

What People with HIV and their Providers
Need to Know about
High-Resolution Anoscopy
and Anal Cancer
for the
HIV Community Planning Council
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Disclosures

- I have no significant financial relationships to disclose that would pose a potential conflict of interest.

Yours and Our Mission:
To create the ideal health care system
for people living with HIV/AIDS.

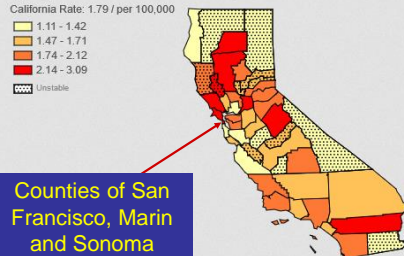
Did you know?

- During 2010-2014, the County of San Francisco had the highest rate of new cases of anal cancer in California.
- San Francisco has the highest number of people living with HIV compared to the rest of the state.
- People with HIV have a much higher risk for anal cancer compared to those without HIV.
- Anal cancer is preventable by early vaccination of boys and girls aged 9-21.
- Anal cancer may be preventable in those not vaccinated but at risk.**

Age-Adjusted Invasive Cancer Incidence Rates in California
Anus, Anal Canal and Anorectum, 2010 - 2014
By County

Age-Adjusted to the 2000 U.S. Standard Population
California Rate: 1.79 / per 100,000

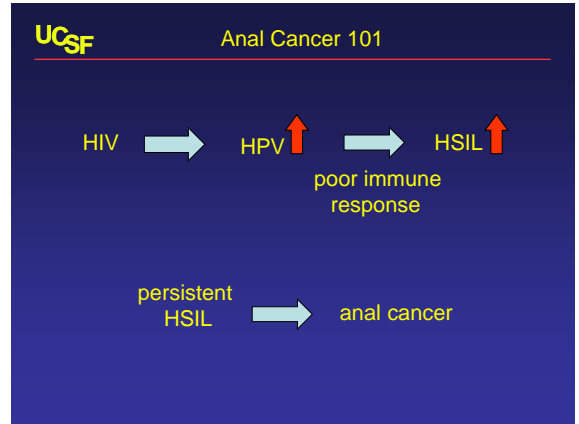
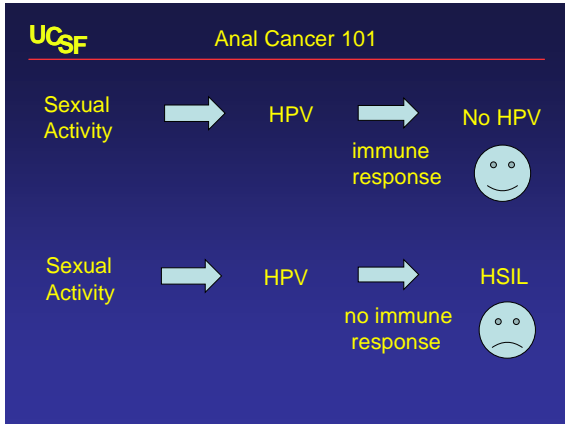
1.11 - 1.42
1.47 - 1.71
1.74 - 2.12
2.14 - 3.09
Unstable



Counties of San
Francisco, Marin
and Sonoma

All rates per 100,000.
Data accessed April 18, 2018. Based on Oct 2016 Extract.
© 2018 California Cancer Registry.





- ### UCSF Case 1
- Too Often ... this Story is Repeated!
 - 44 YO HIV-positive MSM initially followed at SFGH.
 - Treated for potentially precancerous HSIL using IRC in 01/07.
 - Subsequent follow-up over next 3 years was sporadic.
 - He subsequently developed a large painful area on the outside of his anus that was cancer.
 - Treated, but therapy didn't work and he died 8 months later.

UCSF Who is at risk?

	HIV-positive MSM	HIV-negative MSM	HIV-positive Women	Women	Men
Anal Ca incidence/100,000	78-144	35	9.4-30	1.5	1.0
Anal HPV infection	80-95%	60%	66-80%	15-50%	18%
HSIL	50%	24%	9-25%	33-60%	NA

In 2018: estimated that anal cancer will be diagnosed in 8,580 persons 2,960 men and 5,620 women (~4000 when I gave this talk in 2006)

~140,000 cases of colorectal and ~234,000 cases of lung & ~268,000 breast cancer (American Cancer Society Facts and Figures 2018)

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How do we know that HSIL has the potential to turn into cancer?

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Direct Evidence

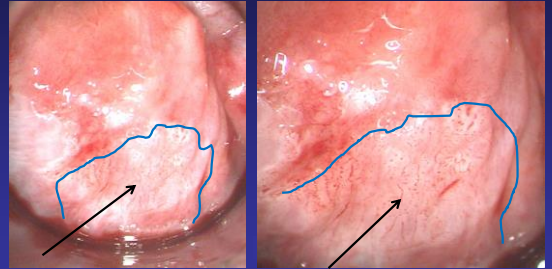
- Early, superficially invasive cancer always develops focally from HSIL.
- Patients who present with new cancers usually have adjacent or surrounding HSIL lesions.
- We reviewed 138 cases of cancer in HIV-positive MSM: 66 had cancer when first seen, 45 had prior HSIL, and it was clearly demonstrated that in 27 ... the cancer developed from a previously biopsied area of HSIL. (**Warning:** picture to follow)

Berry et. al. Int J Cancer. 2014 Mar 1;134(5):1147-55.

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Progression of HSIL to Invasive Cancer

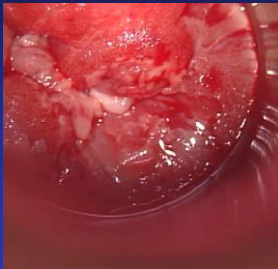
HSIL/AIN 3 November 2001



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Progression of HSIL to Invasive Cancer

SCCA May 2007



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What is high-resolution anoscopy and what do you need to know about this new and exciting procedure?

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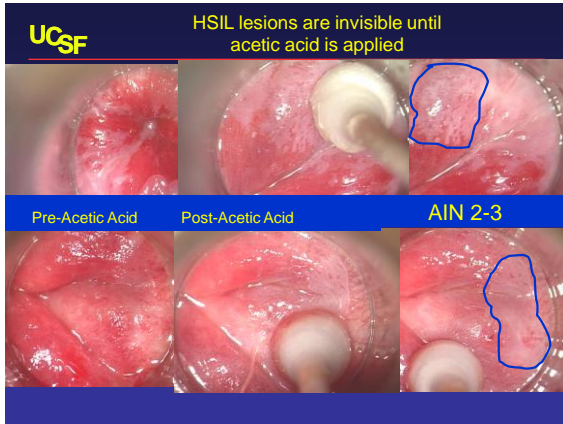
What is high-resolution anoscopy?

- Anus is soaked in 5% acetic acid (vinegar)
- Examined carefully with a colposcope
- Most abnormal appearing areas are biopsied
- Lugol's iodine is used judiciously

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Colposcope & digital video imaging system





UCSF Why is HRA important?

- It's the most effective way of defining and identifying HSIL
- Once HSIL has been confirmed by biopsy, then those lesions can be ablated
- If you can't see it, you can't treat it
- Occasionally HRA-directed biopsies identify cancer

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Is anal cancer preventable?

We don't know yet, but the ANCHOR study is designed to help us find out!

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Anal Cancer Prevention

- There are no guidelines or standards of care for anal cancer prevention.
- We have spent the last 25 years developing a program to maximize our ability to find and treat the HSIL lesions, just the like the gynecologists do to prevent cervical cancer.
- However, currently there is no definitive proof that treating HSIL prevents anal cancer.



Save your HIV+ BUTT

Find out how a simple swab may keep you from getting anal cancer

Joel Palefsky, MD (Principal Investigator)
J Michael Berry-Lawhorn, MD (Protocol Co-Chair)

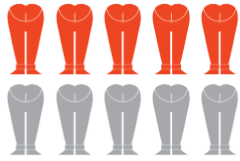
AIDS Malignancy Consortium Protocol A01
Funded by the National Cancer Institute



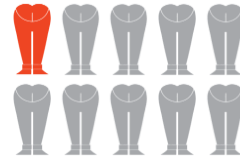
WHAT WE KNOW ABOUT ANAL CANCER

- Anal cancer is more frequent among HIV positive men and women than the general population.
- HIV + MSM are 80 times more likely to develop anal cancer than HIV- men.
- Anal cancer incidence is rising among HIV positive men and women despite HAART.
- Anal cancer is preceded by a precancerous cells called "high-grade squamous intraepithelial lesions" or (HSIL)
- You can be at risk for anal cancer even if you've never had anal sex.

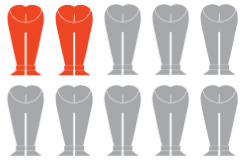
AMONG HIV + Men who have sex with men (MSM),
5 out of 10 HAVE HSIL



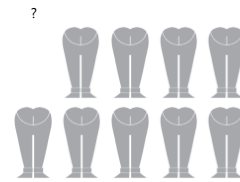
We estimate that 1 in 10 HIV+ MSM
will get anal cancer over their lifetime



AMONG HIV + WOMEN, We ESTIMATE
THAT
2 out of 10 HAVE HSIL



We don't know how many HIV + women
will get anal cancer



WHY THIS STUDY IS NECESSARY

- Although few HSIL will progress to cancer, catching and treating anal cancer as early as possible means
 - fewer side effects from treatment
 - better survival rates, especially for HIV positive men and women
- Currently there is no standard of care for anal HSIL
- Consequently only a few people have access to screening and treatment of HSIL

CERVICAL CANCER SCREENING PREVENTS CANCER

- Current standard of care for cervical HSIL is to remove it. Cervical cancer rates are much lower as a result.
- In countries where cervical Pap smears became routine in 1960s, cervical cancer rates dropped by 70%.



GOALS OF THE ANCHOR STUDY

- Find out if treating anal HSIL prevents anal cancer.
- Understand how HSIL develops and why it sometimes becomes cancer.



WHO CAN JOIN THE STUDY?

Men, Women, and Transgender People who are

- Over 35 years old
- HIV positive
- Have HSIL as determined at a screening visit
- Prior treatment OK if > 6 months
- No history of anal cancer

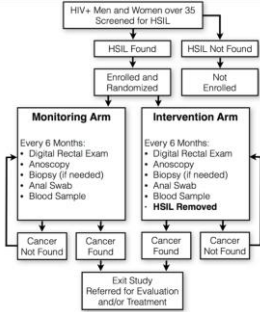
RECRUITMENT GOALS AND STUDY DESIGN

Screen > 17,385

Enroll 5,058

Retain for 5-8 years

Estimated < 50 develop cancer



Study procedures

OVER FIVE YEARS

- Every 6 months: blood draw, 3 anal swabs, high resolution anoscopy, anal biopsies as necessary, a questionnaire
- If in Treatment Arm: Additional treatment visits depending on the treatment used and response to treatment.
- \$100 per visit



ANCHOR SITES



RECRUITMENT MATERIALS



VIDEO



ANCHORSTUDY.ORG

1 844 HIV-BUTT

UCSF Why is the ANCHOR study important?

- We will learn how effective or ineffective treating anal HSIL is in preventing anal cancer.
- If effective, then guidelines/standards of care for all people with HIV can be developed and implemented. If ineffective, then hopefully a better way to screen/early detection.
- Then, the resources necessary to care for all of the people at risk (aging/minorities) affected by HIV can be mandated.

UCSF How can you help?

- Encourage your friends and acquaintances to consider enrolling in the ANCHOR study.
- Encourage all of your care providers to hand out flyers to eligible patients to consider enrolling in the ANCHOR study.
- Help us to fully enroll the San Francisco site as quickly as possible to increase awareness about anal cancer, help people access care, and to learn how best to prevent anal cancer by completing this landmark study.

UCSF Anal Cancer Screening and Prevention

- UCSF Anal Neoplasia Clinic, Research, and Education Center at 1701 Divisadero, Suite 480.
- ZSFGH Anal Neoplasia Clinic meets ½ day per week in Ward 86.
- Kaiser San Francisco and Kaiser Oakland both have HRA clinics and are increasing staffing to meet demand.

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The End!



Thanks for your attention!