Willingness to Join an Anal Cancer Screening and Prevention Trial
Nicolasa Sheon, PhD*; Lance Pollack, PhD*; Joel Palefsky, MD**

*Center for AIDS Prevention Studies, **Department of Infectious Disease, University of California, San Francisco

Introduction

HIV-infected men and women are at elevated risk for developing anal cancer. The AIDS Malignancy Consortium is conducting a five-year randomized, controlled trial to determine whether treatment of anal high-grade squamous intraepithelial lesions (HSIL) can prevent anal cancer. HIV-infected men and women over 35 will be screened and those with anal HSIL will be randomly assigned to have their HSIL removed (intervention arm) or not removed (monitoring arm). Both arms will be monitored for progression to cancer at regular intervals for five years, and cancer incidence in the two arms will be compared. The present study used mixed methods to assess willingness to join the proposed five-year trial among HIV-infected men and women in 20 cities and patients presenting to the UCSF Anal Dysplasia Clinic.

Methods

Qualitative Focus Groups and Interviews
- 30 Focus Groups with HIV+ men and women (n=241) were video-recorded and analyzed using Transana software to explore views on participation in medical research and willingness to join this specific trial ($50 incentive).
- 25 clinicians and case workers were emailed a description of the trial and interviewed by telephone using a structured guide to assess willingness to refer patients to the trial ($100 incentive). All but one were willing to refer patients to the trial.

Quantitative Surveys
- 20 new patients were recruited from the UCSF Anal Dysplasia Clinic for a longitudinal survey about their willingness to participate in the study before and after HSIL diagnosis ($100 incentive for 2 surveys).
- 258 HIV+ Survey Participants recruited from clinics and ASOs in 20 cities completed online survey ($25 incentive).

Demographics

Willingness to Participate
Assuming you had HSIL (high grade anal abnormalities that could progress to anal cancer), what is the likelihood that you would enroll in the study that has been described?

87.1% likely or very likely

How the Trial Was Described
A new clinical trial is being developed for your health and the health of other people. We call this a clinical trial because it will be a scientific study to determine if we can prevent a serious condition, in this case anal cancer. The trial is being conducted by researchers at the UCSF Anal Dysplasia Clinic.

Preference for Study Arm
Pre- and Post-HSIL Diagnosis
We surveyed 20 new UCSF clinic patients (19 male) at two points: time 1 was after initial exam but before HSIL diagnosis, and time 2 was after receiving HSIL diagnosis. Among this population who accepted treatment, when asked which arm they would choose if they had a choice, there was a strong preference for the intervention arm.

Conclusions
- HIV+ men and women reported a desire to join the trial with only slight variations by race/ethnicity.
- Main motivation cited was a sense of gratitude to previous HIV research cohorts and altruism towards the HIV community.
- Even patients diagnosed with HSIL at UCSF clinic were overwhelmingly willing to join study.
- Combined with community-based outreach and education about the high incidence of anal HSIL among HIV-infected men and women, recruitment to the RCT should prove feasible.

Funding
National Cancer Institute, 5R01CA145117, Palo Alto, FL.

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