

Preparing for adolescent HIV vaccine trials: will adolescent participants experience social harms?

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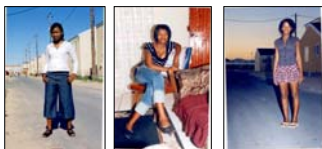
Introduction

High infection rates make adolescents a critical target for HIV prevention research.

Consequently, preparations are underway globally for the initiation of phase I HIV vaccine trials in adolescents.

The risk and implications of social harms resulting from participation have been posited as major challenges to the conduct of HIV vaccine trials in this vulnerable population.

Assessing the likelihood of - and preparing for - this risk is an ethical imperative.



Seen here before the backdrop of the township community in which she lives, Nomsa, member of the Desmond Tutu HIV Centre's adolescent community advisory board, is committed to educating South African youth about HIV vaccine trials

Methods

From 2005 – 2007, an HIV vaccine trial preparatory study was conducted among adolescents from a peri-urban, Xhosa-speaking community near Cape Town, South Africa.

100 adolescents aged 14-17 were enrolled and interviewed 3-monthly for one year.

Social harms data were collected through interviewer-administered surveys.

Crude proportion comparisons for categorical variables were made using the chi² test ($p < 0.05$) of independence to detect trends across multiple levels. All tests were 2-sided.

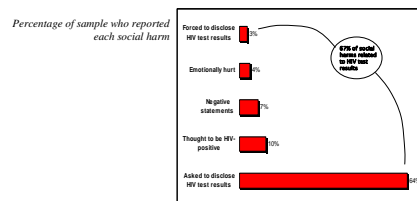
Results

The mean age of participants was 15 years and 70% were female. Retention was 85% at 12 months.

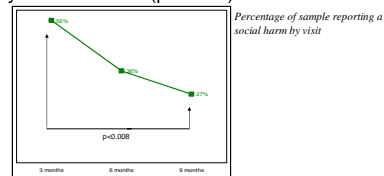
89% had disclosed their participation, and 5% were afraid someone would find out they were participating.

67% reported 1 or more social harm across the study, and the mean number of social harms per participant was 1.72 (range 0 – 7).

The most frequently reported social harm was being asked to disclose HIV test results (64%). Other social harms reported were being thought to be HIV-positive (10%), negative statements made by others (7%), being emotionally hurt (4%) and being forced to disclose HIV test results (3%).



The percentage of participants reporting social harms decreased significantly with each visit ($p < 0.008$).



There was no difference between males and females in terms of ever reporting a social harm, but the mean number of social harms reported was significantly more in females (1.9) than males (1.3) ($p = 0.0424$).



Conclusion

- Adolescents are likely to report large numbers of social harms in HIV vaccine trials, most of which relate to their presumed or actual HIV status. Hence, preparatory and adjunct community education should focus on the HIV-negative criterion for trial participation as well as elimination of stigma and discrimination. In addition, adolescent trials should facilitate disclosure by offering counselling referral services to those who become infected

- Social harms reporting decreased with each visit, meaning that social harms may impact retention. An alternative interpretation is that social harms tend to resolve with time.

- Females report more social harms than males, although this may be a function of reporting rather than experience.

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