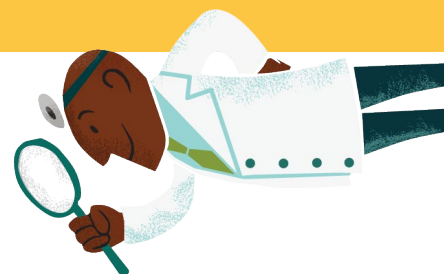


New guidelines for anal cancer screening are possible because of you!



Thanks to you and the work of our entire research team, the ANCHOR Study's results have led to a change in medical care for people with HIV in the United States!

The U.S. Centers for Disease Control (CDC) is working to release updated guidelines on managing opportunistic infections in people with HIV, which we expect will include recommendations to screen for and treat anal high grade squamous intraepithelial lesions (anal HSIL) in people with HIV. Anal HSIL is abnormal tissue on the anal skin caused by the human papillomavirus, or HPV, which can progress to anal cancer.

The International Anal Neoplasia Society (IANS), a group of medical experts focused on anal HSIL and anal cancer prevention, has also just published guidelines recommending anal cancer screening in groups of people at high risk for anal cancer. You can read the IANS guidelines at: <https://pubmed.ncbi.nlm.nih.gov/38297406/>.

Anal cancer is the fourth most common cancer in people with HIV, so it's a meaningful change for people and their providers to know that we can help prevent it. This change is because of you, so thank you for your participation in ANCHOR and making this change happen!

Not every clinical trial is a success. Even fewer studies result in changes to healthcare offered that can prevent illnesses like cancer. We are honored to share in this success with you, and to serve our patients with information that improves medical care. We truly appreciate your partnership with the study over the years!

Joel Palefsky, MD
Protocol Chair

Hillary Dunlevy, MD, MPH
Protocol Co-Chair

Julia Pugliese, MPH
Project Director

ANCHOR study visits ended March 31, 2024

If you haven't talked to your local ANCHOR study team recently, we want to be sure you heard: **ANCHOR study visits ended March 31, 2024.**

The study closed to follow up because we have answered the main research question: anal HSIL treatment reduces the risk of cancer by 57%. See our website, www.anchorstudy.org, for more

information on the study results, a link to the paper in the *New England Journal of Medicine*, and patient-friendly materials that explain the results.

Now that anal HSIL screening and treatment is standard care for people with HIV, we expect that other providers will offer this care more routinely, outside of a clinical trial. Your study team will provide you a follow-up care plan to continue monitoring you for anal HSIL outside of this trial. We encourage you to follow the specific recommendations from your study site for your ongoing anal HSIL care. Treatment is recommended

if your HSIL comes back at any time. Contact your research team if you have any questions about your care plan after the study.

What do the new guidelines mean for all people with HIV?

These new guidelines affect people with HIV who have not yet been screened for anal HSIL. The International Anal Neoplasia Society (IANS) now recommends that all people with HIV over certain ages get screened for anal HSIL and anal cancer. This is based on how often anal cancer occurs in each group:

- Men who have sex with men (MSM) age 35+
- Transgender women age 35+
- Men (not MSM) age 45+
- Women age 45+

Screening involves a digital anorectal exam and an anal swab. If any screening test is positive for potential signs of anal HSIL, high resolution anoscopy (HRA) is recommended. The provider will take a biopsy of any abnormal-looking areas. If the provider finds HSIL, treating it is now recommended because of the ANCHOR Study's findings. If none of the person's screening tests are positive, they should return for screening in the next 12-24 months.

We expect that the Centers for Disease Control (CDC) will soon make similar recommendations. Once this happens, insurers may change how they cover or pay for these procedures. People with HIV should talk to their provider for more information regarding anal cancer screening as part of routine medical care.

A note to participants from our Community Advisory Board (CAB)

The ANCHOR CAB is a group of volunteer study participants and community advocates who advise the study team to plan and run the study with participant perspectives in mind. We have worked with the research team from the beginning and are also very pleased to share in the study's success. The ANCHOR CAB was instrumental in ensuring the \$100 ClinCard payments for each study visit continues through the final visit and ensuring a research summary is given to each participant after their final visit, among other recommendations.

Most of all, we thank our fellow study participants for making the study's success possible. We know firsthand it isn't always easy to make time for study visits and provide extra samples for research. But our choices to stay in this study have collectively made a real improvement in medical care, which will now be offered to all people with HIV. We hope that putting in the time for study visits has also made a positive difference for your health. Every sample and every visit counts toward the study outcomes, and we couldn't have done this without you.

We look forward to further findings from this study on how to best prevent anal cancer in people with HIV. Some members of the ANCHOR CAB are continuing to advise as new studies are planned. We are always happy to speak to participants to ensure your concerns are heard and addressed. If you would like to reach out, contact us through the study website at: <https://anchorstudy.org/cab>.

In partnership,
Michael Dorosh, ANCHOR CAB Chair

What's next for ANCHOR and anal HSIL research?

Treatment of anal HSIL in the ANCHOR Study was successful in reducing progression to anal cancer. However, we want to do even better and develop newer treatments for anal HSIL that are even more effective and tolerable for patients. Please consider taking part in new treatment studies with the AIDS Malignancy Consortium (AMC). Check out the AMC website, www.aids cancer.org, for more information.

Our next steps for ANCHOR are to run laboratory tests that can help tell us what factors may mean anal HSIL is most likely to stay unchanged, go away on its own, or develop into cancer. These tests will be done on the samples (blood and swabs) already collected for this study. We also want to find the best ways to screen for and treat anal HSIL, and how often this care should be given.

We will share information on what we learn from these lab tests on our website, www.anchorstudy.org. See our news section for updates as we publish our findings, and as new studies open to research improving anal HSIL care.

Anal HSIL signs and symptoms to watch for

If you notice any changes in your anal area, like:

- Pain
- Bleeding
- A lump or hard mass

Call your healthcare provider right away! These are signs that you may need to have an exam as quickly as possible. The provider will also offer treatment to help with these symptoms.

Resources for navigating insurance coverage

We understand that dealing with insurance coverage can be difficult, and that things may be different for your cost coverage outside of the ANCHOR study. That's why we are sharing resources through our website for challenging insurance coverage for anal HSIL and cancer screening procedures.

We have developed template letters for your use to appeal (challenge) an insurance coverage denial for anal HSIL screening, follow-up, or treatment. These materials are based on resources and a guide from the *Patient Advocate Foundation*. These letters are pre-populated with justifications for performing anal HSIL screening and treatment in people with HIV, for you to modify for your situation. Letters are available for challenging a denial of coverage, denial of out of network procedures, and a provider's letter of medical necessity. See www.anchorstudy.org for these materials and references that may help you navigate the appeals process.

Thank you for making the ANCHOR Study a success!!!

Thank you very much for your participation in the ANCHOR Study. Please contact your local study site if you can use support in your ongoing medical care for anal cancer prevention.