

January 11, 2023

Carol M. Mangione, MD MSPH
Chair
United States Preventive Services Taskforce
USPSTF Program Office
5600 Fishers Lane,
Mail Stop 06E53A,
Rockville, MD 20857

SUBMITTED ELECTRONICALLY

Dear Dr. Carol M. Mangione, MD MSPH:

Whitman-Walker Health and Whitman-Walker Institute (Whitman-Walker or WW) are pleased to submit these comments in response to the United States Preventive Services Taskforce proposed research plan to assess the efficacy of anal cancer screenings. Whitman-Walker supports the proposed research plan. The plan is well calibrated to collect evidence of the efficacy of anal cancer screenings and collect the necessary research to determine the relative costs, risks, and benefits of anal cancer screenings in populations of asymptomatic adults within populations of increased risk for anal cancer.

Interest and Expertise of Whitman-Walker:

Whitman-Walker Health is a Federally Qualified Health Center serving greater Washington, DC's diverse urban community, including individuals who face barriers to accessing care, and with a special expertise in HIV care and serving lesbian, gay, bisexual, transgender and questioning/queer (LGBTQ) populations.

Whitman-Walker has been a nationally recognized leader in LGBTQ+ community health for almost four decades. In calendar year 2021, we provided health care to over 16,000 patients. In 2021, about 50% of our patients identified as Lesbian, Gay, or Bisexual and 14% as Transgender.

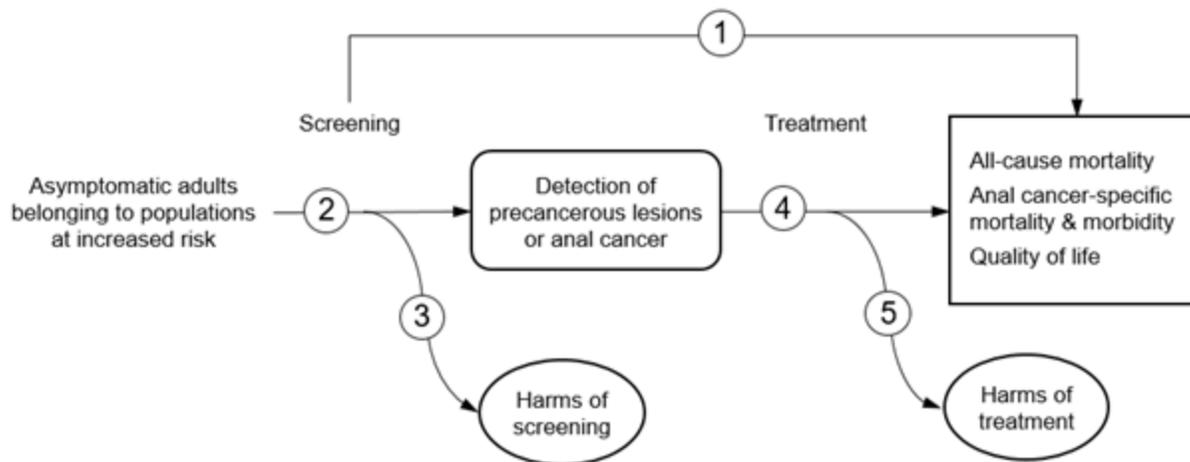
Whitman-Walker Health received the National Committee for Quality Assurance's (NQCA) Patient-Centered Medical Home (PCMH) Recognition. This recognition shows Whitman-Walker uses evidence-based and patient-centered processes to serve patients. These practices focus on highly coordinated care and long-term relationships. Whitman-Walker's medical teams are recognized at the highest level of this recognition at all our care center sites.

Whitman-Walker Institute conducts research, advocates for just and inclusive policies, and engages in clinical and community education to advance the health and wellness of communities of LGBTQ people and people living with HIV. Institute researchers, educators and policy

advocates work closely with the over 200 Whitman-Walker Health providers to enhance the impact of their healthcare delivery and to ensure that direct health care, research, education, and public policy mutually reinforce each other. The Institute’s large and growing Research Department currently has more than 2,500 participants in 40+ active studies. Recent research projects include collaborations with several other large LGBTQ-focused health centers to identify and address the health needs of marginalized communities.

Comments on the Proposed Data Collection

Proposed Analytic Framework



Do you have any comments about the Analytic Framework?

I agree with it; I have no comments.

Proposed Key Question 1: Does screening for anal cancer in high-risk persons change all-cause mortality, anal cancer-specific mortality or morbidity, or quality of life?

I agree with it; I have no comments.

Proposed Key Question 2: What is the accuracy of screening tests for anal cancer?

I agree with it; I have no comments.

Proposed Key Question 3: What are the harms associated with screening for anal cancer?

I agree with it; I have no comments.

Proposed Key Question 4: What is the effectiveness of treatment of anal intraepithelial neoplasia and early-stage (Stage I), localized anal cancer?

I agree with it; I have no comments.

Proposed Key Question 5: What are the harms associated with treatment of anal intraepithelial neoplasia, high-grade squamous intraepithelial lesions, and early-stage (Stage I), localized anal cancer?

I agree with it; I have no comments.

Proposed Contextual Question 1: Does screening for anal cancer in high-risk persons change the incidence of anal cancer and the distribution of cancer types and stages (i.e., stage shift)?

I agree with it; I have no comments

Proposed Contextual Question 2: What is the magnitude of change in all-cause and anal cancer-specific mortality that results from a specified change in anal cancer incidence (and change in distribution of anal cancer stages [i.e., stage shift]) after screening?

I agree with it; I have no comments

Proposed Contextual Question 3 What risk assessment tools are available for use in primary care to identify adults at increased risk for anal cancer?

I agree with it; I have no comments

Proposed Approach to Assessing Health Equity and Variation in Evidence Across Populations

To the extent possible, we plan to describe the population, screening, and intervention characteristics of the included studies. Data on population characteristics will help us explore the degree to which the findings are representative of persons at risk for anal cancer as well as investigate potential differences in benefit and harms by different population groups. These groups include, but are not limited to, categorizations by age; racial, ethnic, and cultural identity; behavioral risk factors; and chronic health conditions.

Do you have any comments about the Approach to Assessing Health Equity and Variation in Evidence Across Populations?

As always, research reviews run the risk of excluding people that are underrepresented in the literature. People living in poverty, with limited access to transportation, time, and money will consequently be underrepresented in research literature. Thankfully, most of the recent research studies have improved their racial diversity racial breakdown. Additionally, research data on populations of men who have sex with men is available. Comparatively, there is not much data on transgender men and women. Despite these gaps in existing literature, we encourage the USPSTF to create a research plan and issue recommendations that can benefit underserved communities.

The Proposed Research Approach identifies the study characteristics and criteria that the Evidence-based Practice Center will use to search for publications and to determine

whether identified studies should be included or excluded from the Evidence Review. Criteria are overarching as well as specific to each of the key questions.

Category	Include	Exclude
Populations	<p>KQs 1, 3: Asymptomatic adults (age ≥ 18 years) with an increased risk of anal cancer (e.g., persons living with HIV, men who have sex with men, persons engaging in anoreceptive intercourse, and immunocompromised persons)</p> <p>KQ 2: Studies of adults with AIN are also eligible</p> <p>KQs 4, 5: Adults with AIN or early-stage (Stage I) anal cancer</p> <p>All KQs: Specific populations of interest include persons living with HIV, men who have sex with men, persons engaging in anoreceptive intercourse, and immunocompromised persons</p>	<p>KQs 1, 3: Children; persons with symptoms of anal cancer; other populations in which testing for anal cancer may be considered part of disease management, such as persons with HPV-related cancers and cancer precursors (i.e., HSILs)</p> <p>KQ 2: Children</p> <p>KQs 4, 5: Children; persons with nonprimary anal cancer or other than Stage I anal cancer</p>
Screening	<p>KQs 1, 3: Anal cytology, HPV testing, or anal cytology with HPV co-testing; studies may also incorporate visual inspection and digital anorectal examination. Anal cytology involves a Pap test sampling cells inside the anus. These screening tests may be followed by other tests for diagnostic evaluation, including anoscopy or proctoscopy, HRA, ultrasound (endoanal or endorectal), or biopsy</p> <p>KQ 2: Anal cytology, HPV testing, or anal cytology with HPV co-testing</p>	No screening; other screening modalities
Interventions	<p>KQs 4, 5: Surgical excision, ablation (e.g., chemical ablation with trichloroacetic acid), fulguration, laser therapy, topical</p>	<p>KQs 4, 5: Chemotherapy, radiation therapy, or natural therapies</p>

	immunomodulator therapy (e.g., imiquimod topical cream), or topical 5-fluorouracil	
Comparisons	<p>KQs 1, 3: No screening, usual care</p> <p>KQ 2: Biopsy</p> <p>KQs 4, 5: No treatment, usual care, or no comparison</p>	Studies without a comparison group; comparative effectiveness studies (head-to-head studies comparing treatments)
Outcomes	<p>KQ 1: All-cause mortality, anal cancer-specific mortality and morbidity, and quality of life</p> <p>KQ 2: Sensitivity and specificity of anal cytology with or without HPV co-testing</p> <p>KQ 3: False-positive results, irritation, pain, bleeding, overdiagnosis, psychosocial harms, and additional tests and subsequent harms (e.g., biopsy causing an adverse event)</p> <p>KQ 4: Incidence of anal cancer (all stages), distribution of cancer types and stages, all-cause mortality, anal cancer-specific mortality and morbidity, and quality of life</p> <p>KQ 5: Irritation, pain, bleeding, erosions, anal fissures, anal stenosis, altered bowel functioning (e.g., incontinence), altered urinary functioning, and altered sexual functioning</p>	Cost
Study designs	<p>Controlled trials are eligible for all KQs</p> <p>KQ 2: Studies evaluating accuracy are also eligible</p> <p>KQs 3, 5 (harms): Prospective cohort studies and case-control studies are also eligible</p>	All other study designs

Study duration	Any length	
Settings	Published in or after 2000	Published before 2000
Countries	Studies conducted in countries categorized as “Very High” on the Human Development Index (as defined by the United Nations Development Program)	Studies conducted in countries that are not categorized as “Very High” on the Human Development Index
Language	English	Non-English
Study quality	Good or fair	Poor (according to design-specific USPSTF criteria)

Abbreviations: AIN=anal intraepithelial neoplasia; HIV=human immunodeficiency virus HPV=human papillomavirus; HSIL= high-grade squamous intraepithelial lesion; HRA=high-resolution anoscopy; KQ=key question; USPSTF=U.S. Preventives Services Task Force.

Populations: For excluded populations: The research plan should not exclude research on people with HSILs. There is much research on the benefits of anal cancer screening on people with HSILs. For example, the ANCHOR study provides evidence of the benefit of anal cancer screenings for people living with HIV, and might be excluded from the research plan because it included only people with HSILs.

Outcomes: For outcomes of interest in K5, we recommend including psychosocial harms and benefits. There is probably more anxiety and stress around diagnosis, but screening also causes emotional and physical stress. Additionally, there are potential positive quality of life outcomes around screening, such as peace of mind gained from screening.

Language: There is a lot of research done out of Spain, so please clarify that studies published in English Language journals by non-English language teams of researchers will be included.

CONCLUSION

Whitman-Walker appreciates this opportunity to provide comment on the research plan. Please feel free to contact us if we can be of assistance in any other way.

Respectfully submitted,



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