IMPACT (Investigating Motivations for Participation in Anal Cancer Prevention Trials)

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Project Description

This project is designed to provide information that will be critical to the performance of a pivotal RCT of screening and treatment of anal intraepithelial neoplasia (AIN) to prevent anal cancer. This project will study determinants of participation in an RCT in which 50% of participants with AIN will be screened and treated, and 50% will be observed without treatment. At the end of a 5-year period, the number of anal cancer cases will be compared in both arms.

The IMPACT study will conduct focus groups with ethnically and geographically diverse populations in cities across the US in order to:

- Identify and assess the determinants of provider willingness to refer eligible participants
- Identify and assess the determinants of patient willingness, motivations, barriers, concerns and incentives to participate in the RCT
- Determine the optimum study design, sample size and recruitment strategies based on what we learn

Information gathered from these focus groups and interviews with health care providers will be analyzed and used to develop a national survey for collecting further data relevant to preparation of the RCT. Given the complexities of the underlying clinical issues that might govern willingness to participate, the increasing proportion of underrepresented minorities that comprise the HIV epidemic, and the varying issues around participation that racial and ethnic groups might have, a rigorous study to measure these determinants is critical.

Significance

Anal cancer is a growing problem in the US, increasing by approximately 2 percent per year among both men and women in the general population. It is particularly common among certain high-risk groups such as HIV+ men and women. Among HIV+ individuals, the incidence of anal cancer has continued to increase despite the availability of effective ART. The incidence of anal cancer among people with HIV is higher than cervical cancer was before routine cervical cytology screening was introduced. However, unlike cervical cancer, there are currently no screening recommendations in place for anal cancer.

This study will be essential to planning a large definitive RCT in HIV+ men and women to test whether treatment of anal cancer precursors identified through anal cytology screening can prevent anal cancer. Planned with the assistance of this study, the proposed RCT will establish a standard of care for HIV+ men and women, but will also have wide implications for screening and treatment for HIV- populations, as well as understanding the factors underlying progression to cervical and anal cancer.

Project Recruitment Dates: December 2009 – October 2011
Project End Date: October 2011