any necessary changes to the program, whether it is editing language used in the survey and in other forms used in the screening to make it more understandable to the general public or a creative suggestion that a participant may have. This feedback will help us to build a version of this program for this specific community. During the piloting period we will meet with key partners and our CAB each week for feedback and suggestions.

Implementation

We want to make sure that this Saliva Rinse Screening for HPV-16 markers for HPV Positive Head and Neck Cancers is implemented well, addresses community needs, and is implemented to scale. We will pilot it at the Blue and White scrimmage and at a few smaller-scale UK athletics events such as the women's basketball games and UK baseball or soccer scrimmages. These will serve as a great setting

to still reach the same target population, but to also pilot and prepare for real implementation. This pilot period will help us to make sure all gaps are met and to see if any issues arise that we need to troubleshoot.

Recruitment

We will recruit participants throughout the community at areas that are frequented by men in the targeted age group. Recruitment for the screening program will take place at Rupp Arena, Kroger Field, outside of University of Kentucky Athletic Events. It will also take place at breweries, gyms, and home improvement stores in the Lexington Community. These locations will be made possible due to community partnerships and partnerships with businesses. Due to the key partnership with UK Athletics the primary focus of the mobile clinic's setup will be UK Basketball and Football games. Our mobile clinics will be set up at Rupp Arena from December through March and at Kroger Field from August through November. Summer is the off season, and this will give us a few months off to evaluate the program in April and May and replenish any staff, if needed and supplies. This is also a time when students who may be helping with the project are home or participating in other programs so staffing will be slightly lower than other months and we want to plan for that.

Each month there will be two mobile clinic set-ups. We will be using former attendance numbers from past athletic seasons to determine which games we should set up the mobile clinics at for highest recruitment. Average attendance of a UK men's basketball game is 20,160 and average attendance for UK men's football games is 53,129, as stated in the Target Population and Need section. The third and final setting of the During months where there are more away games is when we will set up at a brewery or another community establishment during game time.

The mobile clinics will consist of two small tents, tables, 3 healthcare professionals (an oncology trained nurse and 2 clinical research coordinators), all educational materials, swab kits, 3 iPads, and coolers for the collected swabs would comprise the mobile clinic set-up. The set-up of these

mobile clinics at popular sporting events in the community help to reach the specific middle aged male demographic who usually avoid healthcare or clinic settings and make it more casual, comfortable, and easily approachable for our key demographic.

Recruitment materials will be relatable to middle-aged men in Lexington and the surrounding geographical area of Kentucky. Materials will use the tradition of UK basketball and football, and related topics to make the campaign and the subject of HPV positive head and neck cancers more approachable. We will partner with UK athletics to put a mobile clinic/ booth set up outside of all sporting events and the face of our screening campaign would be UK athletic coaches John Calipari and Mark Stoops, both middle-aged men and prominent figures in the Central Kentucky Community. Their faces would be on one of the pamphlets or flyers used for recruitment and to raise awareness and on a short television commercial advertising the campaign that would run locally during UK Athletic Football and Basketball games. These local state sports celebrities are middle aged men who are viewed as "sports heroes" and valued by the community. They have the trust and admiration of our key demographic of focus and with them serving as spokespeople for the campaign will help to make the subject of HPV positive Head and Neck Cancer and screening a more commonly discussed topic among middle-aged men in Central Kentucky and therefore increase interest in, and knowledge of, screening.

Fidelity

To monitor and assure fidelity, a staff member of MCC's Community Impact and Outreach (CIO) Office, the Quality Improvement Research Director will meet with us monthly at the end of recruitment and program periods as we reflect on recruitment numbers, programs statistics including number of participants recruited, number of participants screened, and importantly, participant feedback. This information will be gathered from participant data including the amount of people screened and their demographics, the number of people who attended each event, the number of people who approached the mobile screening tent (a student with the team will be keeping count), and those who got the

screening. All this information will be compiled by the study CRA's using REDCap. We will follow the plan outlined in the GANTT Chart adhering to the schedule of bringing this program to the Central Kentucky community split into three main phases: planning, program implementation, and program evaluation.

The post-survey sent out via email in REDCap includes a few questions for participants to answer in closing about their experience with the screening. This will help us to have real-time feedback and as we track changes, we will know based on participants' feedback after a change if the intended improvement has been made. All entries in REDCap are time stamped and will be divided up into categories based on which phase of the program it is. By having it shown in chronological order we can look at the before and after feedback we got surrounding a change we made in the program and see if it made the changes we were hoping to see in data or got better feedback from participants. We want to be able to track all changes and know when improvements are made and areas that are lacking and may need further improvement. This is the best way for us to track fidelity.

Inclusivity

When it comes to participant inclusion, we want to make sure that our program is available to all middle-aged men in the community regardless of other factors. We will work with the Diversity and Inclusion office at the University of Kentucky. This office will help to review/ develop all materials and educational resources used for the intervention to make sure that the program and all its components are all-inclusive. All staff will also go through diversity and inclusion training during training and pilot phases to make sure implementation is non-stigmatizing. Educational resources and pamphlets will be available in Spanish, as there is a high population of Spanish speakers in the Central Kentucky community. To translate in person conversations, we will use one of the many translators on wheels (translator robots) that MCC has on hand as a resource. It can translate into any language. We would like the two CRAs especially to have done previous work and research in Central Kentucky and

understand the community and its needs well. A member of the Fayette County Health Department will be present during training to give a presentation about the community and its specific needs and resources. We will ask that all materials used in the program are reviewed by an oncologist who specializes in head and neck cancers to ensure that all are medically accurate and subject appropriate. The two CRA's administering the pre-test, short educational intervention, and saliva rinse test will be trained in knowing how to handle any trauma related reactions that might come up from participants.

Maintaining Referrals and Linkages upon results with HPV-16 Markers present

All saliva rinse test results will be uploaded to REDCap under the participant's specific study ID. This information is assigned a study ID to help best protect confidentiality of the participant. If a participant has HPV-16 markers present in their saliva rinse screening and they are positive for HPV, and HPV- positive head and neck cancers. We have specific staff who will follow up with these patients and are trained to do so. Our team has an oncology social worker and oncology specialized nurse who both have experience in patient navigation. These two team members will be trained in relaying the important and sensitive information of screening results with HPV-16 markers present. They will build a partnership with patients, refer them to an oncology head and neck provider at MCC or at an MCC affiliate location near them for follow-up of test results and will also provide them and their family with educational resources and to help them navigate establishing care at these locations. "A questionnaire-based study of patients with HPV positive head and neck cancer treated at a major cancer center revealed significant gaps in patient understanding of HPV's contribution to their cancer, transmission of the virus, and potential precautions. Over one-third of patients in this study wished they received more information about HPV for caregivers. (5) Counseling from our team social worker and oncology specialized nurse should address all major areas of the patient and the patient's family's concerns and help them navigate establishing care with a provider even after referring them. They will be prepared to

answer questions about HPV biology, HPV transmission and transmissibility, impact on prognosis and treatment planning and post-diagnosis harm reduction. (5)

The partnership with MCC gives these participants with HPV positive head and neck cancer results in a direct tie to providers at MCC and access to these resources that otherwise may not be available. This linkage provides a fantastic opportunity for more cancer prevention in the community because it gives the social worker and nurse an opportunity to contact the positive participant's partner or partners and offer resources and help them to get HPV oncology related screenings as well.

Follow-up call

After relaying screening results to participants with HPV-16 markers present the Social Worker and RN on staff will follow-up with those participants who had positive results to see how the referral process is coming along and if they need assistance with anything. During this call, the RN and social worker will fill out a redcap form to track the referral and will be confirming if the participant was able to follow-up or is scheduled to follow-up about their results at MCC or an MCC network affiliate.

Sustainability

This program is extremely sustainable thanks to implementing this program at the University of Kentucky, under the UK Research umbrella. Being a part of this UK network offers many free resources such as help with biostatistics, a lab to process the saliva rinse tests, and graphic design assistance with advertising materials, among many other things. This helps our program save a lot of money. After federal funding ends, we want to make sure that we can keep our screening program operating and serving middle-aged men in Lexington. The first thing we will do is partner with The American Cancer Society (ACS) and the Head and Neck Cancer Alliance for funding and support. To make the program more cost-efficient staffing and materials wise in the years that federal funding runs out we will operate only in the months when we had highest recruitment in the past, we will base this on recruitment numbers from the three years before and alter materials and mobile clinic set-up from this data.

Follow-up and Retention

For follow-up and retention of patients we would send out a long-term follow-up email via REDCap yearly that contains information for where free screening will be available in their community within the next month so timing will be important when sending these out and that aspect will be scheduled by REDCap. A calendar tool will be linked along with the follow up survey where patients can easily and conveniently give feedback about community needs and attitudes about. Since this survey is only sent to them for a couple of years for more long-term follow up, we would send a reminder text message or email (whatever is proven to work best with this age group) With a reminder to schedule another screening. Text message reminders are a very efficient way to do this, and it is a tool that is cost efficient because it can be automated.

Performance Measures and Evaluation

Performance measures are vital to make sure that the saliva-rinse screening program is effective and successful, but they also serve to track the fidelity of the program. Knowing the participant counts and demographics and satisfaction rates of those participants are some of the most important measures to help us understand if we are reaching the population we need to be and if we are making a difference. These measures and feedback help us to determine what is working well in this program and what needs to be changed or improved. All performance measures will be collected and recorded by the program team members after every mobile clinic implementation, which will be bi-monthly. The main performance measure data we are collecting is the saliva-rinse screening participation, the results of the saliva-rinse screening tests, and participants satisfaction with the screening. We will measure participation of the screening program by enrollment data, stored in a RedCap and in a secure, linkblue-protected excel sheet. This sheet and the RedCap forms will be accessible by MCC BPTP and the program staff so that the team is able to upload saliva rinse results to these forms securely. We will measure the

participants' opinion of the screening via a post-survey RedCap form that will be sent out via email 5 days after the screening took place.

This performance measure data will help us to understand how successful recruitment for the screening program was in this specific community of focus, Central Kentucky. We also want to know if we are reaching our key demographic of middle-aged males in the community and if we are creating a positive increase in screening rates of HPV positive head and neck cancers. Enrollment information is recorded in real-time and screening results and post-survey which once processed or received must be uploaded/ sent out within 5 days by the BPTP (test results uploaded onto secure excel sheet) and the CRA's working on our team (entry of results in RedCap from Excel sheet). The exact turnaround in the 5-day period will be dependent on BPTP workload at the time and the recruitment numbers from that mobile clinic and on participant response time completing the post-survey. Redcap will send a reminder email every couple of days for two weeks following the post-survey email is sent out reminding them, until the post-survey is completed. Each participant will be assigned a number starting at 1 in an excel sheet one OneDrive that the entire staff and the MCC BPTP team have access to. This excel sheet is only able to be opened by invitation and accessed with linkblue username and password. The number assigned in the excel sheet will be their participant ID which will be linked to all demographic information collected about them and their pre and posttest answers in RedCap. We will create reports for all data in RedCap after we have received post-survey responses from at least 85% of participants. RedCap will send out reminders until the post-survey is completed to prompt the participants. We predict some participants will be lost to follow up and we will factor that into our reports and data. Saliva-rinse screening tests will be processed by Markey BPTP and uploaded onto the shared excel sheet and into the RedCap database. This information is vital because it is used by the Social Worker and RN on our team to make patient referrals and relay results to them. The main performance measure data we are collecting is: Did the participant complete the saliva-rinse test, was the test positive or negative,

and lastly were the participants satisfied with the screening process. We will collect and organize all this data using both our excel form and the Redcap forms we have created in the Redcap database. This will keep all data organized and easily available to review and monitor for accuracy and fidelity.

The following are examples of the performance measures we will be tracking and creating reports in RedCap based on. These reports will help us to do a process evaluation and an outcome evaluation.

Measure	Measure Tracking
Number of participants recruited	Study IDs assigned to each participant-used in REDCap and OnCore
Demographic info of participants recruited	REDCap
Number of participants who completed pre-survey	REDCap
Participants who received saliva rinse screening	REDCap and OnCore
Number of participants with HPV-16 markers detected	REDCap and OnCore
Number of participants who received follow-up and cancer care referral from team members	REDCap form OnCore
Number of participants who completed post-survey	REDCap
Participant satisfaction with the overall screening process	REDCap
Participant satisfaction with the amount of time the screening process took	REDCap
How likely participant is to get the screening the following year	REDCap
How likely participant is to recommend screening to a friend	REDCap
Number of patients who were called for a follow up call (7 days out from initial call)	REDCap
Number of patients who reported that they -followed-up or are scheduled to follow-up with a provider at MCC or a network affiliate location	REDCap and Excel Sheet

Applicant Organization and Key Partners

Applicant Organization

The applicant organization is Markey Cancer Center (MCC) at the University of Kentucky. Markey Cancer Center is the only NCI designated cancer center in the state of Kentucky and is a strong center for

research and innovation. This intervention would not be possible without MCC's resources, network, staff, training, and support. MCC has lots of experience working on screening programs and has successfully implemented many in the Central Kentucky community including: a mobile mammography screening clinic and a mobile melanoma screening clinic.

We will build off the existing infrastructure for these mobile screening programs that will help make this project run seamlessly. MCC will staff the employees for the mobile clinic, including all research staff, RN's (can be CNA's) to provide saliva rinse tests, social workers to help with patient follow-up and linking care educational materials and help with training needs. All staff members from MCC will already have proper healthcare and research study training, which is especially important to the project.

Kentucky Cancer Program (KCP), which falls under the MCC umbrella is a program that operates through a team of Regional Cancer Control Specialists (RCCS) who are residents of the communities they serve and work on bringing increased awareness of cancer prevention and risk factors, increased cancer screenings and early detection measures, and increased access to cancer treatment and care resources to local communities across Kentucky. KCP has implemented many mobile cancer screening programs successfully in Kentucky and knows how to bring a valuable tool to at-risk populations in a community. It would be vital for us to ask for guidance and help from KCP's director and assistant director and more specifically the 3 RCCS who serve the Central Kentucky Community. The individuals, especially the RCCS', have existing relationships within the community that will be imperative to help get the word out and help our mobile screening clinic best reach the population of focus in this area.

MCC will provide access to the biospecimen team who can process all saliva test samples that are brought to them. We will be sure to acknowledge BTSP support of our intervention in all ways to make sure this vital part of the team and process feels recognized and appreciated.

Another resource MCC can provide is access to the Kentucky Cancer Registry (KCR) and their immense database of cancer in Kentucky. A KCR representative will be a part of our CAB and will do data visualization for our team and provide valuable insights and data on risk factors, cancer rates, and screening rates cancer in Central Kentucky broken down by population.

MCC's Affiliate Network (MCCAN) is comprised of cancer centers across Kentucky. When the social workers on the team are following up with a patient whose saliva rinse test comes back positive for HPV and P16 linkages and they refer them to Markey Cancer Center they may want to refer some of the patients to an affiliate network site depending on how far away they are located and the resources they have related to access. We want to be sure that patients with positive results get the care they need. This is vital as it helps us bring participants care to where they are, both in follow-up and in the future. As stated earlier, one of the biggest barriers to care in many regions of Kentucky is access so this will be especially important.

Overall, we will work with the existing infrastructure, research processes, and training that MCC has already established as all have been proven to be effective in the Central Kentucky community.

Groups within the Applicant Organization that will be a key part of this project:

- Biospecimen Team
- MCCAN
- KCP East Central Kentucky
- KCR
- UK RCO office
- MCC Community Impact and Outreach Office

Key Partnership

The key partner in this intervention is UK Athletics, a renowned university athletics program that is well-known not only in the state, but nationwide and is held in esteemed view by the Central Kentucky community. Their cooperation and partnership are imperative to the success of this intervention, not only because our mobile clinics will be set up in UK Athletics spaces during UK Football

and Basketball games, but also because of the reach and resources the UK Athletics marketing and advertising team has. They will help with printed advertisements, signage at the mobile clinics, and media advertisements. We want to utilize the great advertising resources their team possesses as we get the word out about this free screening program. Our team will work closely with their director and assistant director of key partnerships on all advertising needs and their events manager to help coordinate the mobile clinic set-ups. The University of Kentucky Athletics program prides itself on serving its community and its community involvement in critical issues, so it is important that they serve. We will also work closely with UK Athletics UK Healthcare Representative. UK Healthcare and UK Athletics often team up to support important healthcare causes in the community and MCC and UK Athletics have joined forces in the past to raise funds and awareness for breast cancer during the yearly pink meet for UK Gymnastics and this program would ask for similar resources and support. This screening program will be another important part of serving their local Lexington community that they can support and collaborate on.

Our key demographic is middle-aged men in Central Kentucky and what better way to impactfully reach this population than through an advertising campaign focused on the UK Football and Basketball teams and backed by Celebrity Spokesmen in Central Kentucky, Kentucky, and beyond: UK Head Basketball coach John Calipari, and UK Head Football coach Mark Stoops. Both men fall in the age demographic we are trying to reach themselves, have a large social media and radio presence with their own weekly radio talk shows. Studies show having a celebrity representative. We are incentivizing participants with a raffle for prizes including many that will be donated by UK Athletics including autographed items, gear, and tickets to increase participation.

Community Advisory Board:

Our Community Advisory Board (CAB) will consist of fourteen representatives from key stakeholder groups/ partners. This Advisory board will offer invaluable advice about our evidence-based program and its implementation in their community. The CAB will meet monthly to discuss program progress. Our CAB is a diverse group of both traditional and non-traditional partners, and that mix will provide the greatest insights and unique perspectives on how we can best implement our evidence-based program in the Central Kentucky community. These Members include:

CAB Member	Explanation
A Representative from Lexington Fayette County Health Department	This is a community partner, important in measuring and understanding community needs. We need support and feedback from this entity to successfully implement a health-outcome based intervention in Central Kentucky.
Mayor's office representative	We want to keep the local city government on this public health improvement project taking place in the community.
2 Representatives from UK Athletics	These two individuals will represent our main partnership, UK Athletics. One representative will be from the Operations and Events office while the other will be from the Advertising and PR team at UK Athletics. They help us work out the locations and coordination of the mobile clinic set up at UK Athletics Events. This representative will also help us coordinate our face of the program campaign featuring cameo appearances from UK coaches Calipari and Stoops and help us to effectively get the word out about the mobile screening.
4 Middle-Aged Male in from Central Kentucky Community	These individuals will give valuable feedback throughout the process as we figure out the best way to connect with and recruit our key demographic of middle-aged men in Central Kentucky to our program and how to assure retention.
KCP East Representative	A Cancer Regional Control Specialist (RCCS) More specifically from the bluegrass Central Region. This individual is already established in the Central Kentucky Community as a trustworthy cancer care resource and connection. They can help to get the community interested and help us design recruitment and retention strategies that work in that community.
2 Former MCC HPV+ HNC patient	This representative will help guide and shape our referral program for HPV HNC positive patients.
Representative from MCC screening program	His representative can give valuable input and offer resources that MCC has created from existing screening programs

Representative from MCCANN	This representative will help us as we discuss and make changes to our referral process for participants with positive tests. This program is well versed in marketing cancer research, screening programs, and care to the community members of Kentucky.
Representative from MCC Community Impact and Outreach Office	This representative will help to link our team with any services within Markey we may need for support. This individual will also take the data we get from KCR and help us best communicate our data and conclusions to this community.

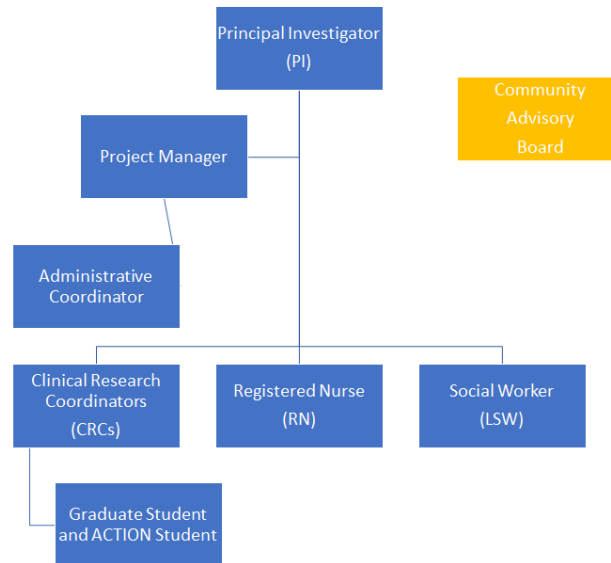
Project Management

Each staff member will have a well-defined and unique role and all staff will complete all required training before we start implementing this evidence-based program in the Central Kentucky community. We will set guidelines for clear team expectations and open communication that makes this team a place where collaboration thrives. The team will meet with collaborators and our CAB once every two weeks and as an independent team once a week. The Primary Investigator and Program Manager will meet once a week to make sure all aspects of the program are on track and in accordance with the GANTT Chart. The entire team will meet with the Program Manager and Primary Investigator once a week at another time to work through all important tasks and to make sure the project stays on track with the timeline. To monitor the program's progress and ensure we are following the timeline, we will have a team planner page set up for staff of the Microsoft Teams platform. This platform creates a team planner with all necessary tasks assigned to staff members in a timeline layout. It will be reviewed at weekly staff meetings. In dedication to making sure our evidence-based saliva rinse test screening program meets its expected goals and outcomes we will follow a strict timeline and maintain frequent quality assurance reviews to make sure data and measures are high quality. This will also help our team to identify any challenges or barriers early on and address them. As we recruit staff members for this program, we look to specifically recruit candidates who have worked in oncology and with oncology

screening programs. It is also important that all staff be familiar with the Central Kentucky community, its needs, and the existing resources available, especially those offered within MCC.

Potential Challenges:

There are a few potential challenges that could arise when implementing this evidence-based saliva rinse screening. Most of the challenges that are expected are with follow-up and initial recruitment of this population. Although this mobile screening clinic is being presented in a non-invasive way in an approachable setting, we are targeting a population that is less likely than their female counterparts to get cancer screenings and attend annual checkups with their primary physician, dentist, and other providers. This challenge will be addressed by advertising that this screening is quick and non-invasive and by setting up mobile screening clinics in more casual and approachable settings for this population at UK Athletic Events, where they will already be in attendance. When it comes to potential challenges with follow up, this is a challenge all studies must be prepared for. It has been accounted that around 30 percent of participants may be lost to follow up, but REDCap features such as reminder emails that are sent out automatically until post-surveys are complete and follow-up calls with participants who had P16 markers present will be utilized. The hope is that these measures will increase the likelihood of follow-up from participants and therefore better data.



UK Athletics Partner, Director, and Assistant Director of Key Partnerships: The Director and Assistant Director of Key Partnerships for UK Athletics and their cooperation and partnership are imperative to the success of this intervention, not only because our mobile clinics will be set up in UK Athletics spaces during UK Football and Basketball games, but also because of the reach and resources the UK Athletics marketing and advertising team has. They will help with printed advertisements, signage at the mobile clinics, and media advertisements.

Primary Investigator (PI), MD, MPH (Master of Public Health): The PI will be responsible for monitoring the overall screening program and to be sure it is meeting all quality assurance and community needs. The PI will have both a medical background and a public health background through both MD and MPH. The PI will make sure that the program is being implemented according to the plan and timeline displayed in the GANTT chart. Since the PI cannot devote a huge amount of time to this specific project most of the responsibility will fall on the Project Manager.

Program Manager, MPH: The Program Manager will be responsible for the day-to-day and all operations of the screening program. The Program Manager will have effective communication and leadership skills and will lead team meetings, make sure all staff is professionally trained, they will oversee creating the

excel form of all project activity and the excel form where all participants are entered, and data is updated. The Program Manager will handle collaborations and partnerships with all partners. The Program Manager will also run the process and outcome evaluations to be sure that the program is meeting its goals and serving the community well.

Licensed Social Worker (LSW), MSW: This staff member's primary role will be to follow up with and inform participants who have HPV positive markers detected and have positive results. This social worker will have experience working with oncology patients and will have a vast knowledge of the resources available to these patients. The LSW will work closely with the RN and will send the participant information along to the RN so that she can set up the referral. The LSW will also make follow-up calls to patients referred to MCC or MCC affiliate providers 7 days after the referral and initial call, relaying any positive screening results.

Registered Nurse (RN), BSN, OCN: The RN on the team will be an oncology certified nurse who has worked with screening interventions at MCC in the past. The RN will be a key connection for participants who receive HPV positive results. The RN will have an established relationship with head and neck cancer providers and their teams at MCC and at MCC affiliate sites. The RN will oversee all positive patient referrals to establish further screening and treatment with providers in their area. The RN will work hand in hand with the LSW and both will also make follow-up calls to the patients who have been referred to MCC or MCC affiliate providers 7 days after the referral and initial call relaying positive screening results. This is to assure that screening participants have been able to establish care and help with any issues that may arise with navigating that process.

Clinical Research Coordinators (CRC), BS: There will be two CRCs on the team, and they will be an important part of implementing and maintaining the screening program. The CRCs will help to set up the physical mobile clinic. They will be responsible for recruiting patients and enrolling all patients in real-time using iPad (or paper copies if needed). The CRCs will be responsible for making sure each

participant receives a proper participant ID in the study excel sheet. They will constantly monitor this sheet to make changes and add data entries as they receive them. The CRCs will be responsible for making sure the patient fills out all the pre-test questions in the RedCap survey form on the iPad and will be there to answer any questions the participants might have about the screening. The CRCs will then administer the short educational intervention and the saliva rinse screening. Both CRCs will have to have sharp problem-solving skills and be well trained in how to administer the educational intervention and saliva-rinse test in a thorough, but timely manner.

Administrative Coordinator, BA: The Administrative Coordinator will schedule and coordinate all team meetings and handle all paperwork related to program funding. This administrative coordinator will order supplies and ensure the project adheres to the proposed budget.

Our team is passionate about connecting staff members with professional development opportunities. We will make sure these are available in every year of the program, as training and growth are continuous. Because of the great benefits and work environment we can offer our team under the MCC and UK systems we expect low turnover rates. MCC has been proven to have high retention rates of employees. Performance evaluations will take place twice a year and during this time staff are encouraged to bring up any issues they may have or anything they may be struggling with as a part of their work. This is a rigorous screening program so we will discuss burn-out and well-being during our weekly meetings. We will connect them with all work-life wellbeing resources that UK offers for employees as it can be emotionally taxing to work in the field of oncology, we want to make sure they are easily able to access counseling or other resources that help them to feel their best both in and out of the workplace. Employee wellbeing is a top priority for our team.

Budget:

For this grant, we are asking for 1,217,235 dollars to fund the grant over three years (from April 2023 - April 2026). Our program's proposed reach is 500-550 participants every year. The majority of the

funding will go to paying the salary and fringe benefits for all staff members on the research study team. When creating this budget, we referred to the UK Research Office Budget Preparation Plan (17).

Personnel and Fringe Benefits:

This portion of the budget will take most funding because staffing is the most important part of our evidence-based screening program. We want to cut down on staff turnover and to help with that we want to make sure we are paying all staff members fairly and including competitive benefits. There is a budget chart below that shows the breakdown of paying for our specific personnel and their fringe benefits based on their time percentage put into the program. Staff salaries increase by 3% every year, in accordance with UK and MCC guidelines. We also factored in fringe benefits following UK budget guidelines and that comes in at 22 percent. These fringe benefits help to make the job more competitive and decrease staff turnover as much as possible.

Travel:

Through working under the MCC umbrella, our staff members will have access to many training resources and training for free, which will save us a lot of money in the budget and help with financial sustainability of the program. Aside from that, to make sure that the team is at the forefront of research program/ project management and quality assurance and want to set aside funding to ensure that the program director and other key staff members can travel to regional trainings. Our Program Manager will attend yearly training specifically for program management and we have allotted \$2,000 a year and 6,000 total over three years. In years 2 and 3 of the program our 2 CRAs and the Program Manager will travel to Atlanta, Georgia for a Regional Annual training centered around screening programs. Additional training funding will be set aside to send 3 staff on this two-day regional training. This portion of the budget will be \$16,000 over 3 years to cover training program fees and related travel costs.

Supplies:

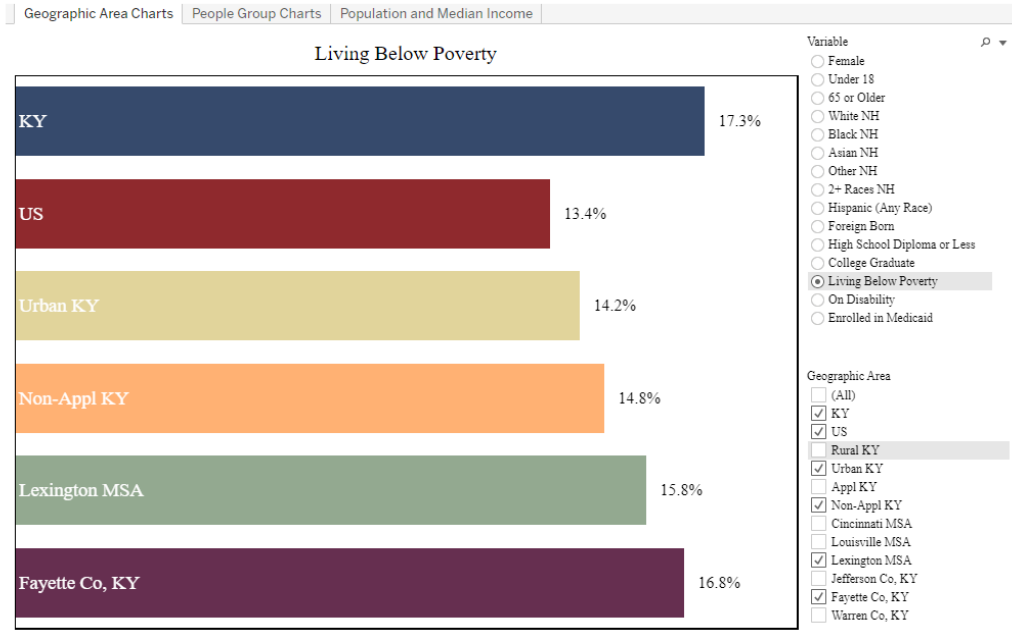
Another positive when it comes to sustainability of the program is that the supplies needed are low cost and the most expensive of those items will only have to be bought once, such as the iPads, although we added in the cost of an extra to serve as a replacement if needed by year three. The estimation of supplies needed yearly was based on the target goal of recruiting around 500-550 participants yearly. Most of these supplies including the saliva rinse tests for screening, the mini water bottles participants use to rinse their mouths, napkins, and educational pamphlets are single-use and will have to be replaced every time so we will purchase one for every single expected participant and we added 50 more of each to the total as a buffer for any lost or damaged supplies or higher than expected recruitment. The coolers will be replaced every year to account for damage. The total allowance for supplies, over three years, is \$8,821.

Other:

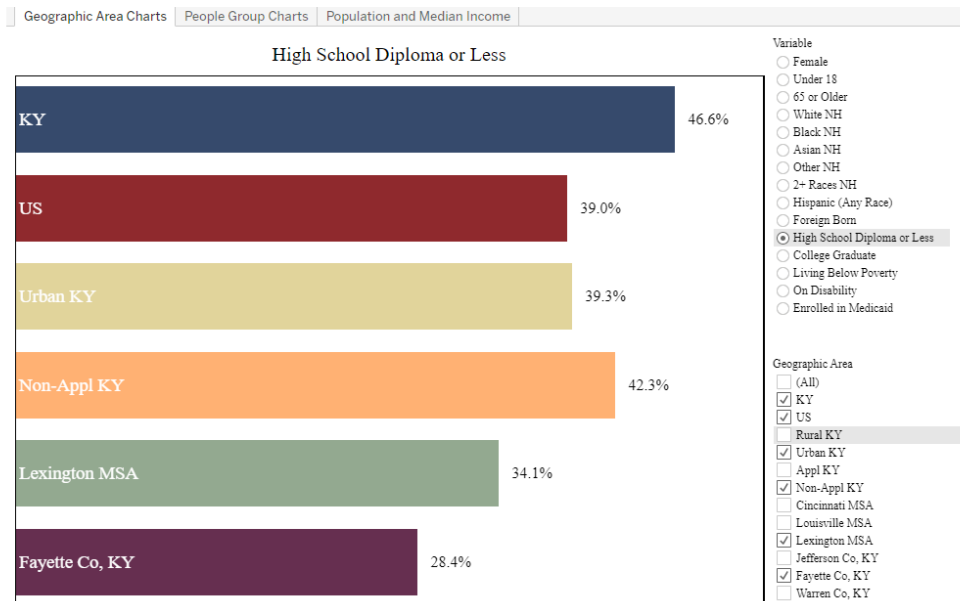
Another positive aspect of working under the MCC umbrella is that we will not need to contract out any services and therefore will not have any contractual fees. We will not have to pay for the processing of the specimens from the saliva rinse tests because MCC BTP (Biospecimen Processing and Tissue Procurement) will help our team by using their lab and machinery to process the specimens. In exchange we will make sure we acknowledge and give recognition to the BTP group. We will also receive lots of help from the Kentucky Cancer Registry team with specific data visualization needs our program may have. Under the other category of our budget, we factored in the costs for a monthly raffle prize for participants. This raffle prize will be worth \$50, and we will draw for these twice a month after each mobile clinic is set up. These raffle prizes will be related to UK athletics or the breweries/businesses we set up outside of. These raffle prizes will be used to incentivize participants to fill out the post-survey they receive via email. Once it is filled out, they are entered in a raffle to win a raffle prize. The total allotment for this portion of the budget is \$2,700 over the 3-year grant period.

Appendix:

Social Determinants of Health (SDOH)



Social Determinants of Health (SDOH)



Sources

1. Page, Fletcher. "Kentucky Men's Basketball Once Again No. 1 in Home Attendance." *Journal, Courier Journal*, 8 Aug. 2017, www.courier-journal.com/story/sports/college/kentucky/2017/08/08/kentucky-mens-basketball-once-again-no-1-home-attendance/550403001/.

2. "Heads up on Head and Neck Cancers." *UK HealthCare*, ukhealthcare.uky.edu/wellness-community/blog/heads-head-neck-cancers.

3. *ASSESSMENT & IMPROVEMENT PLAN - Lexington*. 2018, www.lfchd.org/wp-content/uploads/2018/04/CHA-CHIP-2017.pdf.

4. Wan, Yunxia et al. "Salivary miRNA panel to detect HPV-positive and HPV-negative head and neck cancer patients." *Oncotarget* vol. 8,59 99990-100001. 10 Oct. 2017, doi:10.18632/oncotarget.21725

5. Finnigan, John P Jr, and Andrew G Sikora. "Counseling the patient with potentially HPV-related newly diagnosed head and neck cancer." *Current oncology reports* vol. 16,3 (2014): 375. doi:10.1007/s11912-013-0375-8

6. Evers, Mark B, et al. *Human Papillomavirus (HPV) Vaccination in Kentucky: An ...* ukhealthcare.uky.edu/sites/default/files/hpv-es-report-final-november-28-2016.pdf.

7. Rapado-González, Óscar et al. "Association of Salivary Human Papillomavirus Infection and Oral and Oropharyngeal Cancer: A Meta-Analysis." *Journal of Clinical Medicine* 9.5 (2020): 1305. *Crossref*. Web.

8. Mourad, Moustafa et al. "Epidemiological Trends of Head and Neck Cancer in the United States: A SEER Population Study." *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons* vol. 75,12 (2017): 2562-2572. doi:10.1016/j.joms.2017.05.008

9. Smith, Elaine M., et al. "Human papillomavirus and risk of oral cancer." *The laryngoscope* 108.7 (1998): 1098-1103.

10. Tang, Kai D et al. "Oral HPV16 DNA as a screening tool to detect early oropharyngeal squamous cell carcinoma." *Cancer science* vol. 111,10 (2020): 3854-3861. doi:10.1111/cas.14585

11. Tang, Kai Dun et al. "Unlocking the Potential of Saliva-Based Test to Detect HPV-16-Driven Oropharyngeal Cancer." *Cancers* vol. 11,4 473. 3 Apr. 2019, doi:10.3390/cancers11040473

12. Chai, Ryan C et al. "A pilot study to compare the detection of HPV-16 biomarkers in salivary oral rinses with tumour p16(INK4a) expression in head and neck squamous cell carcinoma patients." *BMC cancer* vol. 16 178. 3 Mar. 2016, doi:10.1186/s12885-016-2217-1

13. "HPV-Associated Oropharyngeal Cancer Rates by Race and Ethnicity." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 3 Sept. 2020, www.cdc.gov/cancer/hpv/statistics/headneck.htm.

14. Agalliu, Ilir et al. "Associations of Oral α -, β -, and γ -Human Papillomavirus Types With Risk of Incident Head and Neck Cancer." *JAMA oncology* vol. 2,5 (2016): 599-606. doi:10.1001/jamaoncol.2015.5504

15. Kreimer, Aimée R et al. "Evaluation of human papillomavirus antibodies and risk of subsequent head and neck cancer." *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* vol. 31,21 (2013): 2708-15. doi:10.1200/JCO.2012.47.2738

16. Tang, Kai Dun et al. "High-risk human papillomavirus detection in oropharyngeal cancers: Comparison of saliva sampling methods." *Head & neck* vol. 41,5 (2019): 1484-1489. doi:10.1002/hed.25578

17. Tang, Kai Dun et al. "An Occult HPV-Driven Oropharyngeal Squamous Cell Carcinoma Discovered Through a Saliva Test." *Frontiers in oncology* vol. 10 408. 31 Mar. 2020, doi:10.3389/fonc.2020.00408

18. *UK Facilities Description Library Log in Page*, ris.uky.edu/pdo/reflib/PIView.aspx.

19. "Budget Preparation." *Budget Preparation | University of Kentucky Research*, www.research.uky.edu/office-sponsored-projects-administration/budget-preparation.

20. Pbrock. "NCAA Men's Basketball Attendance." *NCAA.org - The Official Site of the NCAA*, 17 Aug. 2020, www.ncaa.org/championships/statistics/ncaa-mens-basketball-attendance.

21. Pbrock. "NCAA Football Attendance." *NCAA.org - The Official Site of the NCAA*, 9 Apr. 2020, www.ncaa.org/championships/statistics/ncaa-football-attendance.

22. Martín-Hernán, Fátima et al. "Oral cancer, HPV infection and evidence of sexual transmission." *Medicina oral, patología oral y cirugía bucal* vol. 18,3 e439-44. 1 May. 2013, doi:10.4317/medoral.18419

Figures:

Figure 1.1 - https://www.researchgate.net/figure/Age-adjusted-incidence-rates-for-human-papillomavirus-HPV-associated-cancers-in-the_fig2_234086813

Figure 1.3- Rapado-González, Óscar et al. "Association of Salivary Human Papillomavirus Infection and Oral and Oropharyngeal Cancer: A Meta-Analysis." *Journal of Clinical Medicine* 9.5 (2020): 1305. Crossref. Web.