# FAQ

# NIMH Project Accept (HPTN 043)

## What is NIMH Project Accept (HPTN 043)?

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.

## Where was the study conducted and who participated?

The study was conducted in 34 communities in Africa (South Africa: 8 in rural KwaZulu-Natal, 8 in Soweto; Tanzania: 10; Zimbabwe: 8) and 14 communities in Thailand (Chiang Mai Province). The study was open to men and women aged 18-32 years at time of enrollment.

## What were the study design and intervention components?

Forty-eight communities were randomized to receive either the community-based intervention plus standard clinic-based voluntary counseling and testing (CBVCT) [intervention], or SVCT alone [control].

The intervention included a multi-level structural and behavioral approach to HIV prevention with four major strategies:

1. **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.

2. **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.

3. **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.

4. **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.

## What were the study objectives?

The primary objective of the study was to determine whether communities that received at least 36 months of intervention would have a lower rate of HIV incidence at a community level, increased rate of 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 a population-based sample of community residents of 18 to 32 years of age, not only those who participated in the intervention.

The secondary objectives of the study were to test the hypotheses that CBVCT communities, relative to SVCT communities, would report significantly; less HIV risk behavior, higher rates of HIV testing, more favorable norms regarding HIV testing, more frequent discussions about HIV, more frequent disclosure of HIV status, less HIV-related stigma and fewer HIV-related negative life events.

An additional objective was to determine whether CBVCT is cost-effective compared to SVCT.

## What were the study findings?

NIMH Project Accept (HPTN 043) demonstrated that an intervention with community mobilization, mobile HIV counseling and testing (VCT), post-test support services, and real-time performance feedback increases the number of people who know their HIV status, and reduces HIV risk behaviors, especially among people with HIV who might otherwise transmit the virus to others. The prevention strategy also resulted in a modest 14% reduction in HIV infection in the intervention communities compared to the control communities. (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 primary endpoint was HIV incidence, assessed in a single, cross-sectional, post-intervention survey of >50,000 participants. HIV status was confirmed at the central laboratory at Johns Hopkins using special assays developed for this study. HIV incidence was estimated using a multi-assay algorithm (MAA) that included the BED capture immunoassay, an avidity assay, CD4 cell count, and HIV viral load (window period: 259 days).

The reduction in incidence in the subgroup of women older than 24 years was 30.2%. (RR = 0.70; 95% CI 0.54 -0.90; p<0.01)**.** HIV incidence was reduced only by 1.5% in 18-24 year olds, but by 25.4% in 25-32 year olds. There was no difference 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 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).

The study demonstrated that HIV testing increased by 45% among men and 15% among women in the intervention communities compared to the control communities. With increased testing, there is increased HIV detection, which makes referral to care possible. The study intervention resulted in an almost four-fold increase in the detection of new HIV cases at the three sites where differential utilization could be assessed. (Sweat M, Morin S, Celentano D, Mulawa M, Singh B, Mbwambo J, Kawichai S, Chingono A, Khumalo-Sakutukwa G, Gray G, Richter L, Kulich M, Sadowski A, Coates T; Project Accept study team. Community-based intervention to increase HIV testing and case detection in people aged 16-32 years in Tanzania, Zimbabwe, and Thailand (NIMH Project Accept, HPTN 043): a randomised study. *Lancet Infect Dis*. 2011 Jul;11(7):525-32. Epub 2011 May 3.)

HIV-infected participants in the intervention communities reported 8% fewer sexual partners as well as 30% fewer concurrent partnerships than HIV-infected participants in the control communities.

The intervention reduced the number of sexual partners reported by HIV-infected individuals by 8% (95% CI 1%-16%;p = 0.03) in intervention compared to control communities . 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 individuals 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).

NIMH Project Accept (HPTN 043) was safe and did not increase harm to communities. The study demonstrated that a community-wide HIV testing intervention had no effect on negative life events (break-up of marriage or sexual relationship, physical abuse by a sexual partner, neglect by family, rejection by peers, or being discriminated against by providers or employers).

## Why is the study important and how is it unique?

NIMH Project Accept (HPTN 043) demonstrated that it is possible to implement interventions in entire communities and evaluate results for the entire community. 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 (HPTN 043) 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.

Many HIV prevention program, especially in sub-Saharan Africa, have reported difficulty in reaching men. NIMH Project Accept (HPTN 043) was able to show that it is possible to effectively engage men in community-based HIV testing programs.

## What do the study findings mean for future HIV prevention efforts?

Since the study was effective in increasing both HIV testing in communities and the detection of previously undiagnosed HIV cases, NIMH Project Accept (HPTN 043) will help inform emerging work on HIV "test and treat" linkage to care studies such as HPTN 065 and HPTN 071. HPTN 065 (TLC-Plus) is a multi-component intervention study to assess the feasibility of a community-level test, link to care, plus treat strategy in the United States. There are three components of the study: biomedical (testing and ART), behavioral (positive prevention), and structural (financial incentives). Other innovative features include strategic partnerships with local Departments of Health, the Centers for Disease Control and Prevention (CDC), and community providers; use of routinely collected surveillance data; and a mix of methodologies involving community comparisons, site randomization, and individual randomization. Enrollment began in March 2011, and results are anticipated in the first quarter of 2014. HPTN 071 (PopART—Population Effects of Antiretroviral Therapy to Reduce HIV Transmission) is a research study that will determine the impact of a package of HIV prevention interventions on community-level HIV incidence. These prevention interventions include universal voluntary HIV counseling and testing and early initiation of antiretroviral therapy for all of those testing HIV positive.

The study's ability to achieve modest reductions in HIV incidence suggests that the addition of other components (i.e. 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.

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 be potentially successful.

## Who funded the study?

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