

**Anal Pap Screening for Women Living with Human Immunodeficiency Virus: Improving Provider
Knowledge and Practices**

Sarah C. McAllister BSN, RN

Oregon Health Sciences University in Portland, Oregon

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Chair: Jonathan Soffer, DNP, A.N.P.

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Abstract

Anal cancer (AC) is one of the most common cancers among people living with Human Immunodeficiency Virus (HIV) and carries substantial morbidity and mortality. Current evidence supports screening people living with HIV (PLWH) with anal cytology or Papanicolaou smear (anal Pap) annually and treating precursors with ablation through high resolution anoscopy (HRA) (Lee et al., 2022). However, there are no national consensus guidelines for AC screening among PLWH, which has led to large gaps in screening practices. This QI project aimed to improve provider's knowledge, comfort, and willingness to screen for AC with anal Paps for cisgendered women living with HIV (WLWH). The methods included revising best practice recommendations for an HIV clinic, a 30-minute educational presentation about these recommendations to a women's health clinic, and creating an education tool for providers to use with patients. Results from pre- and post-intervention surveys were compared to evaluate the impact of the educational presentation. Providers improved their recognition of AC risk factors, reported increased comfort discussing risk factors and screening methods with WLWH, and had increased willingness to provide screening via anal Pap for WLWH, but not other high-risk populations. The results indicate that an educational presentation in conjunction with developing local best practice recommendations can be an effective intervention to foster evidence-based practice when national guidelines are lacking. More recently, new evidence supports screening other high-risk populations, therefore future projects would benefit from similar interventions and should go a step further to assess for subsequent changes to the rate of anal Pap screening and any patient level barriers.

Keywords: anal cancer (AC), anal cytology, anal Pap, women living with HIV (WLWH), people living with HIV (PLWH)

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Problem Description

While the incidence of AC is rare in the general population occurring at a rate of 2 per 100,000 people per year in the United States (US), it has been steadily increasing at a rate of 2.2% per year and carries a significant morbidity with a 5-year survival rate of 70.4% (National Cancer Institute [NCI], 2023). PLWH are at the highest risk for developing AC: the incidence for men living with HIV (MLWH) who have sex with men (MSM) is 130 per 100,000 and the incidence for WLWH is 30 per 100,000 (Clifford et al., 2020). AC is considered one of the most common cancers among PLWH, yet there are no formal national consensus guidelines for screening among this high-risk population (Albuquerque et al., 2019; Cachay et al., 2023). Until recently, there was little evidence demonstrating the benefit of treating precancerous anal lesions found on anal cytology in reducing the rate of progression to AC. In 2022, results from the Anal Cancer-HSIL Outcomes Research (ANCHOR) trial finally demonstrated that for PLWH, treating high-grade squamous intraepithelial lesions (HSIL) with ablation significantly reduced the incidence of anal SCC by 57% (Lee et al., 2022). This evidence supports screening efforts for the early detection and treatment of anal dysplasia among PLWH.

Without national best practice recommendations for screening, organizations and providers caring for PLWH have looked to several regional and professional societies that do have them. However, these recommendations vary widely, which has created large variances in knowledge and practices (Apaydin et al., 2018; Chen et al., 2019; Gaspar et al., 2020; Higashi et al., 2021). As a result, screening opportunities are often missed. Most screening efforts have focused on HIV-positive MSM due to the much higher incidence of AC relative to WLWH. Consequently, screening among WLWH remains low, with one study finding that they were four times less likely to be screened for AC than HIV positive MSM (Wells et al., 2018). Yet, WLWH still have a significantly high incidence of AC relative to the general

population, and the incidence is increasing for WLWH while slowly declining for HIV positive MSM (van der Zee et al., 2023). Additionally, low screening rates are of particular concern as all women are more likely to be diagnosed with anal cancers at a later stage, receive radiation, and have a lower 5-year survival rate relative to all males (Celie et al., 2017). Poor screening rates for WLWH were observed at two clinics, which became the locations for this quality improvement project.

Available Knowledge

The literature review revealed seven best practice recommendations from regional and professional societies. Four recommend screening for AC with annual anal Pap (cytology) testing, and if results are positive then referral for HRA for biopsy and possible ablation (Albuquerque et al., 2019; Gaisa et al., 2021). The recommendations are modeled from secondary prevention strategies for cervical cancer (Cimic et al., 2019; Palefsky et al., 2022). Both cervical and anal cancers are predominantly due to high-risk Human Papilloma Virus (HPV) strains and have histological similarities being in similar squamocolumnar junction tissues (Cimic et al., 2019). A recent systematic review and metaanalysis found anal cytology to have a sensitivity of 81% and specificity of 62%, which is similar to cervical cytology (Clarke et al., 2022).

WLWH are more likely to contract HPV, have persistent infections, multiple strains, reduced clearance of HPV, faster progression to cancer, and higher risk for HPV-vaccine failure (Chowdhury et al., 2023; Kaufman et al., 2022). Therefore, the most recent and comprehensive recommendations are to screen *all* WLWH annually (Hirsch et al., 2022). The feasibility of this recommendation is supported by several studies that show WLWH have a high acceptability of anal pap tests and HRA procedures (De-Masi et al., 2018; Kaufman et al., 2020; Lam et al., 2018; Proctor et al., 2019; Rodriguez et al., 2019). However, other research demonstrates WLWH have a low perceived risk for AC, indicating a need for wider public health campaigns and provider led risk-based discussions (Fein et al, 2021; Rodriguez et al., 2019).

Research is sparse regarding how providers address AC risk and screening for PLWH, and even scarcer for WLWH. Three studies were identified in the literature review that assess provider knowledge, practices, and barriers to AC screening among PLWH (Apaydin et al., 2018; Chen et al., 2019; Gaspar et al., 2020) and one specific to WLWH (Higashi et al., 2021). All studies found a lack of, or unclear national and local recommendations as common system level barriers. This had a direct impact on provider level barriers as all studies found large variances in provider knowledge and practices. One study found a significant knowledge deficit in providers' ability to recognize AC risk factors, which directly influenced screening recommendations (Chen et al., 2019). Three studies found providers lacked awareness about society recommendations and frequently had skepticism about the reliability of anal cytology and the benefits of screening to reduce AC incidence (Gaspar et al., 2020; Higashi et al., 2021; Koskan et al., 2019). Interestingly, all studies were conducted prior to the ANCHOR trial publication, thus providers may now be more open to AC screening with anal Pap to better align with current evidence.

The literature review did not reveal any studies that specifically assessed educational interventions for providers about AC screening with anal Pap. However, two quality improvement studies were identified that developed and evaluated AC screening protocols which included provider education components (Cardenas et al., 2022; Mangusan et al., 2018). While the findings from such projects are not necessarily reproducible, their processes are notable for this QI project. Cardenas et al. (2022) bundled AC screening with routine gynecological appointments for WLHW and found increased provider and patient engagement with anal Pap screening. Mangusan et al. (2018) was also able to increase screening rates of AC among PLWH. Notable in their project was the inclusion of key stakeholders in creating a best practice guide that standardized the screening process and included a simplified algorithm for managing cytology results and follow-up.

Rationale

HIV disproportionately affects racial, sexual, and gender minorities, populations with significant health disparities who have historically been understudied resulting in a paucity of population-based health information and delays in clinical practice guidelines (Baptiste-Roberts et al., 2018; Lightfoot et al., 2021). To foster health equity and meet the needs of vulnerable populations, developing local best practice recommendations is imperative and deserves robust systematic review, analysis, and implementation. Thus, this QI project was guided by Eugene Bardach's Policy Analysis framework (see Appendix A), a broadly applicable model for systematically solving clinical dilemmas and promoting evidence-based practices (Bardach & Patashnik, 2023; Engelman et al., 2019). Bardach's eight steps, or domains, include: defining a problem, assembling evidence, constructing alternatives, selecting criteria, projecting outcomes, confronting trade-offs, decision-making, and sharing results.

Per Bardach's first step, to best define the local problem a root cause analysis (see Appendix B) was conducted and revealed the need for updated and easily accessible best practice recommendations for AC screening among PLWH. The subsequent literature review supported this in conjunction with a provider educational intervention. The remaining steps of the Bardach model guided the creation of meaningful, evidence-based recommendations that formed the basis of the educational presentation. Specifically, the model called for constructing alternative recommendations by analyzing regional and society ones and comparing these with current evidence. This narrowed possible recommendations, which helped project the feasibility of changes and effects on providers and patients.

Specific Aims

This quality improvement project aimed to improve the knowledge and practices of providers caring for WLWH regarding AC screening via anal Pap. Five aims were established to attain this goal with a project deadline of February 2024 (see Appendix C). The first aim was to analyze and revise the HIV clinic's AC screening best practice recommendations for PLWH. The second aim was to evaluate the current knowledge and practices of providers in the women's clinic. The third aim was to present the

literature synthesis and the revised recommendations to the women's clinic. The fourth aim was for providers caring for WLWH to report an improvement of their AC screening knowledge, practices, and willingness to provide screening after the educational presentation. The final aim was to have the revised recommendations adopted as best practice for all primary care clinics within the institution.

Methods

Local Context

This QI project involved two clinics within the same institution that provide primary care services to WLWH: a primary care clinic with an HIV specialty group and a women's health clinic. The clinics are located within an urban area of the Pacific Northwest, within a county that has the largest HIV-positive population in the state (Oregon Health Authority [OHA], 2023).

The primary care clinic staffs approximately 65 providers, but only five comprise the HIV clinic. These providers routinely collect anal Paps and created the previous AC screening recommendations that were revised for this project. While WLWH receive most of their primary care in the HIV clinic, they often obtain their cervical pap smears and other women's health related care from the women's clinic. The women's health clinic does not have an HIV focused provider team, they do not routinely provide anal Paps, they do not have their own AC screening recommendations, nor can they access the previous one owned by the HIV clinic. Additionally, the women's clinic requires a separate process for creating their own official recommendations, which was outside the scope of this project.

Interventions

Phase 1: Evaluation and Tentative Revisions to Previous AC Screening Recommendations

The HIV clinic's 2019 Anal Cancer Screening Recommendations for PLWH was reviewed and then compared to current evidence and existing regional and societal recommendations. Initial revisions were based on this process and then proposed to key stakeholders. This included one NP From the HIV clinic; one MD and one NP from the anoscopy clinic; and one MD from the women's clinic.

Phase 2: Educational Presentation for the Women's Clinic and Surveys

A 30-minute educational presentation (see Appendix D) for providers in the women's clinic reviewed the HIV clinic's tentative recommendations, the current evidence, instructions for how to perform anal Paps, and an algorithm for managing results. The presentation was conducted using Microsoft Power Point over a Webex video during a clinic staff meeting. A pre-survey (see Appendix E) was delivered to providers via a web link in Webex 5-minutes prior to the presentation and a post-survey (see Appendix E) emailed after the presentation and again two weeks later. The surveys assessed AC screening knowledge, attitudes, and practices among providers before and after the educational presentation. The surveys were co-created with the MD from the anoscopy clinic.

Phase 3: Evaluation of Survey Results and Formation of Educational Tool

The results of the pre and post surveys (see Appendix F) were compared and analyzed to assess for any improvements in AC screening knowledge, practices, and willingness to provide screening to both WLWH and other high-risk women. Using the finalized recommendations, provider feedback, and the survey results, a patient education tool (see Appendix G) was created to aid providers in discussions around AC risk and screening for PLWH.

Phase 4: Final Revisions to Recommendations and Submission to Best Practice Panel

The results were also used to inform the final revisions of the HIV clinic's AC screening recommendations. Final recommendations and the educational tool were sent to the women's clinic. Recommendations were also submitted for consideration as best practices into all primary care clinics within the hospital.

Study of the Interventions

In the study of interventions, external variables that could affect responses were considered when creating the survey questions and evaluating the impact of the educational presentation. Baseline knowledge, practices, and willingness to screen were established with a pre-survey and then reassessed

in a post-intervention survey to identify any changes. The results and evaluation process were used to further inform final revisions to recommendations and the patient education tool.

Measures

The primary outcome measure for this QI project was to improve provider's knowledge, practices, and willingness to screen for AC via anal Pap among WLWH. A second outcome measure was to increase provider's willingness to consider screening other high-risk, HIV-negative groups. The results from the pre- and post-survey were compared to measure for these outcomes.

The process measures included the proportion of those who attended *and* completed the pre- and post-surveys. The balancing measures included: prior education that providers received regarding AC and anal Paps for PLWH; and monitoring for new recommendations from the United States Preventative Services Taskforce (USPSTF), New York State Health Department AIDS Institute (NYSHDAI), Infectious Diseases Society of America (IDSA), International Anal Neoplasia Society (IANS), and Center for Disease Control and Prevention (CDC).

Analysis

This QI project used qualitative methods through pre- and post-intervention surveys regarding the impact of the educational presentation. The results were compared between surveys to assess for any changes to respondent's knowledge, practices, and willingness to provide AC screening WLWH and other high-risk HIV-negative populations. Results were entered into an Excel document for analysis and interpretation. The survey data included the respondent's profession and specialty, which populations they deemed highest risk for AC, and then questions regarding practices via a Likert scale of 1-5 (1 was *strongly disagree*, 3 was *neither agree nor disagree*, and 5 was *strongly agree*). Averages of the results were placed into horizontal-bar graphs (see Appendix F), the percent change was assessed for each question from pre to post survey results, and themes and inferences were derived from any changes observed in the context of possible external factors.

Ethical Considerations

Providers from the primary care clinic, the women's clinic, and the anoscopy clinic were consulted about this QI project through face-to-face meetings and email. A Letter of Support was ultimately obtained from the primary care clinic and the women's clinic (see Appendix H). The Oregon Health Science University (OHSU) Investigational Review Board (IRB) determined this QI project to be non-research September 8th, 2023 (see Appendix I). Emails were sent to all staff regarding the scheduling of the educational presentation during a staff meeting and the modules were not mandatory. The primary ethical consideration during the project was to ensure confidentiality of survey responses, thus no identifying data was collected within the surveys or results.

Additional ethical considerations were accounted for regarding the secondary effects of the intervention in terms of how it could negatively affect the vulnerable population it is intended for: PLWH. Specifically, questions were posed and discussed between stakeholders regarding potentially increasing unnecessary, invasive procedures. To address this, specific guidance was included in the presentation and recommendations regarding who and when to screen and *not* to screen.

Results

The pre-intervention survey was administered immediately prior to the presentation and had a response rate of 100% (n=14). All respondents specialized in women's health. 11 were Medical Doctors, 2 were Nurse Practitioners, and 1 was a Physician Assistant. Of the seven independent risk factors for AC that respondents were asked to identify, 100% correctly identified HIV-positivity, but all other risk-factor categories had variable responses. Most providers (57%) indicated they *did not feel comfortable* discussing AC risk and screening methods. 28.6% of providers indicated they were *strongly not willing* or *neutral* about screening asymptomatic WLWH for AC with anal Pap. Over 50% were *not confident* in how or when to refer for HRA. In terms of considering screening for other high-risk, HIV-negative groups of women, 21.4% were *strongly not willing* or *neutral* and 75% were willing on some level.

The post-intervention survey was administered via a weblink sent by email after the presentation and resent by email two weeks later (see Appendix F for comparison between the pre- and post-survey results). The post-survey response rate was 85% (n=12) and respondents answered 100% of questions. 11 respondents were MDs and 1 was a PA. More providers correctly identified each category as high-risk, except for *HPV Positivity* and *History of Anal Condyloma* categories, which slightly decreased. Most providers (83%) reported some level of comfort discussing AC risk and screening methods, and *none* indicated they were *not* comfortable. More providers indicated they were willing to screen WLWH with anal Paps and most indicated comfort in how and when to refer for HRA. In terms of screening for AC in other high-risk, HIV-negative groups of women, most providers were still open to this, but those that were *strongly* open decreased by more than 50%.

The results from the post survey responses and further consultations with key stakeholders were used to form the educational tool for providers to use with patients. The finalized recommendations are still pending submission for consideration as best practices for all primary care within the institution.

Discussion

Summary

The primary aim of this QI project was to improve provider knowledge about AC risk factors and increase their willingness to screen WLWH for AC via anal Pap. The project was developed by applying a policy analysis framework for revising best practice recommendations and creating a related educational intervention. The overarching goals were to increase provider comfort with risk-based discussions about AC for all high-risk populations and increase AC screening rates via anal Pap for WLWH. The generally positive results post-intervention demonstrates the usefulness of this QI process for future improvement work; specifically for QI projects attempting to translate new evidence into practice when national or local consensus guidelines are inadequate or non-existent.

Interpretation

The benefits of the educational intervention were evidenced by more providers correctly identifying risk factors, and significant improvements in provider comfort ratings for discussing risk factors, screening methods, and willingness to provide screening via anal Pap for WLWH. The slightly decreased willingness to consider screening for other high-risk populations was interesting, but not surprising. For instance, after HIV-positive MSM, women with solid organ transplants and vulvar dysplasia are the second and third highest risk populations, which is higher than all WLWH (Clifford et al., 2020). However, the evidence for treating precursors largely exists for PLWH and would be questionable to extrapolate to these other groups. This was addressed within the presentation and discussed in the Q&A afterwards.

The results underscore the benefits of an educational presentation that is informed by updating a local best practice guide. Additionally, two other processes made this successful: consulting key stakeholders when creating the presentation to optimize its meaning and utility; and engaging providers by informing them during the presentation that their feedback and expertise would be helpful for final revisions to the HIV clinic's best practice recommendations.

Limitations

This QI project had several limitations that include: due to the time constraints of this project and the prolonged (annual) intervals between routine anal Paps, it was not possible to assess the effects on actual screening rates; it was not possible to create a single recommendation guide for both clinics because each had a separate processes for development and approval; the sample size was too small to consider the statistical power of findings; and lastly, it was not feasible to assess patient barriers to anal Paps, which could have strengthened the recommendations and the educational tool.

Conclusion

AC screening with anal Pap is currently the most feasible and reliable method for detecting AC precursors in primary care setting among PLWH (Gaisa et al., 2021). Treating high-grade precursors with

ablation through HRA reduces PLWH's risk for AC by 57%, therefore, screening is imperative for this population (Leet et al., 2022; Palefsky et al., 2022). Incidence of AC is rising among WLWH, but screening remains low (van der Zee et al., 2023; Wells et al., 2018). The improvements measured in this QI project and others from the literature review, showed the effectiveness of provider educational interventions in supporting evidence-based practices for AC screening among WLWH. Specifically, educational interventions should be developed in conjunction with a best practice guide from an HIV specialty and include a synthesis of current evidence, streamlined recommendations and algorithms, and an invitation for providers to share their feedback and expertise on best practices. Future QI work for WLWH should focus on improving barriers to consistency and compliance in AC screening. Additionally, as more evidence is mounting in support of screening and treating other HIV-negative high-risk populations, QI projects like this one will be beneficial for improving evidence-based practices across specialties as consensus guidelines fall behind.

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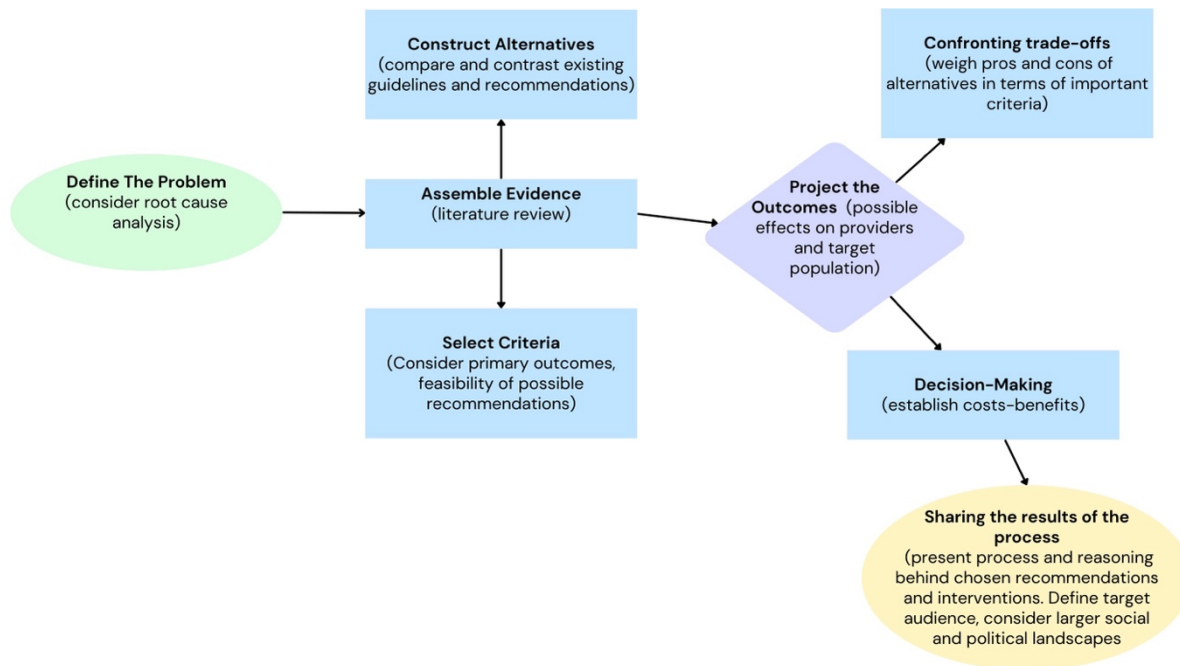
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Bardach Policy Framework



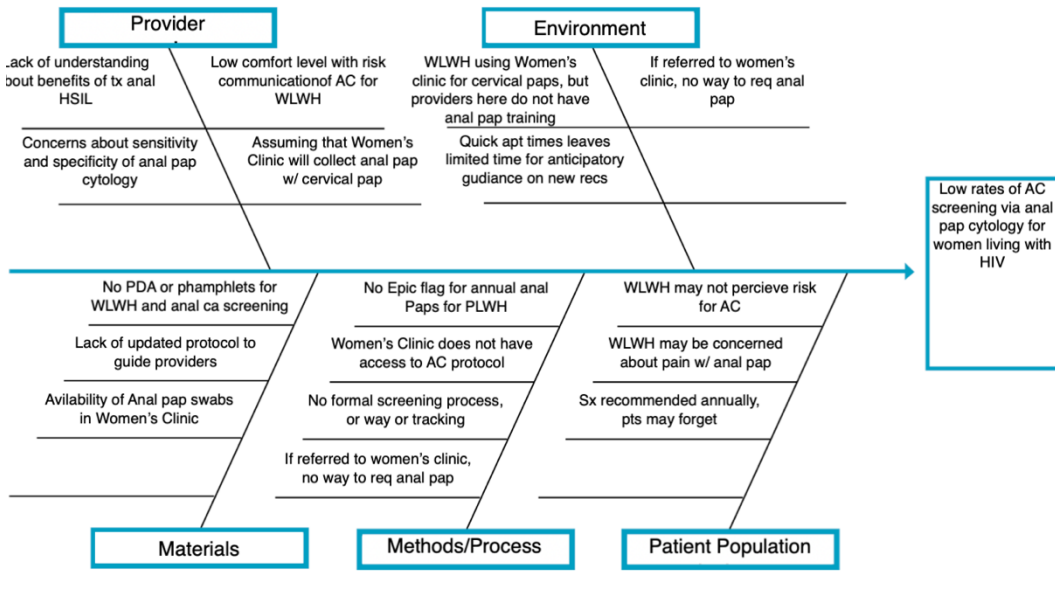
(Graphic created by the author of this QI project; information adapted from Bardach & Patashnik, 2023 and Engelman et al., 2019)

Root Cause Analysis Diagram

Template: Cause and Effect Diagram

Team: McAllister - DNP-FNP **Project:** DNP Project 703a

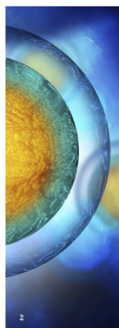
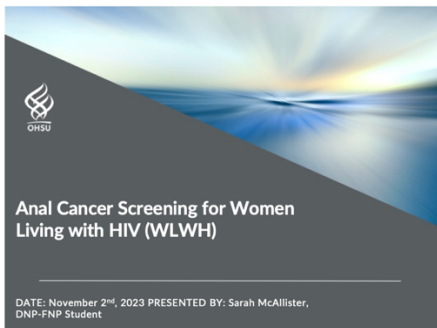
- 1) Input the effect you'd like to influence.
- 2) Input categories of causes for the effect (or keep the classic five).
- 3) Input causes within each category.



Project Timeline

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec- Mar
Finalize project design and approach (703A)	X							
Complete IRB determination or approval (703B)				X				
Phase 1 (703B) <i>Evaluation and Tentative Revisions to Previous AC Screening Recommendations</i>					X	X		
Phase 2 (703B) <i>Educational Presentation for the Women's Clinic and Surveys</i>							X	
Phase 3 (703B) <i>Evaluation of Survey Results and Formation of Educational Tool</i>							X	
Phase 4 <i>Final Revisions to Recommendations and Submission to Best Practice Panel</i>							X	X (Dec)
Final Data analysis (703B)								X
Write sections 13-17 of final paper (703B)								X
Prepare for project dissemination (703B)								X

Presentation for Women's Clinic



Local Problem Description

- Lower than expected rates of AC precursor screening for HIV positive patients, in particular WLWH
- WLWH seen by both [redacted] Team and [redacted]; missed opportunities for both
- [redacted] needs updated AC Screening Recommendations
- Would like to know what other departments are discussing or practicing who care for similar patients



Objectives

- Provide guidance on screening for Anal Squamous Cell Carcinoma (anal SCC) among WLWH
 - Epidemiology of Anal Cancer
 - Identify high risk groups
 - Evidence for screening
 - How to perform Anal Pap test
 - Managing results

3



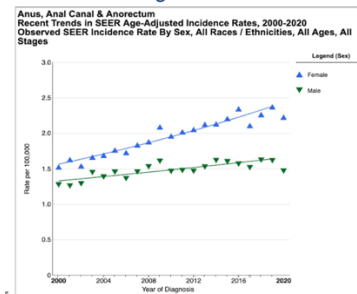
Anal Cancer Quick Facts

- Anal SCC make up 90% of all anal cancers^{1,2}
- 90-100% of Anal SCC is HPV positive; most common genotypes = 16/18^{2,3}
- Immunosuppression confers greatest risk⁴
- Majority of anal HSILs are *asymptomatic*^{5,6}
- Some predictors of progression^{4,6} =
 - Older age
 - Persistent HPV infection
 - Larger lesion size

4



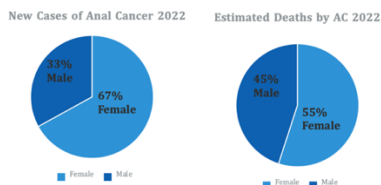
AC Incidence Rising⁷



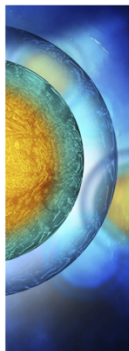
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Differences by Sex for Estimated New Cases and Deaths⁸



6

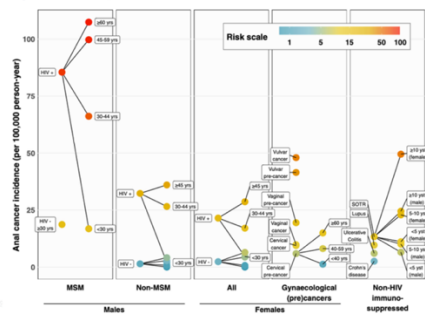


Evidence for Screening for AC and Treating Precursors

- ANCHOR Study⁹ (2022): "Anal Cancer/HSIL Outcomes Research Study (ANCHOR)"
 - A pivotal RCT Study in managing HSIL among HIV+ persons.
 - Results: Treating HSIL in HIV+ persons, mainly through ablation, significantly reduced incidence of SCCA by 57%



High Risk Groups⁴



7

Guidelines?

- **Currently NO national consensus guidelines**
- Regional and professional recommendations exist, but all vary
- For now → Focus on HIV positive patients

Society/Institute Recs that favor cytology

PLWH	New York State Department of Health AIDS Institute 2022 ¹⁹ Infectious Disease Society of America: Primary Care Guidance for Persons with HIV 2020 ²¹
Others	The American Society of Colon and Rectal Surgeons 2018 American Society of Transplantation Infectious Disease Community of Practice 2019 International Anal Neoplasia Society (Pending)



Recommendations for Screening

- **Before Screening** = Shared Decision Making Conversation

Screening Process:

- Step 1: Assess Anal SCC symptoms
- Step 2: Preferred method = Anal cytology with high-risk HPV test
 - DARE can be considered in conjunction, always after anal pap
- Step 3: Management anal cytology results
- Step 4: If indicated, referral to HRA



Screening Recommendations for WLWH

WHO to Screen?

- Offer screening at baseline and annually for:
- All HIV positive women
- Consider these risk factors when screening WLWH:
- Hx of biopsy diagnosed HPV mediated vulvar HSIL and vulvar cancer
 - Hx of high risk HPV infection
 - Hx of genital condylomas
 - Persistently low CD4 counts
 - *Older age

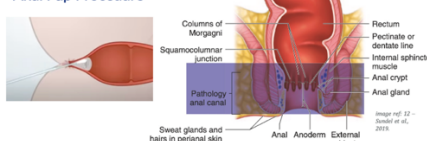
Who NOT to screen?

- Do not offer screening to:
- Pts with life expectancy <10 years
 - Pts who cannot access or will not follow-up with HRA for abnormal results
 - Pts w/ established dx of anal dysplasia (but should be referred to HRA clinic if not already)

*AGE: Due to lack of evidence, no recommendation what age to begin or end AC screening
When to begin: reasonable to start >35 years old
When to end: consider ending when life expectancy <10 years



Anal Pap Procedure

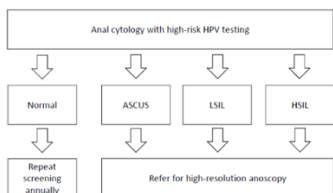


1. Preferred position = lithotomy
2. Use Dacron swab (polyester tipped with plastic shaft)
3. Moisten swab tip with water; *no lubricant*
4. Gently insert to pectinate line = approx 1-2 inches
5. Slowly withdraw while rotating and applying pressure to anal canal
 - Take 30 seconds (UCSF recommendation)
 - Pressure should slightly bend swab
6. 30 second swish in BD SurePath 10 mL collection vial

Anal Pap Cytology Procedure video: <https://www.youtube.com/watch?v=im5216d4kAb>, Shannell West Coast Pathology Lab



How to manage results?

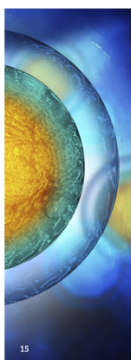
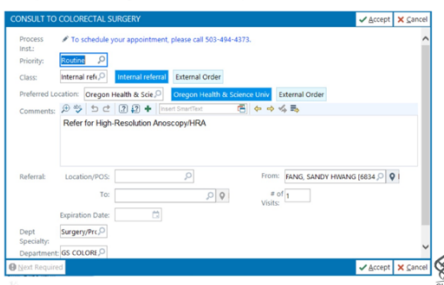


ASCUS = Atypical squamous cells of undetermined significance
LSIL = Low-grade squamous intraepithelial lesion
HSIL = High-grade squamous intraepithelial lesion



Referral to HRA

*All patients with greater than or equal to ASCUS



Recs for pts who decline cytology

- Perianal inspection and annual Digital Anorectal Exam (DARE)
- Counsel patients to report new symptoms including rectal bleeding, mass/lumps, pruritus, or discharge
- Routinely ask about new symptoms at visits



Digital Anorectal Exam (DARE)

- DARE is used to detect anal cancer, NOT a screening tool for anal dysplasia
- Additional invasive procedure w/ low specificity and sensitivity for anal cancer
 - Can only detect gross, palpable lesions
- OHSU Tabor clinic recommends for WLWH:
 - Can consider in conjunction with anal cytology, especially if new symptoms
 - Perform AFTER anal cytology
 - Consider annually for pts who decline anal cytology or will not follow-up with HRA for abnormal results



Provider and Patient Resources

For Providers:

- Anal Pap Cytology Procedure video - https://www.youtube.com/watch?v=aivef52Hg6s&ab_channel=WestCoastPathologyLabs
- NYSHDAI 2022 Guideline - <https://www.hivguidelines.org/guideline/hiv-anal-cancer/>

For Patients:

- UW – HPV and Anal Pap Testing - <https://patient.uwhealth.org/healthfacts/7056>
- Johns Hopkins HRA for pts: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/anoscopy-high-resolution-anoscopy>
- NYSDH: HPV facts and testing: <https://www.health.ny.gov/publications/3837.pdf>



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OHSU

Thank You

Appendix E

Pre and Post Intervention Surveys

1. Are you a medical doctor (MD), nurse practitioner (NP), or physician's assistant (PA), Other?

- 1 Medical Doctor
- 2 Nurse Practitioner
- 3 Physician's Assistant
- 3 Other:

2. What is your practice specialty?

- 1 Primary Care Physician
- 2 Infectious Disease Physician
- 3 OB/GYN
- 4 Other (specify):

3. Which characteristics of patients are considered high-risk for anal cancer? (MAY CHECK MULTIPLE BOXES)

- 1 HIV-positive
- 2 Organ transplant recipient
- 3 Men who have sex with men (MSM)
- 4 History of vulvar dysplasia
- 5 History of anal condyloma
- 6 History of vulvar condyloma
- 7 HPV-positive

4. Please rate to what extent you agree with the following statements

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
I feel comfortable talking with patients about anal cancer risk and screening methods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am willing to screen women living with HIV who are asymptomatic for anal cancer with anal pap cytology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am open to offering anal pap tests for other high-risk groups of women	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel confident knowing when to refer patients for High Resolution Anoscopy (HRA)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

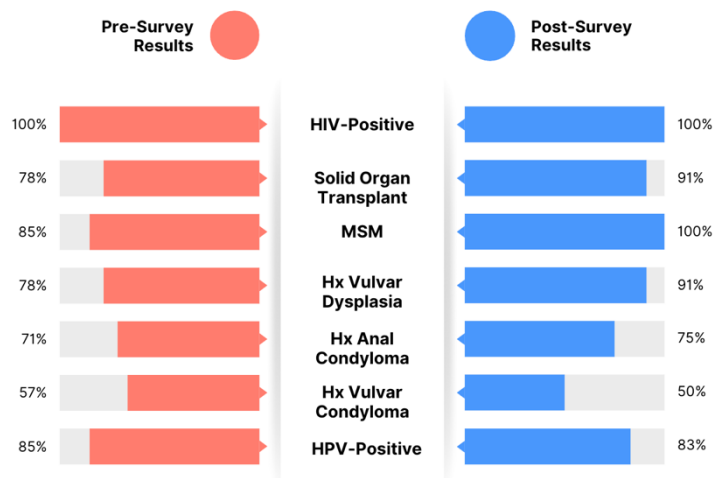
5. Do you have additional comments, questions, feedback?

Appendix F

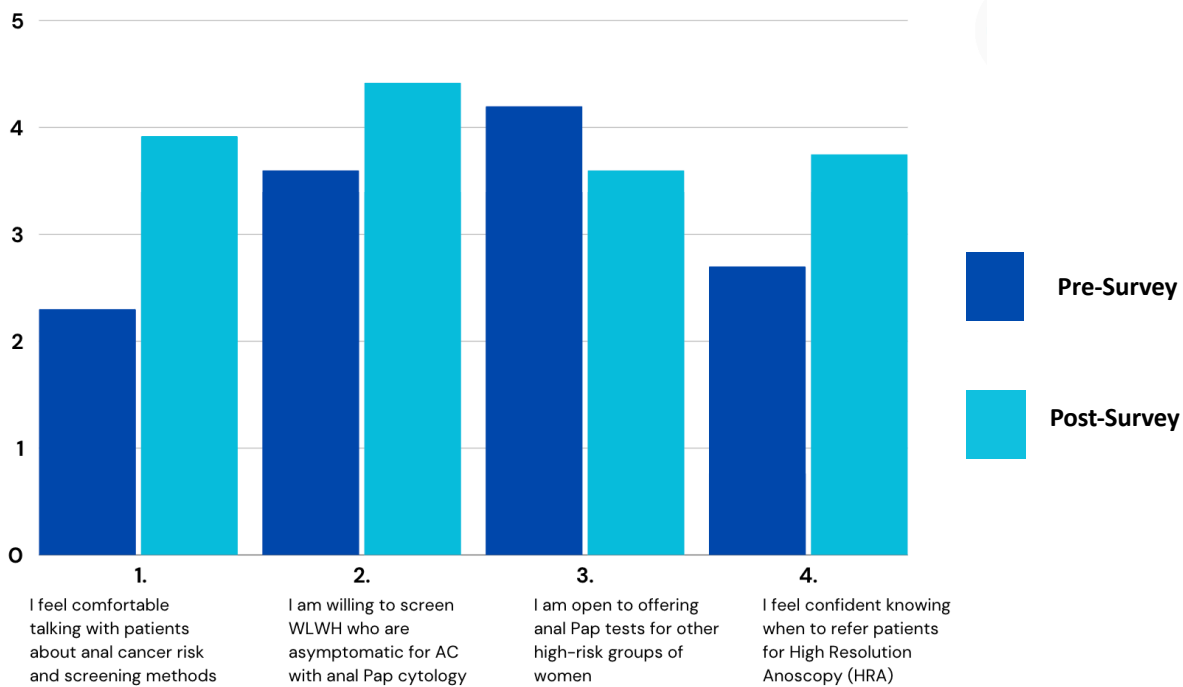
Survey Results

Pre-Survey N = 14; Post-Survey N = 12

Identifying Risk Factors for AC



Provider Practice Related Questions



Key (Y-axis)

1= Strongly Disagree 2=Somewhat Disagree 3=Neither Agree nor Disagree 4=Somewhat Agree 5= Strongly Agree

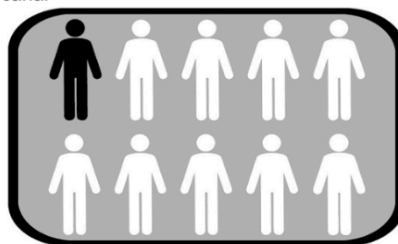
Appendix G

Patient Education tool

Anal Cancer Screening at OHSU for People Living with HIV

Quick Facts

- Anal cancer occurs in the tissues surrounding the anal canal
- People living with HIV are at the highest risk for anal cancer
 - 1 in 10 HIV positive men who have sex with men will develop anal cancer in their lifetime
 - Among female and transgender people, the life-time risk is currently unknown, but likely high
- 90% of anal cancer is caused by the HPV virus
- Screening with anal pap smear helps detect pre-cancer cells
- Removing pre-cancer cells *greatly* reduces a person's risk of developing anal cancer by nearly 60%
- HPV Vaccination: if given *before* exposure to HPV, can prevent HPV infection and most anal cancers



Risk Factors

- Lowered immune system (examples: HIV/AIDS and solid organ transplant)
- Chronically low CD4 counts
- History of infection with HPV
- History of vulvar pre-cancer or cancer caused by HPV
- History of anal receptive intercourse and/or multiple sexual partners
- History of anal warts
- Older age (>60 years old)
- Tobacco smoking

Preventing Anal Cancer

- Get the HPV vaccine before exposure! Recommended in childhood or <26 yo. Safe and approved until 45 yo, but less likely to work if already exposed
- Use condoms during sex
- Don't smoke, or quit smoking

Screening for anal precancer and cancer

How? A provider performs an anal pap smear (a small swab rubbed against the skin inside the anus) to check for abnormal cells and the HPV virus. No special preparation is needed.

Who and how often? Recommended annually for all patients who are HIV positive and >30 years old, or sooner if a person has more risk factors or new symptoms.

What about results? There are several kinds of pre-cancer cells, but for any positive result showing abnormal cells and/or HPV, the next step is for an outpatient procedure called high resolution anoscopy (HRA). This is performed by a different provider who looks at the skin of the anus more closely and can take a biopsy and/or remove pre-cancerous cells.

Who should not have the anal pap done? Patients who cannot or will not access follow-up HRA service. Patients who have an established pre-cursor lesion should go straight to HRA and/or be seen by a specialist.

Patient Resources

- UCSF anal cancer overview: <https://ancre.ucsf.edu/anal-cancer-overview>
- ANCHOR Study FAQs with excellent anal cancer overview: <https://anchorstudy.org/frequently-asked-questions>

Appendix H

Letters of Support from Clinical Sites

Letter of Support from Clinical Agency

Date: [8/7/2023]

Dear Sarah McAllister,

This letter confirms that I, Jonathan Soffer DNP, ANP, allow Sarah C. McAllister (OHSU Doctor of Nursing Practice Student) access to complete her DNP Final Project at our clinical site. The project will take place from approximately September 25th, 2023 to January 31st, 2024.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s):**
 - XXXXXX
 - XXXXXX
- **Project Plan:** Use the following guidance to describe your project in a brief paragraph.
 - **Identified Clinical Problem:**
 - Need a more comprehensive and accessible local protocol for AC screening recommendations among people living with HIV (PLWH), and one with specific guidance on women living with HIV (WLWH). A need for provider education regarding the recommendations, recent evidence regarding the benefits of anal pap screening, and anal pap skills review.
 - **Rationale:**
 - This QI project is guided by the CDC's Policy Analytical Framework, an established model for health policy identification, analysis, development, and implementation. As per the framework's first domain, Problem Identification, stakeholders were consulted and a root cause analysis was performed. The process revealed a need for more comprehensive and current organization-based recommendations for anal SCC screening among WLWH that are accessible and meaningful to both [redacted] and [redacted] women's health, and a need for provider awareness and education about the recommendations. The literature review showed the importance of provider education about anal SCC risk, screening, and treatment in WLWH. Thus, the primary intervention of this QI project is an educational presentation on the current evidence for anal SCC screening and precursor treatment, and the revised policy, to improve the knowledge, comfort, and practices of providers caring for WLWH.
 - **Specific Aims**
 - The first aim is to analyze and revise the organization's anal cancer screening guideline for PLWH and scaling the policy from the primary clinic to the women's clinic. The second aim is to evaluate provider's current knowledge and practices. The third aim is for providers caring for WLWH to report an improvement of their Anal Cancer screening knowledge, practices, and comfort level after an educational presentation in November 2023
 - **Methods/Interventions/Measures:**
 - Epic data analysis retrospective review
 - Policy evaluation, revision, and expansion
 - Pre-survey assessment of provider knowledge, attitudes, and practices 1 month prior to and then just prior to educational presentation
 - Provider education through presentation
 - Post-survey after 30 min education session
 - **Data Management:**
 - All data collected during the project will be anonymous and/or de-identified. Data from the epic analysis will be collected and transcribed into Microsoft Word and Microsoft Excel. Surveys will be sent to providers via email through Qualtrics.
 - **Site(s) Support:**

- This site will allow access to clinic screening materials, policies, and provider lists. Additionally, this site will authorize a pre and post survey to providers and an educational presentation during a scheduled staff meeting.

During the project implementation and evaluation, Sarah C. McAllister will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Sarah C. McAllister and Jonathan Soffer (student's DNP Project Chairperson).

Regards,

Jonathan R Soffer, ANP, DNP soffer@ohsu.edu 503-494-8311

DNP Project Preceptor (Name, Job Title, Email, Phone): _____

Jonathan R Soffer, ANP, DNP 8/10/23

Signature Date Signed

Letter of Support from Clinical Agency

Date: [8/7/2023]

Dear Sarah McAllister,

This letter confirms that I, Dr. Amie Leaverton, allow Sarah C. McAllister (OHSU Doctor of Nursing Practice Student) access to complete her DNP Final Project at our clinical site. The project will take place from approximately September 25th, 2023 to January 31st, 2024.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s):**
 - [redacted]
- **Project Plan:** Use the following guidance to describe your project in a brief paragraph.
 - **Identified Clinical Problem:**
 - Need a more comprehensive and accessible local protocol for AC screening recommendations among people living with HIV (PLWH), and one with specific guidance on women living with HIV (WLWH). A need for provider education regarding the recommendations, recent evidence regarding the benefits of anal pap screening, and anal pap skills review.
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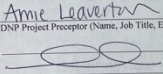
During the project implementation and evaluation, Sarah C. McAllister will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Sarah C. McAllister and Jonathan Soffer (student's DNP Project Chairperson).

Regards,

Amie Leaverton

DNP Project Preceptor (Name, Job Title, Email, Phone): _____

 8/28/2023

Signature Date Signed

Appendix I

IRB Letter of Approval



IRB MEMO

Research Integrity Office

3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

September 8, 2023

Dear Investigator:

On 9/8/2023, the IRB reviewed the following submission:

Title of Study:	Improving Provider Knowledge About Anal Cancer Screening for Women Living with Human Immunodeficiency Virus: A Quality Improvement Project
Investigator:	Jonathan Soffer
IRB ID:	STUDY00026233
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research website](#) and the [Information Privacy and Security website](#) for more information.

Sincerely,

The OHSU IRB Office