# Increasing Human Papillomavirus (HPV) Anal Cancer Screening with Multimodal Patient Education in a LGBTQ+/HIV Clinic

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#### Abstract

**Background:** Research indicates that lesbian, gay, bisexual, transgender, and queer plus (LGBTQ+) individuals are approximately 25% less likely to pursue preventative cancer screenings compared to their cisgender or heterosexual counterparts. Human immunodeficiency virus (HIV) disproportionately impacts LGBTQ+ individuals, particularly those who are transgender or men who have sex with men (MSM). Immunodeficient patients, like HIV+ persons, face elevated risks of HPV-related cancers. These reasons emphasize the importance of offering HPV cancer screenings to eligible HIV+ and/or at-risk LGBTQ+ persons. **Methods:** The Plan-Do-Study-Act model was utilized for this quality improvement (QI) project. Baseline data included the number of current established patients and their general demographics (gender, HIV status, age) and the number of completed HPV anal pap tests within the year prior to the intervention. These numbers were also reviewed following the intervention. A literature review was conducted to identify specific population concerns and educational methods for implementation.

**Intervention:** Three patient education pieces were created: a simplified flyer or promo for social media, an informational one-pager for physical posters, and a detailed slide-based presentation with voiceover. An anonymous patient survey was provided for completion by individuals undergoing pap testing to evaluate the effectiveness of the intervention materials.

**Results:** In 2023, the clinic reported zero anal pap tests. After the implementation of the intervention, two anal pap tests were completed, with a third occurring after the implementation period. Patients reported doing so because of the education modalities.

**Conclusion:** Multimodal patient education has the potential to increase HPV anal cancer screening rates.

*Keywords:* LGBTQ, HIV, HPV, anal cancer, anal dysplasia, quality improvement, multimodal education

# Increasing Human Papillomavirus (HPV) Anal Cancer Screening with Multimodal Patient Education in a LGBTQ+/HIV Clinic

The National Cancer Institute and the Institute of Medicine have designated patients in the LGBTQ+ community as a medically underserved population (Nelson et al., 2023; Nisly et al., 2018). As of 2022, 17% of American adults under the age of thirty identify as lesbian, gay or bisexual with about 8% of 30-49 year olds identifying as such (Brown, 2023). Approximately 1.6% of the United States (U.S.) adult population identifies as transgender or nonbinary (Brown, 2023). The LGBTQ+ community has been and continues to be inordinately impacted by the HIV epidemic, especially among MSM and transgender individuals (Human Rights Campaign, 2017).

Persons within the LGBTQ+ community and those with HIV face complex barriers when attempting to access healthcare services. Societal judgment and potential embarrassment increase their hesitancy towards pursuing conventional healthcare options and preventive health screenings (Drysdale et al., 2020; Nair et al., 2021). There are also significant cancer disparities within the LGBTQ+ population due to the population's diverse make-up and risk factors combined with systemic barriers (Nelson et al., 2023). Immunodeficient patients, like those living with HIV, are at increased risk for cancers related to HPV especially if they have had any previous positive HPV tests (Peitzmeier, 2013). Among other important preventative health recommendations, HPV cancer screenings should be offered to all eligible HIV+ and LGBTQ+ individuals according to current evidence-based guidelines and with shared decision making concerning the patient's unique sexual history and risk profile.

#### Significance

HPV is a double-stranded DNA virus primarily transmitted through sexual contact. This virus can lead to benign disease as well as precancerous and malignant lesions in multiple areas of the body including the oropharynx and anogenital regions (Otter et al., 2019). As HPV can be asymptomatic or challenging to visualize, individuals usually acquire HPV inadvertently.

Approximately 85% of Americans will be infected with at least one form of HPV within their lifetime (Hirsch et al., 2022). According to the CDC (2023), over 37,000 new cases of HPV-related cancers are diagnosed every year, with 91% of cancers in the cervix and anus resulting from HPV infection. In higher-income countries like the U.S., anal cancers caused by HPV are growing in incidence with some areas and populations surpassing cervical cancer rates (Hirsch et al., 2022). HPV can be transmitted through various contact pathways meaning that all forms of partnerships, no matter the gender identities or sexual orientations of the individuals, can lead to HPV transmission and infection: female-to-male, male-to-male, and female-to-female (McNamara & Ng, 2016).

The prevalence of anal cancer has been increasing for several years, with a higher incidence in patients living with HIV. An estimated 6,500 new cases of HPV-based anal cancers are diagnosed in the U.S. each year (Bucher et al., 2019). Patients with a history of genital cancers, people who participate in receptive anal intercourse or play, and individuals with chronic HPV infection have been found to have the greatest risk for developing HPV anal cancer (Bucher et al., 2019). According to Wieland and Kreuter (2019), females with a history of cervical HPV, especially HPV16, are at an increased risk of also having anal HPV-associated high-grade squamous intraepithelial lesions (HSIL). Other risk factors include being HIV+ or otherwise immunocompromised (organ transplant recipient), having multiple sex partners, smoking and tobacco use, and being a Caucasian female or Black male (American Cancer Society, 2020). Over 33 percent of patients diagnosed with anal cancer have a life expectancy of five years or less (Wieland & Krueter, 2019).

# **Specific Problem**

The QI project was conducted in a LGBTQ+ inclusive, HIV-centered care clinic in an underserved community in Mid-Michigan. Interprofessional collaboration was utilized to analyze the needs of the practice and the specific population that they serve. After multiple discussions with clinic representatives, the greatest concern was patient adherence to recommended

preventative health and cancer screenings. The clinic manager also shared that the area they noticed the lowest rates of compliance was related to HPV prevention, especially the uptake of HPV vaccination. Clinic data showed that only 14.5% of their established patients are fully vaccinated against HPV. With this low HPV vaccination protection and a high percentage of at-risk HIV+ patients within the clinic population, improving HPV cancer screening is incredibly important to the overall health of the patients and was deemed the most appropriate topic for this QI intervention.

Anal HPV testing was chosen due to the increased risk of HPV anal cancer in HIV+ persons of all genders, as well as due to a lower rate of female patients within the clinic that would require cervical HPV testing within the timeframe of this intervention. A chart review by the clinic liaison revealed that zero individuals had received anal HPV pap testing within the last fiscal year, starting January 2023. Clinic staff also reported personal experiences of numerous patient encounters where anal tests were refused despite provider recommendation and encouragement.

Although the providers are cognizant of the current HPV testing guidelines, a lack of patient understanding and necessity affects the overall screening rates for many health maintenance policies, but especially for HPV. Societal misconceptions concerning the transmission of and risk of HPV are prevalent. Many HIV+ patients are unaware that routine general screening guidelines are not written for their unique needs and that they require more specialized care due to the effects HIV has on their immune system. Other patients within the LGBTQ+ community may feel that screening is not necessary for them based on their sexual practices and a misconception that HPV is only sexually transmitted between certain genders or types of sexual contact (Peitzmeier, 2013).

Available literature supports the need for improved patient education to combat misinformation and misunderstandings concerning HPV testing. As the providers in this clinic work towards an inclusive and gender-affirming practice environment, increasing patient

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education on HPV and recommended screenings for all anatomical sites would help the patient become a more involved and engaged member in the support of their own health and well-being.

## Available Knowledge

Studies have shown that LGBTQ+ individuals are approximately one-quarter less likely to undergo preventative cancer screenings, such as Papanicolaou (pap) testing, when compared to cisgender and heterosexual individuals (Haviland et al., 2020; Nelson et al., 2023). This discrepancy in cancer screening rates is particularly concerning given that the LGBTQ+ population overall experiences elevated malignancy risk and increased risk factors (Nelson et al., 2023). Individuals in the LGBTQ+ community have higher rates of tobacco, alcohol, and other drug use which are known risks for numerous cancers (Haviland et al., 2020; Klein & Nakhai, 2016; Nelson et al., 2023). There is also a higher prevalence of sexually transmitted diseases (STDs) and HIV infection in this population, especially in MSM, homosexual individuals, and transgender persons (Klein & Nakhai, 2016; Leone et al., 2023).

The effects of social determinants of health such as socioeconomic status, employment and financial insecurity, education level, and geographic location are intensified for LGBTQ+ patients leading to further health inequities (Haviland et al., 2020). Fears of discrimination and unwelcoming practice environments may cause some LGBTQ+ individuals to hide their sexual orientation and gender identity (SOGI) information or sexual practices resulting in misinformed screening education and implementation (Compton et al., 2022; Haviland et al., 2020). Sexual and gender minority individuals are at greater risk for cancers caused by HPV due to provider and patient misconceptions concerning the transmission and risks associated with HPV in their population (Drysdale et al., 2020; Haviland et al., 2020; Solazzo et al., 2020). Disparities within the LGBTQ+ and HIV+ communities are often increased due to providers lacking knowledge of these populations' unique screening needs and recommendations, combined with assumption-based communication and insufficient cultural competency (Haviland et al., 2020). For some patients, individual and personal factors are the biggest influence in their decision or ability to pursue a particular screening. Emotional distress and psychosocial reactions negatively affect cervical cancer screening in transmasculine individuals as they battle with gender incongruence. This conflict often leads to elevated concerns surrounding pelvic examination and pap testing as the procedure is required to be performed on a part of their anatomy that does not align with their gender expression (Haviland et al., 2020 & Pietzmeier, 2013). Other individuals within the LGBTQ+ community and those with HIV may have various personal anatomical reasons why they are uncomfortable with HPV screening, especially due to the invasive nature of anal and cervical pap testing.

#### Screening Guidelines

HPV-based cancer prevention and screening is multi-faceted, occurring at many stages throughout a patient's life. HPV vaccination is considered the best preventative measure to protect against HPV infection and the development of HPV cancers. Nationally, less than half of persons within the LGBTQ+ community are fully vaccinated against HPV (Drysdale et al., 2020).

The majority of published universal screening guidelines are based on cisgender individuals, and there are few recommendations that consider the unique needs of transgender patients and other at-risk gender minority persons (Haviland et al., 2020). More specific guidelines need to be considered for people living with HIV due to their increased risk of being immunocompromised and more susceptible to opportunistic infections and conditions. Table 1 summarizes current screening recommendations through Howard Brown Health (Bucher et al., 2019) for HPV-based dysplasias of the cervix and anus. Not included in the table below, the guideline also recommends that HPV pap testing be performed in other high risk groups such as people with a history of cervical/vaginal/vulvar HSIL or cancer and those who have had solid organ transplants. Screening should occur at diagnosis of HSIL or cancer and two to five years post-transplant and then annually for both groups. Table 1:

HPV SCREENING GUIDELINES	CERVICAL	ANAL
GENERAL POPULATION (HIV NEGATIVE)	<30 YEARS OLD - REFLEX HPV TEST IF ABNORMAL CYTOLOGY 30-65 YEARS OLD - CYTOLOGY WITH HPV CO-TEST EVERY 5 YEARS OR CYTOLOGY ALONE EVERY 3 YEARS (USPSTF, 2018)	NO RECOMMENDATION
INDIVIDUALS WHO PARTICIPATE IN ANAL- BASED SEXUAL PRACTICES	NO SPECIFIC RECOMMENDATION	>40 YEARS OLD - DIGITAL ANAL RECTAL EXAMINATION (DARE), ANAL CYTOLOGY, HPV TESTING ANNUALLY (BUCHER ET AL., 2019)
HIV POSITIVE PERSONS	<30 YEARS OLD - REFLEX HPV TEST IF ABNORMAL CYTOLOGY >30 YEARS OLD (LIFELONG) - CYTOLOGY AT DIAGNOSIS AND EVERY 12 MONTHS UNTIL 3 NORMAL TESTS, THEN EVERY 2 YEARS OR CYTOLOGY WITH HPV AT DIAGNOSIS THEN EVERY 3 YEARS (NIH, 2023)	<30 YEARS OLD - ANNUAL DARE >30 YEARS OLD - DARE, ANAL CYTOLOGY, HPV TESTING ANNUALLY (BUCHER ET AL., 2019)

# **Review of Literature**

### **Search Strategy and Selection Criteria**

A literature review was completed using the databases PubMed and CINAHL. Between the two databases, the same search terms were utilized: hpv OR "human papillomavirus" AND cervical OR cancer screen\* AND LGBTQ OR lesbian OR transgender\* OR bisexual\* AND educat\* OR intervent\* OR promot\* OR program\*. Other parameters included the date range 2018-2023 for the most recent literature, Humans as the subjects, and English language articles. This search led to 75 articles in PubMed and 53 in CINAHL.

From the PubMed and CINAHL articles collected as above, duplicates were eliminated first. Articles were then excluded if the country of origin was outside of the U.S., the article was based on HPV vaccination only, or was found to be unrelated to the original search topic. Other articles were excluded upon abstract and text review due to a lack of QI or intervention-based

focus. Some broader articles were retained for background and significance information. The main inclusion criterion was that the article addressed implementation of a specific intervention or mentioned intervention-based ideas. The overarching aim throughout the literature review was to provide patient-centered education modalities to ensure increased preventative screening adherence among specific communities, especially in the LGBTQ+ community and those living with HIV. Thirteen articles were used to guide intervention possibilities within the focused community.

#### Literature Themes

The common themes that emerged throughout the literature regarding HPV screening included the need for increased patient education, increased provider education, and the consideration of provider- versus self-collected HPV test methods.

### **Multimodal Patient Education**

The Community Preventive Services Task Force (CPSTF, 2020) recommends that interventions concerning HPV testing and screening be multimodal including patient involvement and provider contributions (Peitzmeier, 2013). Patient education including pamphlets and brochures, as well as phone and text reminders, were shown to be cost effective, encouraged patient adherence to HPV cancer screening, and increased the rate of screenings overall (CPSTF, 2020). When considering these types of interventions, creating materials that are inclusive and use language tailored to at-risk populations like the LGBTQ+ community, were also found to assist in improving uptake of HPV screenings (Haviland et al., 2020).

# **Provider Education**

Anti-LGBTQ+ stigma and societal biases create barriers to accessing healthcare, with individuals in this group frequently delaying care to avoid the possibility of discrimination. In order for HPV screenings to increase among the LGBTQ+ population, providers need to be educated on the unique health needs of this group. Within the literature review, numerous

studies (see, e.g., Klein et al., 2016 & Nair et al., 2021) discuss the need for improved provider training in culturally affirming care and the importance of establishing a clinical environment that is LGBTQ+ inclusive and non-discriminatory. Haviland et al. (2020) stressed the necessity of educating providers on the proper screening guidelines for persons in the LGBTQ+ community.

#### HPV Self-Swab

Another common intervention within the literature was the implementation of self-swabbing for HPV, including cervical and anal tests (Daponte et al., 2023). According to a study by McNeil et al. (2016), self-collected anal paps are easy for patients to utilize and are effective at screening for anal HPV in HIV+ participants. Another recent study on self-collected anal tests (in Nyitray et al., 2021 & Nyitray et al., 2023) showed that these swabs provided similar sensitivity and specificity to provider-collected tests and are a viable alternative to screening, particularly for individuals who may be uncomfortable with provider-performed testing (Reisner et al., 2018).

#### Rationale

The Model for Improvement was created by the Associates in Process Improvement as a framework to be utilized by organizations to precipitate internal advancement processes (Institute for Healthcare Improvement, n.d.). This framework includes the Plan-Do-Study-Act (PDSA) method which is regularly used in healthcare for QI initiatives and thus was followed for this specific QI project. There are four steps that make up the PDSA cycle: plan, do, study, act.

The "plan" stage involves identifying a problem and developing a solution (Institute for Healthcare Improvement, n.d.). For this project, the plan stage started with completing an analysis of the clinic. The largest concern identified for the clinic regarded HPV screening rates. A thorough literature review was performed identifying current HPV screening guidelines and those who are at highest HPV risk. The literature presented a researched method to improve screening rates: multimodal patient education. With this in mind, detailed and clinic-specific

educational modalities were created detailing those who are at increased risk and explaining why they should have HPV screening completed.

The intervention created in the plan stage is implemented during the "do" phase of the PDSA framework (Institute for Healthcare Improvement, n.d.). An in-person meeting was held with the clinic providers and staff to provide education on the current anal HPV screening guidelines and the patient materials created. Infographics were posted in exam rooms, bathrooms, and the lobby. Additionally, a promo flyer was posted to the clinic's social media page. Anonymous surveys for the patients regarding which educational modality influenced them to get screened was highly encouraged and explained to the staff.

An analysis of the results of the intervention and the impact of the intervention are addressed during the "study" step (Institute for Healthcare Improvement, n.d.). After the 12-week intervention period, the number of anal HPV screenings completed during this timeframe were compared to rates prior to the intervention period. A meeting with a statistician took place to further interpret the data collected.

Lastly, the process is reviewed during the "act" phase, to determine if the intervention needs to be adjusted for better outcomes in the future (AHRQ, 2020). This step consisted of analyzing and addressing whether or not the intervention was successful and if any changes would be necessary to continue the project or for re-implementation in the future at other clinical sites.

#### Goals and Aims

The aim of the QI project was to increase HPV anal screening rates in the HIV-care clinic by providing inclusive and culturally-affirming patient education that improves patient knowledge of HPV and current screening guidelines. The main goal was to empower patients to take active control of their health, by providing them with evidence-based tools to assist in their learning and understanding of current recommended preventative screenings. To achieve the aim and goal, the plan was to implement various modalities of patient-centered education regarding the guidelines for HPV screening, the types of HPV screenings, who should be screened, and why screening is important.

#### Methods

# Context

The medical clinic site for this QI initiative was instituted in 2019 with funding from the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, an act implemented with the ultimate goal of ending the HIV epidemic and providing supportive care to those who are underinsured (HRSA, 2022). In addition to HIV care, the clinic provides inclusive and equitable gender-affirming primary care to promote the well-being of all individuals. With the known disparity that individuals with HIV and the LGBTQ+ community are at greater risk for HPV infection, increasing HPV screening rates among persons at this clinic aligns with the mission and values of the clinic as communicated by the clinic liaison: to provide total care for all patients through education, prevention, treatment, and collaboration with community partners.

Increasing provider education and cultural competency was a strong theme throughout much of the literature when considering HPV screening rates. After completing a clinic visit and discussing the nature of the clinic environment, including their goal of establishing a LGBTQ+ affirming practice, a provider-based educational intervention was judged to be redundant. The providers are familiar with the current recommended HPV anal screening guidelines and believe the greatest need is in patient education and encouragement. To ensure that the staff understood the goal of the project, the QI intervention and educational materials were discussed with clinic medical providers, nurses, medical assistants (MAs), and front desk staff.

Although available research supported the addition of HPV self-swabbing as a viable intervention to improve HPV screening rates among the LGBTQ+ community, this was not a feasible intervention opportunity within the clinic due to the infrastructure and medical director's comfort with this technique.

### Intervention

Patient education materials are considered cost-effective and easy to implement in various practice environments. Using multiple forms of media (e.g. print, electronic, audio) increases the number of individuals reached by the intervention as each patient learns new information in varied ways and comprehends health information differently.

There were numerous possibilities for patient educational methods within the clinic's practice environment. The lobby of the clinic represented a welcoming space with pamphlets of information available, as well as a television with continuous infomercials focused on health and well-being. Within each exam room, an electronic interactive monitor was available to the patient and provider for medical education materials during their wait time or to be used during the visit. This information could also be shared with the patient via email address or by scanning the QR code with their cell phone.

Initial plans for clinic-specific educational opportunities included:

- Clinic social media page promo or video/presentation voiceover
- Clinic website infographic on "patient education" section
- Reminders and education on interactive screens in patient exam rooms
- Lobby television video/presentation voiceover
- Infographic posters in exam rooms and bathrooms
- Pamphlets and hand-outs

Three forms of educational materials were created and offered to the clinic representatives with the intent of displaying them on multiple platforms. The educational materials were implemented as a supplement to the practice's current materials and provided a range of resources for the patients concerning HPV screening guidelines and testing options. The first was a flyer with simplified information and bright colors that intended to draw awareness as a physical poster within the clinic and as a repeated social media post (Appendix A). A more detailed infographic one-pager, formatted with eye-catching colors, included peer reviewed data and statistics utilizing LGBTQ+ inclusive language (Appendix B). This would be placed throughout the clinic as a flyer and then on the clinic's website under their patient education section. The largest educational piece was a slide-based presentation with recorded voiceover explanations to provide patients with more detailed information about HPV screening with easy-to-understand phrases (Appendix C). Slides explained the greater necessity of HPV anal testing, especially in the HIV+ and LGBTQ+ communities, and addressed the ease of the screening. This was included to try to relieve the minds of the patients that may hold back on completing screening due to the perceived uncomfortable or invasive nature of the swab. The presentation was available as a slide presentation or as a timed video with a plan to be displayed on the lobby television, the interactive screens in the patient exam rooms, and the clinic website.

#### **Measures and Analysis**

To identify intervention effectiveness, anal HPV screening metrics were collected before implementation of the educational modalities and 12 weeks after. The assessed population included all patients within the clinic, male and female, above the age of 18. For more specific analysis, the number of established HIV positive patients was also collected, as this is one of the more at-risk groups and a main focus of the clinic's care. De-identified data was collected within HIPAA compliant guidelines and with written approval from the clinic safety officer. Ideally a percentage of patients within the clinic who received anal HPV screening would be available and used for comparison before and after the intervention.

In order to analyze the impact and if the intervention was beneficial, patient feedback and viewing may be helpful in understanding what media attracted the patients and where educational gaps may still exist. A potential source of data would be the viewing numbers from any interactive screens or social media pages. A de-identified, anonymous, and voluntary survey (Appendix D) was created with plans to offer it to patients who received HPV screening to assess the effectiveness of the different forms of the project's educational materials.

## **Ethical Considerations**

The U.S. Food and Drug Administration (FDA) mandates that projects involving human subjects be evaluated and approved by an Institutional Review Board (IRB) to ensure the safety and identity of individuals (FDA, 2019). An essential component of this project was to guarantee that all patient information was protected and kept private. Close collaboration with the clinic safety officer and clinic manager was essential. HIPAA requirements were followed throughout the entire project, and clinic and patient identifying information have been excluded from any and all writing. This project proposal was submitted to Michigan State University's IRB for review on October 27th, 2023 and was deemed "not research", with approval received on November 8th, 2023, before implementation of the QI project (Appendix E).

### Results

## Implementation

The created educational materials were sent to the clinic leaders via email for approval and recommended changes ten days before the planned intervention initiation. On the day of implementation, December 9, 2023, the educational materials were presented in-person to the clinic staff including a play-through and explanation of the slide-based presentation. QI project parameters were discussed at that time, and staff could ask questions about the materials or process. During that meeting, a couple of the providers requested their preference for inclusive language terminology on the infographic and presentation slides. Although the original wording was supported by peer-reviewed research on the topic, the changes were performed and new media versions were established promptly (Compton et al., 2022). The IT representative was given the slide-based presentation files and the infographic to distribute on the clinic's website and exam room interactive screens. With final approval, the infographic one-pager was printed in color by the clinic on  $8-\frac{1}{2}$ " by 11" paper and posted in every patient exam room, the lab, both bathrooms, and the hallway outside the clinic. The social media promo that had been printed to show the staff, was also placed in a couple locations for variety.

The clinic manager created a post on the clinic's social media page using the educational promo on December 14, 2023. While they expressed the intention to repost this information every few weeks, this aspect of the intervention was unfulfilled. Periodic messages were sent to the clinic staff to check in on the intervention and site visits were performed to pick up the completed patient surveys and address any concerns. Despite receiving approval and confirmation of intent, the slide-based presentation did not appear on the intended platforms. Within the small clinic, the person in charge of IT was the only one with access to adjust the website and add information to the exam room interactive screens. Unfortunately they could not be reached for assistance in the matter. In the end, this meant that none of the educational methods were presented on the clinic's website or exam room screens as originally intended which could have potentially been a strong source of patient outreach.

### Outcome

The overall aim of the QI project was to raise awareness of the growing risk of anal cancer and build a better patient understanding of the guidelines for HPV screening in a clinic where a large portion of the patients may be in two at-risk populations: HIV+ and/or LGBTQ+.

As reported by the clinic manager in 2023, there were zero anal pap tests performed at the clinic between January 1 and December 9, 2023. The clinic's patient population at the time of data collection consisted of 106 patients with HIV who were seen regularly within the clinic. Twenty of them were in the 18 to 29-year-old age range, 42 were aged 30 to 44, and 44 were over the age of 45. Gender was not considered for the statistics as all persons with HIV are at risk for HPV infection no matter their assigned gender at birth.

Within the Bucher et al. guidelines (2019), the recommended group that should be screened when considering HIV status alone (not MSM or anal receptive intercourse) would be the HIV+ patients who are over age 30. Within the clinic, 86 established patients were qualified to be screened annually. Following the educational intervention, two eligible patients aged 30 years or older, completed anal pap testing in the month of January 2024 on the 20th and 26th

(Graph 1). These completed tests increased the 0% screening rate from the previous year, 2023, to 2.32%. In March, although the technical intervention period had ended, another patient received HPV anal testing because of the educational flyers that remained in the clinic. That brought the annual screening rate of the HIV+ 30-year-old plus age group up to 3.5% for the year 2024.

# Graph 1:

# HPV Anal Cancer Pap Tests

Total Completed from January 2023 to March 2024



The patient surveys were collected throughout the intervention and at the end of the 12-week period resulting in nine surveys. Unfortunately, none of the surveys correlated with the dates of the two completed screenings and appeared to have been given to patients somewhat randomly, including individuals who did not plan to complete HPV testing in any form. A possible miscommunication may have occurred on the instructions provided to the front desk staff on when to complete the surveys, as they were solely meant for patients undergoing the HPV anal cancer screening that day to assess what influenced their decision to pursue the test. This meant that the surveys were not a reliable measure of what mode of education was most

effective and could not be used for analysis. Despite this barrier, the three patients who completed the anal screening after the intervention verbally reported to the provider that they were influenced by the project's educational materials posted within the clinic.

#### Discussion

#### Summary

With the implementation of patient-focused educational modalities, the HPV screening rate within the small HIV-care clinic, and for the HIV at-risk age group, increased from 0% in 2023 to 3.5% within 3 months of the 2024 year. Due to the relatively inexpensive nature of the educational materials and overall intervention, the QI project has the potential to increase HPV anal cancer screening rates and could be expanded to other areas with little to no changes. Other materials created for the QI project, but ultimately not implemented by the clinic, could also be used by other clinics desiring more detailed patient education or outreach.

#### Interpretation

Due to the complications with the anonymous survey completion, the main data available to associate the intervention with the outcome was based on verbal reports by the patients involved. The clinic manager reported that each of the three patients who completed anal pap tests in 2024 stated that they did so because of the educational materials provided by the QI project. There is the possibility that there could have been a greater increase in screening uptake with materials displayed on more platforms or the addition of repeated promos.

The anticipated outcome of the project was to increase the screening rate within the clinic even by one individual, as the clinic had had zero completed previously. Throughout the research literature, preventative screening rates regularly improved with diverse and multimodal patient-focused and education-based interventions. To have successfully influenced three individuals positively with the QI educational materials can be seen as an accomplishment for the clinic. By adhering to screening guidelines, these patients are proactively managing their

health and increasing the likelihood of detecting potential anal dysplasias early, allowing for prompt treatment before more serious malignancies can develop.

The ease of sustainability of the QI project contributes to the hope of maintaining the educational methods within the clinic in order to continue to impact the patients who visit in the future. As of the first week of April 2024, the infographic flyers were still present throughout the clinic and in the building's entrance hallway. The clinic can utilize the existing educational materials in any form and implement the video presentation if they so choose.

#### **Barriers & Limitations**

The majority of available peer-reviewed literature does not consistently utilize LGBTQ+ affirming language especially in data sets. Gender identities and sexual orientations are usually not differentiated when presenting data, with values most commonly placed in binary gender groups: women/female & men/male. This limited terminology led to difficulty in adapting the evidence-based statistical information to meet the preferences of the clinic providers and be inclusive for the specific patient population, while also ensuring the statistics retained validity.

A limitation addressed early on in the project involved the makeup of the clinic population. The original plan was to address HPV screening for both cervical and anal areas, but since the majority of the clinic population were patients with male anatomy, and in general cervical cancer screening guidelines require less frequent testing, the decision was made to address anal screening only. This brought in an additional challenge of limited national guidelines as well as peer-reviewed methods for improving anal screening specifically.

Timely and reliable communication with the clinic was a limitation at times. Emailing was chosen as the best form of contact by the clinic staff, but some emails took multiple weeks to receive replies or unfortunately went without response. Text messaging with the clinic manager yielded quicker response times, but due to their other clinic responsibilities, turn-around time for data requests and information were often delayed.

Implementation of the intervention materials were impacted by internal clinic barriers including general clinic structure, lack of labor force, and time constraints. The majority of the physical QI intervention implementation was outside of the ability of these authors to control or set-up within the time desired. Updating the clinic website, posting on the social media page, and setting up the exam room interactive screens required the time, effort, and resources of the clinic staff. This facet resulted in some of the interventional methods not being implemented to the fullest extent intended.

Although the intervention was implemented for a continuous 12-week timeframe, the clinic only had trained and licensed providers (MD, DO, or NP) present to perform the HPV tests two days per week. This may have limited the ability for some patients to receive screening depending on their personal lives and preferences. Additionally, this could have influenced the likelihood of verbal recommendations or reminders for screening if, despite provided education, other clinic staff members were hesitant to discuss anal screening with patients. However, there was a benefit in that providers were available on weekends, which may have opened up options for patients who work throughout the week.

#### **Guideline Update Post-Implementation**

In early 2024, the International Anal Neoplasia Society (IANS) released the first international anal cancer screening guideline from worldwide evidence-based research addressing specific at-risk populations (Almada, 2024). This recommendation places vulnerable patients into two risk categories (see Image 1 from Almada, 2024). Risk Category A includes HIV+ persons, patients with a history of vulvar malignancies, solid organ transplantees, MSM, and transgender women. Stier et al. (2024), the main study related to the guideline, found that HIV+ MSM and transgender women 35 years of age and older are forty-one times more likely to develop anal cancer than the general population. The incident rate increases to nearly fifty-ninefold within this demographic for individuals over 45. HIV+ men over 45 who have sex with women are 23.5 times more likely to develop anal cancer than the U.S.

population. Risk Category B covers patients who are at an increased risk of anal dysplasia, but to a lesser extent than category A, requiring a more shared decision making approach concerning their individual risks and screening needs. Within this group are individuals 45 years and older with a history of cervical/vaginal precancer or cancer, those who required chronic systemic steroid therapies, or patients with autoimmune and immunosuppressive diseases.

Although this new guideline was not applied to the QI project due to the publication occurring after the intervention period had begun, the release of a validated anal cancer screening guideline is an important implication for healthcare providers in their future practice. All providers, not just those working with HIV+ persons, need to be aware of the at-risk groups represented in this international guideline and address this screening for the health and safety of their patients.



#### Image 1:

#### Conclusion

After the project concluded, conversations with clinic staff took place for feedback on the QI intervention. They expressed gratitude for the educational material implementation and the

assistance in enhancing HPV anal cancer screening practices at their site. Encouraged by the impact of the QI project, they anticipate a further improvement in the HPV anal cancer screening rates within their clinic.

Increasing anal pap testing, especially within the HIV and LGBTQ+ communities, helps promote health and prevent harm to these at-risk populations. Low uptake of HPV vaccination, especially among adults over 30, means that the risk for HPV infection in any form increases. The only peer-reviewed screening measure to prevent these infections growing into higher-grade malignancies is HPV pap testing, to catch dysplasia and start treatment early. Increasing patient and provider knowledge of the current and updated guidelines are vitally important to providing safe, equitable, and inclusive patient care. Although the intervention outcome was not statistically significant, the results were clinically meaningful for the focused clinic and their patients. The QI project demonstrated how straightforward and budget-friendly patient education has the potential to enhance patient adherence to screenings and increase clinic screening rates.

The sustainability of the QI project was assisted by the simplicity and reproducibility of the educational materials created. Infographic flyers can contain valued information, while also providing QR codes containing links to more in-depth education that is reliable and evidence-based. Keeping the educational materials in digital formats allows for desired adjustments, immediate reproduction, and technological or internet-based inclusion. The social media promo could be reposted regularly on any clinic media platform, be included on websites, or be posted throughout the clinic in a physical form.

Future implementation efforts could include a longer time-frame for the intervention as CPSTF (2020) encourages multimodal education to be presented in repetition over a period of six months to reinforce the material and yield improved outcomes. Utilizing more diverse forms of internet-based technologies, as well as the interactive patient screens, could provide a greater impact to attract a more diverse population. Efforts could be made to expand the project with re-implementation of the educational materials in different formats such as larger posters, take-home pamphlets, podcasts, and other social media platforms.

The project could be extended to other clinical contexts especially if they have a large patient population with persons affected by HIV, or are a LGBTQ+ safe and affirming practice environment. Women's health groups could also benefit from the project and increased knowledge of the HPV anal cancer screening guidelines, as patients with cervical HPV and malignancies are at increased risk of developing anal HPV dysplasias. Each educational piece could be adjusted to different color schemes or templates complimentary to various office settings.

Considering that the U.S. national screening guidelines for HPV anal dysplasias are few and far between, providers need to be aware and educated on the smaller evidence-based research that does release these guidelines. This is vitally important especially in areas and clinics that focus on at-risk and marginalized groups such as those living with HIV and individuals in the LGBTQ+ community. At-risk HPV anal screening guidelines are available and well-researched with recognition for patient safety, health, and quality of life. Sustaining efforts that encourage high-risk individuals to undergo anal HPV screening will require a comprehensive educational approach of providers and patients to ensure consistent and appropriate recommendation of this screening.

Additional research concerning HPV anal cancer testing and guidelines, especially in the LGBTQ+ and HIV+ communities, is necessary to not only raise awareness within the medical field, but to assist in providing patients with clear guidelines specific to their healthcare needs. Further data from interventions like this QI project are essential to continually improve and develop guidelines for more specific anal cancer screenings. When patients are provided with up-to-date and straightforward healthcare advice, they can better advocate for their own health, safety, and quality of life and in turn provide encouragement to others within their community.

#### References

Agency for Healthcare Research and Quality - AHRQ. (2020). Plan-do-study-act (PDSA) directions and examples. Retrieved August 10, 2023 from

https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html

Almada, J. (2024). First international anal cancer screening guidelines. The Anal Cancer Foundation. Retrieved March 13, 2024 from

https://www.analcancerfoundation.org/news/first-international-anal-cancer-screening-gui delines/

- American Cancer Society (2020). Risk factors for anal cancer. About anal cancer. Retrieved July 21, 2023 from https://www.cancer.org/cancer/types/anal-cancer/causes-risks-prevention/risk-factors.html
- Brown, A. (2023). 5 key findings about LGBTQ+ Americans. LGBTQ Attitudes & Experiences. Pew Research Center. Retrieved July 24, 2023 from https://www.pewresearch.org/short-reads/2023/06/23/5-key-findings-about-lgbtq-america ns/
- Bucher, G., Torrence, A., Schneider, J., Houlberg, M., Munar, D., & Kelgovitz-Baker, K. (2019).
   Anal dysplasia screening guidelines. Howard Brown Health. Retrieved from https://howardbrown.org/wp-content/uploads/2019/08/Howard\_Brown\_Health\_Anal\_Can cer\_Screening\_Guidelines-2019.pdf

Centers for Disease Control and Prevention (2023). HPV and cancer statistics: How many cancers are linked with HPV each year? Division of Cancer Prevention and Control. Retrieved July 10, 2023 from https://www.cdc.gov/cancer/hpv/statistics/cases.htm Community Preventive Services Task Force (2020). Guide to Community Preventive Services.

TFFRS - Cancer Screening: Interventions Engaging Community Health Workers Cervical Cancer. Retrieved August 9, 2023 from

https://www.thecommunityguide.org/pages/tffrs-cancer-screening-interventions-engaging -community-health-workers-cervical-cancer.html.

- Compton, M. L., Taylor, S. S., Weeks, A. G., Weiss, V. L., Hogan, M. M., Wang, H., & Ely, K. A. (2022). Cytology and LGBT+ health: establishing inclusive cancer screening programs. Journal of the American Society of Cytopathology, 11(5), 241–252. https://doi.org/10.1016/j.jasc.2022.06.003
- Daponte, N., Valasoulis, G., Michail, G., Magaliou, I., Daponte, A. I., Garas, A., Grivea, I.,
  Bogdanos, D. P., & Daponte, A. (2023). HPV-Based Self-Sampling in Cervical Cancer
  Screening: An Updated Review of the Current Evidence in the Literature. Cancers,
  15(6), 1669. https://doi.org/10.3390/cancers15061669
- Drysdale, K., Cama, E., Botfield, J., Bear, B., Cerio, R., & Newman, C. E. (2020). Targeting cancer prevention and screening interventions to LGBTQ communities: A scoping review. Health & Social Care in the Community, 29(5), 1233–1248. https://doi-org.proxy1.cl.msu.edu/10.1111/hsc.13257
- FDA (2019). IRBs and protection of human subjects. Retrieved September 28, 2023 from https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-revi ew-boards-irbs-and-protection-human-subjects-clinical-trials
- Haviland, K.S., Swette, S., Kelechi, T., & Mueller, M. (2020). Barriers and facilitators to cancer screening among LGBTQ individuals with cancer. Oncology Nursing Forum, 47(1), 44-55. DOI: 10.1188/20.ONF.44-55
- Health Resources & Services Administration (HRSA). (2022). Program Parts & Initiatives | Ryan White HIV/AIDS Program. Retrieved July 25, 2023 from https://ryanwhite.hrsa.gov/about/parts-and-initiatives
- Hirsch, B.E., McGowan, J.P., Fine, S.M., Vail, R., Merrick, S.T., Radix, A., Hoffmann, C.J., Gonzalez, C.J. (2022). Screening for anal dysplasia and cancer in adults with HIV. Johns

Hopkins University. NYSDOH AI. Retrieved July 21, 2023 from

https://www.ncbi.nlm.nih.gov/books/NBK556472/

Human Rights Campaign (2017). How HIV impacts LGBTQ people. HRC Foundation. Retrieved August 17, 2023 from

https://www.hrc.org/resources/hrc-issue-brief-hiv-aids-and-the-lgbt-community

- Institute for Healthcare Improvement (n.d.). How to improve: IHI. Retrieved September 28, 2023 from https://www.ihi.org/resources/Pages/HowtoImprove/default.aspx
- Klein, E.W. & Nakhai, M. (2016). Caring for LGBTQ patients: Methods for improving physician cultural competence. The International Journal of Psychiatry in Medicine, 51(4), 315-324.
   DOI: 10.1177/0091217416659268
- Leone, A. G., Trapani, D., Schabath, M. B., Safer, J. D., Scout, N. F. N., Lambertini, M., Berardi, R., Marsoni, S., Perrone, F., Cinieri, S., Miceli, R., Morano, F., & Pietrantonio, F. (2023).
  Cancer in Transgender and Gender-Diverse Persons: A Review. JAMA oncology, 9(4), 556–563. https://doi.org/10.1001/jamaoncol.2022.7173
- McNamara, M. & Ng, H. (2016). Best practices in LGBT care: A guide for primary care physicians. Cleveland Clinic Journal of Medicine, 83(7), 531-541. https://doi.org/10.3949/ccjm.83a.15148
- McNeil, C. J., Kong, C. S., Anglemyer, A., Levy, V., & Maldonado, Y. (2016). Results of the Women's Self-Performed Anal Pap Trial in Human Immunodeficiency Virus-Infected Women. *Sexually Transmitted Diseases, 43*(7), 433–435. https://doi-org.proxy2.cl.msu.edu/10.1097/OLQ.00000000000448
- Nair, J., Waad, A., Byam, S., & Maher, M. (2021). Barriers to care and root cause analysis of LGBTQ+ patients' experiences: A qualitative study. Nursing Research, 70(6), 417-424. https://doi.org/10.1097/NNR.000000000000541

Nelson, N.G., Lombardo, J.F., Shimada, A., Ruggiero, M.L., Smith, A.P., Ko, K., Leader, A.E.,

Mitchell, E.P., Simone, N.L. (2023). Physician perceptions on cancer screening for LGBTQ+ patients. Cancers 2023, 15, 3017. https://doi.org/10.3390/cancers15113017

- NIH (2023). Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. National Institutes of Health, the Centers for Disease Control and Prevention, and the HIV Medicine Association of the Infectious Disease Society of America Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Retrieved August 17, 2023 from https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-oppo rtunistic-infections/human-0?view=full
- Nisly, N., Imborek, K., Miller, M., Dole, N., Priest, J., Sandler, L., Krasowski, M., & Hightower, M. (2018). Developing an inclusive and welcoming LGBTQ clinic. Clinical Obstetrics and Gynecology, 61(4), 646-662. DOI: 10.1097/GRF.0000000000000405
- Nyitray, A.G., Schick, V., Swartz, M.D., Giuliano, A.R., Fernandez, M.E., Deshmukh, A.A.,
  Ridolfi, T.J., Ajala, C., Brzezinski, B., Sandoval, M., Nedjai, B., Smith, J.S., & Chiao, E.Y.
  (2021). Rationale and design of the Prevent Anal Cancer Self-Swab Study: a protocol for a randomised clinical trial of home-based self-collection of cells for anal cancer screening. BMJ open, 11(6), e051118. https://doi.org/10.1136/bmjopen-2021-051118
- Nyitray, A.G., Nitkowski, J., McAuliffe, T.L., Brzezinski, B., Swartz, M.D., Fernandez, M.E., Deshmukh, A.A., Ridolfi, T.J., Lundeen, S.J., Cockerham, L., Wenten, D., Petroll, A., Hilgeman, B., Smith, J.S., Chiao, E.Y., Giuliano, A.R., & Schick, V. (2023). Home-based self-sampling vs clinician sampling for anal precancer screening: The Prevent Anal Cancer Self-Swab Study. International journal of cancer, 153(4), 843–853. https://doi.org/10.1002/ijc.34553

Otter, S., Whitaker, S., Chatterjee, J., & Stewart, A. (2019). The human papillomavirus as a

common pathogen in oropharyngeal, anal, and cervical cancers. St. Luke's Cancer Centre, Royal Surrey County Hospital, Guildford, UK. Clinical Oncology, 31(2), 81-90. https://doi.org/10.1016/j.clon.2018.10.004

- Peitzmeier, S.M. (2013). Promoting cervical cancer screening among lesbians and bisexual women. The Fenway Institute and Fenway Health. Boston, MA. Retrieved from https://lgbtqiahealtheducation.org/wp-content/uploads/Promoting\_Cervical\_Cancer\_Scre ening\_LBWomen.pdf
- Reisner, S.L., Deutsch, M.B., Peitzmeier, S.M., White Hughto, J.M., Cavanaugh, T. P., Pardee,
  D.J., McLean, S.A., Panther, L.A., Gelman, M., Mimiaga, M.J., & Potter, J.E. (2018). Test
  performance and acceptability of self- versus provider-collected swabs for high-risk HPV
  DNA testing in female-to-male trans masculine patients. PloS one, 13(3), e0190172.
  https://doi.org/10.1371/journal.pone.0190172
- Solazzo, A. L., Agénor, M., Austin, S. B., Chavarro, J. E., & Charlton, B. M. (2020). Sexual orientation differences in cervical cancer prevention among a cohort of U.S. women.
  Women's Health Issues: official publication of the Jacobs Institute of Women's Health, 30(4), 306–312. https://doi.org/10.1016/j.whi.2020.02.002
- Stier, E.A., Clarke, M.A., Deshmukh, A.A., Wentzensen, N., Liu, Y., Poynten, I.M., Cavallari,
  E.N., Fink, V., Barroso, L.F., Clifford, G.M., Cuming, T., Goldstone, S.E., Hillman, R.J.,
  Rosa-Cunha, I., La Rosa, L., Palefsky, J.M., Plotzker, R., Roberts, J.M., & Jay, N. (2024).
  International anal neoplasia society's consensus guidelines for anal cancer screening.
  International Journal of Cancer, 154(10), 1694-1702. https://doi.org/10.1002/ijc.34850
- USPSTF (2018). Cervical Cancer: Screening. U.S. Preventive Services Task Force. Retrieved August 2, 2023 from

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-s creening#citation18

Wieland, U. & Kreuter, A. (2019). Anal cancer risk: HPV-based cervical screening programmes.
The Lancet. Infectious diseases, 19(8), 799–800.
https://doi.org/10.1016/S1473-3099(19)30296-8

# Appendix A

Patient Education - Social Media Promo



# Appendix B



# Appendix C

Patient Education - Detailed Slide-Based Presentation



# What is HPV?

- HPV = Human Papillomavirus
  - A virus primarily transmitted through sexual contact
- Approximately 85% of Americans will be infected with at least one form of HPV within their lifetime.
- Can be:
  - Benign disease
  - Precancerous
  - Malignant
- the oropharynx and anogenital regions
  - 91% of cancers in the cervix and anus result from HPV infection
- 37,300 new cases of HPV-related cancers are diagnosed every year



(CDC, 2020; Hirsch et al., 2022; Otter et al





# Who is at risk for HPV anal cancer?

- HIV+ or immunocompromised
- Receptive anal intercourse or play
  - Females with a history of cervical HPV16 are at an increased risk of anal
- · History of other genital cancers
- Caucasian female or black male

All forms of partnerships, no matter the gender identities or sexual orientations of the individuals, can lead to HPV transmission and infection: female-to-male, male-to-male, and female-to-female.

(American Cancer Society, 2020; Bucher et al., 2019; Wieland and Kreuter, 2019)



4

3

Age	Recommended Screening	Frequency
	HIV Positive	
Under 30	DARE	Annually
30 and above	aCyt, rHRHPV, DARE	Annually
HIV Negativ	e, Having Anoreceptive Sex or Play wi	ith Multiple Partners
40 and above	aCyt, rHRHPV, DARE	Annually
	History of cancer of the Cervix, Vagina	, or Vulva
Any	aCyt, rHRHPV, DARE	At time of diagnosis and annually
	History of HSIL of the Cervix, Vagina,	or Vulva
30 and above	aCyt, rHRHPV, DARE	At time of diagnosis and annually
	Solid Organ Transplant Recipier	nts
Any	aCvt. rHRHPV, DARE	2-5 years post-transplant and annually









# Appendix D

#### Anonymous Patient Survey

### Anonymous HPV Screening Survey Questions (please circle your answer)

\*This survey was created by MSU doctoral students to evaluate the effectiveness of various educational methods to increase the rates of HPV screening at Sunshine Family Cares. Completion of this survey is voluntary and you may refuse to answer any question. You may withdraw or stop participating at any time without consequence. By completing the survey, you are indicating your voluntary agreement to participate.

- Have you ever had HPV screening before?
  - ° Yes
  - No
  - Unsure
- · If you answered "Yes" above, what type?
  - Cervical
  - Oral
  - Anal
  - Unsure
- Did any clinic-based education influence you to receive HPV screening today?
  - Yes
  - o No
- If you answered "Yes" above, what educational mode influenced you? (select all that apply)
  - Provider recommendation
  - Video/Clinic TV
  - Pamphlet
  - Clinic Facebook page
  - Clinic Website
  - Interactive Screens
  - Flyers

Contact person: Anna McCarthy/Kayla Huber Email: mccar585@gmail.com/huberka8@msu.edu Appendix E

#### **MSU IRB Approval Letter**

# MICHIGAN STATE

UNIVERSITY

#### DETERMINED NOT "RESEARCH" Revised Common Rule

November 8, 2023

To: Anna McCarthy

Re: MSU Study ID: STUDY00009901 Principal Investigator: Anna McCarthy Determination Date: 11/8/2023

Title: DNP Student Project - Increasing Human Papillomavirus (HPV) Anal Cancer Screening with Multimodal Patient Education in a LGBTQ+/HIV Clinic

The activity described in this submission was determined not to be "research" as defined by the Common Rule as codified in the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human research subjects.

#### Definition of Research

For DHHS, "*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.



Office of Regulatory Affairs Human Research Protection Program

> 4000 Collins Road Suite 136 Lansing, MI 48910

517-355-2180 Fax: 517-432-4503 Email: irb@msu.edu www.hrpp.msu.edu (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions." [45 CFR 46.102(I)]

#### Determination

The goal of this QI project is to increase the screening rate of anal HPV in all persons in this clinic including those in the LGBTQ+ and HIV+ communities. This is a QI project for which the intent is to not obtain new and generalizable simple knowledge.

Hence, the activity does not involve research.

Therefore, the federal regulations for the protection of human subjects would not apply to this activity and Michigan State University (MSU) Institutional Review Board (IRB) approval is not needed to proceed. However, please note that while MSU IRB approval is not required, other federal, state, or local regulations or requirements or ethical or professional standards may still be applicable based on the activity.

**Modifications:** If any of the activities described in this submission change, please contact the IRB office as the activity may involve human subject research and require IRB approval. For example, this determination is not applicable to activities that may be regulated by U.S. Food & Drug Administration (FDA), such as those involving drugs, medical devices, human food additives, color additives, electronic products, or any other test articles regulated by the FDA.

**Modifications to Funding: Changes in funding may alter this determination.** For example, MSU IRB review and approval is required if MSU receives an award through a grant, contract, or cooperative agreement directly from a federal agency, even where all non-exempt research involving human subjects are carried out by employees or agents of another institution. In addition, the new funding source may have additional or different requirements.

**For More Information:** See HRPP Manual Section 4-3, Determination of Human Subject Research (available at <u>hrpp.msu.edu</u>).

**Contact Information:** If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at <u>IRB@msu.edu</u>. Please visit <u>hrpp.msu.edu</u> to access the HRPP Manual, templates, etc.

#### Appendix F

### **Clinic Approval Letter**

September 15, 2023

Michigan State University College of Nursing 1355 Bogue St, #218 East Lansing, MI 48824

To Whom It Concerns:

I am familiar with the quality improvement project being conducted by Kayla Huber and Anna McCarthy entitled "Equity in Healthcare: Strengthening HPV Cancer Screening in the LGBTQ+ Population at an HIV-Care Focused Clinic". I understand that provide the mentorship of the above-named students and will require the application of the proposed process including: reviewing our current processes and/or practice, accessing benchmark and performance data including records for review, assessing practice protocols and procedures related to the project, participating in improvement team meetings, educating providers and staff, revising related current policy/procedures, and implementing project-based patient education.

I have read the project's proposal and am comfortable with the project as described being conducted at our institution. I understand that this project will be carried out following sound, ethical principles. **Sector Sector Sector** gives permission for the students to disseminate project data and outcomes at Michigan State University College of Nursing for the purpose of academic course completion. Therefore, as a representative of **Sector Sector** I agree that Kayla Huber's and Anna McCarthy's quality improvement project may be conducted at our institution.

Sincerely,