

NIMH Project Accept (HPTN 043)

Key Messages

SCIENTIFIC AUDIENCE

NIMH Project Accept (HPTN 043)¹ demonstrated that an intervention with community mobilization, mobile HIV counseling and testing (VCT), post-test support services, and real-time performance feedback improves rates of testing in communities among both men and women in the peak age range for HIV infection (18 to 32 years); reduces HIV risk behaviors, especially among HIV-infected individuals; increases the number of people who know their HIV status; reduces HIV risk behaviors, especially among people with HIV who might otherwise transmit the virus to others, and results in a modest reduction in HIV infection. The intervention was especially effective in reaching men, with both increased HIV testing and greater reductions in HIV risk behavior among HIV-positive men (compared to control communities). No increase in negative effects in communities was found, including increased violence towards women as a result of knowing their HIV status. Inclusion of accessible, community-based VCT is likely to be a key component of an integrated combination approach to HIV prevention and care and suggests that community-wide testing plus treatment programs can potentially be successful.

Summary

- All outcomes were evaluated among community residents of 18 to 32 years of age, not only those who participated in the intervention. All HIV prevention studies to date have measured change in HIV incidence among study participants; thus generalizability of results to entire communities has been limited. NIMH Project Accept measured HIV incidence in a randomly-selected community cohort, and included people who may or may not have participated directly in any of the interventions. Thus, the results evaluate the intervention in the entire community and not only among enrolled participants.
- The intervention resulted in an overall reduction in incident HIV infections of 13.9% (relative risk [RR] = 0.86; 95% confidence interval [CI]: 0.72-1.02; p = 0.08). This reduction was greater in 25-32 year olds (25.4%) (RR = 0.75; 95% CI: 0.54-1.04; p = 0.08) compared to 18-24 year olds (1.6%) (RR = 0.98; 95% CI: 0.80-1.22; p = 0.86).
- The reduction in incidence in women over 24 years of age was 30.2% (RR = 0.70; 95% CI 0.54 - 0.90; p<0.01). There was no change in HIV incidence among women under 24 years of age. There were not sufficient incident infections among men to examine intervention effects by age group.
- The intervention increased HIV testing by 45% among men and 15% among women in intervention communities compared to control communities. Many women had already been tested in antenatal clinics but the increase was still significant; especially important is the ability to reach men who typically have not been reached by HIV prevention interventions.

- The intervention produced an almost four-fold increase in the detection of previously undiagnosed HIV cases at the three sites where differential utilization could be assessed.
- The intervention reduced the number of sexual partners reported by HIV-infected individuals by 8% (95% CI 1%-16%; $p = 0.03$). This effect was primarily due to behavior change among HIV-positive men (18% reduction in the number of partners; 95% CI 5%-28%; $p < 0.01$) rather than among HIV-positive women (2% reduction; $p = 0.40$).
- Multiple sexual partners were reported less frequently among HIV-infected participants in intervention vs. control communities (RR = 0.70; 95% CI 0.54-0.92; $p = 0.01$). This effect was observed primarily among HIV-positive men (RR = 0.71; 95% CI 0.57-0.89; $p < 0.01$) rather than among HIV-positive women (RR = 0.91; 95% CI 0.72-1.16; $p = 0.43$).
- The NIMH Project Accept (HPTN 043) intervention was safe, as measured by the lack of any differences in adverse life events in the intervention as opposed to the control communities.

Study Design

NIMH Project Accept (HPTN 043) is the first community-randomized trial to test a combination of social, behavioral, and structural approaches for HIV prevention, and to assess the impact of an integrated strategy for HIV prevention on HIV incidence as well as behavioral and social outcomes at the community level.

Forty-eight communities were randomized to receive either the community-based intervention plus standard clinic-based voluntary counseling and testing (intervention), or clinic-based voluntary counseling and testing alone (control). Eight communities were located in rural Zimbabwe; 10 in rural Tanzania; 8 in Soweto, South Africa; 8 in rural KwaZulu-Natal, South Africa; and 14 in Northern Thailand. The primary objective of the study was to determine whether communities that received at least 36 months of intervention would have a lower HIV incidence, increased rate of HIV testing, and lower rate of high-risk sexual behavior, compared to control communities. Details on the intervention have been published in *JAIDS (Khumalo-Sakutukwa G, et al. J Acquir Immune Defic Syndr. 2008 Dec 1;49(4):422-31)*. All outcomes were evaluated among community residents of 18 to 32 years of age, not only those who participated in the intervention. All HIV prevention studies to date have measured change in HIV incidence among study participants; thus generalizability of results to entire communities has been limited. NIMH Project Accept measured HIV incidence in a randomly-selected community cohort, and included people who may or may not have participated directly in any of the interventions. Thus, the results evaluate the intervention in the entire community and not only among enrolled participants.

The intervention included a multi-level structural and behavioral approach to HIV prevention with four major strategies. **The first strategy – Community Mobilization** – was designed to change community norms around HIV awareness, particularly the benefit of knowing one's HIV status. This strategy was implemented through the following components: community preparedness and mobilization, involving major stakeholders in community working groups; HIV education, provided by project outreach workers; testimonials on the benefits of testing given by community-based volunteers who were among the early adopters of HIV testing; and linkage of the project to larger community goals.

The second strategy – Increased Access to Voluntary Counseling and Testing – was designed to remove barriers to knowing one’s HIV status and to reinforce the goal of making testing more normative. This strategy was implemented through the following components: provision of free, parallel rapid tests by mobile vans or in community settings with same day results; condom distribution; and counseling sessions that included individualized risk reduction assessments, motivational interviewing to promote behavior change, and linkage to available community services.

The third strategy – Post-Test Support Services – was designed to increase safety and minimize the potential negative consequences of testing by providing various forms of support. This strategy was implemented through the following components: large information-sharing sessions; smaller support groups; coping effectiveness workshops; stigma reduction workshops to develop leaders against discrimination; and individual counseling designed to link those tested to services the community. The three strategies were designed to be synergistic and to result in sustainable change in communities mediated by more adaptive community norms.

The fourth strategy – Real-Time Performance Feedback – was designed to ensure that milestones were set for each of the intervention components, and that utilization data was continuously examined to ensure that milestones were being met as the intervention components were implemented.

Study Findings

HIV testing was 45% greater among men and 15% greater among women in the intervention communities compared to the control communities. The study intervention resulted in an almost four-fold increase in the detection of previously undiagnosed HIV cases at the three sites where differential utilization could be assessed. This was reported in *Lancet Infectious Diseases* (Sweat et al. *Lancet Infect Dis.* 2011 Jul;11(7):525-32. Epub 2011 May 3).

Sexually active HIV-infected participants in the intervention communities reported fewer sexual partners and lower rates of concurrent partnerships than sexually active HIV-infected participants in the control communities. HIV-infected participants in intervention communities reported 8% (95% CI 1%-16%; $p = 0.03$) fewer sexual partners than HIV-infected participants in control communities. This effect was stronger among HIV-positive men (18% reduction, 95% CI 5%-28%; $p < 0.01$) than among HIV-positive women (2% reduction; $p = 0.40$). Among sexually active HIV-positive participants, multiple partners were reported less frequently in intervention vs. control communities (RR = 0.70; 95% CI 0.54-0.92; $p = 0.01$). This effect was stronger among HIV-positive men (RR = 0.71; 95% CI 0.57-0.89; $p < 0.01$) than among HIV-positive women (RR = 0.91; 95% CI 0.72-1.16; $p = 0.43$).

There was a modest reduction in HIV incidence in the intervention communities compared to the control communities. There was an overall reduction in HIV incidence of 13.9% (RR = 0.86; 95% CI 0.72 to 1.02; $p = 0.08$), with a reduction of 1.6% in 18-24 year olds (RR = 0.98; 95% CI 0.80 to 1.22; $p = 0.86$), 25.4% in 25-32 year olds (RR = 0.75; 95% CI 0.54 to 1.04; $p = 0.08$), and 30.2% reduction in women over 24 years of age (RR = 0.70; 95% CI 0.54 to 0.90; $p < 0.01$). There was no difference in HIV incidence among women under 24 years of age. There were not enough incident cases among younger men and older men to evaluate the effect of the intervention reliably in these subgroups.

The community-based intervention was safe; there was no increase in negative life events (break-up of marriage or sexual relationships, physical abuse by a sexual partner, neglect by family, rejection by peers, or being discriminated against by providers or employers) reported in intervention compared to control communities.

HPTN 043 (Project Accept) demonstrated that an intervention comprising community mobilization, mobile HIV voluntary counseling and testing, and post-test support can change community norms and provide a modest reduction in HIV transmission risk. Increased HIV counseling and testing was associated with increased HIV detection, which also made it possible to refer HIV-infected participants to care and with a modest reduction in HIV incidence.

Implications and Next Steps

- NIMH Project Accept (HPTN 043) has demonstrated that it is possible to implement interventions in entire communities and evaluate results for the entire community. Most HIV prevention studies to date have produced results for individuals enrolled in cohorts, but have not demonstrated results for entire communities.
 - NIMH Project Accept (HPTN 043) has shown that it is possible to effectively engage men in community-based HIV testing programs. Many HIV prevention programs, especially in sub-Saharan Africa, have reported difficulty in reaching men. Men were not only engaged in NIMH Project Accept (with higher rates of testing in intervention vs. control communities), but HIV-infected men reported greater reductions in sexual risk behavior in intervention vs. control communities.
 - This intervention was effective at increasing both HIV testing in communities and the detection of previously undiagnosed HIV cases – important findings that can help to inform emerging work on HIV “test-and-treat”/ linkage to care studies such as HPTN 065 and HPTN 071.
 - NIMH Project Accept (HPTN 043) achieved modest reductions in HIV incidence, suggesting that the addition of other components (ie, referral to care, assistance in maintenance in care and adherence to medications) might be successful in achieving greater reductions in HIV incidence in entire communities.
1. Coates TJ, Kulich M, Celentano DD, Zelaya CE, Chariyalertsak S, Chingono A, Gray G, Mbwambo JKK, Morin SF, Richter L, Sweat M, van Rooyen H, McGrath N, Fiamma A, Laeyendecker O, Piwowar-Manning E, Szekeres G, Donnell D, Eshleman SH; the NIMH Project Accept (HPTN 043) study team. Effect of community-based voluntary counselling and testing on HIV incidence and social and behavioural outcomes (NIMH Project Accept; HPTN 043): a cluster-randomised trial. *Lancet Global Health*, 9 April 2014 (Early Online Publication) doi:10.1016/S2214-109X(14)70032-4.

NIMH Project Accept (HPTN 043) Website: <http://www.cbvct.med.ucla.edu/>