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

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Summary
Background In developing countries, most people infected with HIV do not know their infection status. We aimed to assess whether HIV testing could be increased by combination of community mobilisation, mobile community-based voluntary counselling and testing (VCT), and support after testing.

Methods Project Accept is underway in ten communities in Tanzania, eight in Zimbabwe, and 14 in Thailand. Communities at each site were paired according to similar demographic and environmental characteristics, and one community from each pair was randomly assigned to receive standard clinic-based VCT (SVCT), and the other community was assigned to receive community-based VCT (CBVCT) plus access to SVCT. Randomisation and assignment of communities to intervention groups was done by the statistics centre by computer; no one was masked to treatment assignment because the interventions were community based. Intervention was provided for about 3 years (2006–09). The primary endpoint of HIV incidence is pending completion of assessments after the intervention. In this interim analysis, we examined the secondary endpoint of uptake in HIV testing, differences in characteristics of clients receiving their first HIV test, and repeat testing. Analyses were limited to clients aged 16–32 years. This study is registered with ClinicalTrials.gov, number NCT00203749.

Findings The proportion of clients receiving their first HIV test during the study was higher in CBVCT communities than in SVCT communities in Tanzania (2341 [37%] of 6250 vs 579 [9%] of 6733), Zimbabwe (5437 [51%] of 10700 vs 602 [5%] of 12150), and Thailand (7802 [69%] of 11290 vs 2319 [23%] 10033). The mean difference in the proportion of clients receiving HIV testing between CBVCT and SVCT communities was 40·2% (95% CI 15·8–64·7; p=0·019) across three community pairs (one per country). HIV prevalence was higher in SVCT communities than in CBVCT communities, but CBVCT detected almost four times more HIV cases than did SVCT across the three study sites (952 vs 264; p=0·003). Repeat HIV testing in CBVCT communities increased in all sites to reach 28% of all those testing for HIV by the end of the intervention period.

Interpretation CBVCT should be considered as a viable intervention to increase detection of HIV infection, especially in regions with restricted access to clinic-based VCT and support services after testing.

Funding US National Institute of Mental Health, HIV Prevention Trials Network (via US National Institute of Allergy and Infectious Diseases), and US National Institutes of Health.

Introduction HIV counselling and testing can reduce anxiety about infection and assist individuals in making informed reproductive health and breastfeeding decisions. Importantly, HIV counselling and testing lowers risk behaviours, especially in people infected with HIV and couples who are tested together. Gaining knowledge of HIV infection status is also the gateway to lifesaving HIV/AIDS treatment, which substantially reduces HIV transmission. Findings of statistical modelling suggest that treatment of high proportions of people infected with HIV in a community could slow or even stop an HIV epidemic. However, more than 33 million people are infected with HIV, mostly in developing countries, of whom fewer than 30% are aware of their own infection status, and only 10% are aware of their partner’s HIV infection status. HIV counselling and testing reduced behavioural risk in a randomised trial published in 2000. Since then, and with the advent of expanded AIDS treatment in developing countries, bold efforts have been made to expand HIV testing with major increases in financial support for voluntary counselling and testing (VCT) programmes, evolving strategies to increase uptake, and improvements in the linkage between HIV testing and treatment. Strategies include expansion of freestanding VCT clinics, home-based testing, VCT clinics for adolescents, expansion of HIV testing for pregnant women, provider-initiated testing in health-care settings, and mass testing campaigns. Nevertheless,
the proportion of people aware of their HIV infection status has remained well below that which is needed to substantially affect the epidemic in terms of reduction in behavioural risk, linkage to care and treatment, community awareness of the scope of the epidemic, and reduction in HIV-related stigma and discrimination. With so few people aware of their HIV infection status and thus unable to access treatment, the potential for antiretroviral treatment to reduce HIV infectivity is also compromised. Mobile VCT could help to expand knowledge of personal HIV infection status. However, rigorous studies examining the benefit of mobile VCT in reaching large proportions of vulnerable populations have not been done.

Easily accessible mobile VCT services coupled with community mobilisation programmes and psychosocial support after testing could increase rates of HIV testing and diagnosis, reduce individual risk behaviours, improve reproductive health decision making, increase access to treatment, reduce HIV/AIDS-related stigma and discrimination, and ultimately lower HIV incidence. In this analysis, we focus on the effect of mobile services on uptake of VCT for HIV infection and HIV case detection.

Methods
Study sites and participants

The Project Accept trial is underway in ten communities in Tanzania (Kisarawe District), eight communities in Zimbabwe (Mutoko District), 14 communities in Thailand (Chiang Mai Province), and sixteen communities across two sites in South Africa (eight in KwaZulu-Natal and eight in Soeto). Ethnographic mapping was done during the formative phase of the study and the findings were used to select pairs of communities with similar access to health services, economic activities, population density, and civic organisation. We report results from sites in Tanzania, Zimbabwe, and Thailand. In the South African sites, standard clinic-based VCT (SVCT) has been available since the start of the study through several public and private providers; we excluded the South African sites from our analyses because we did not have data from the service providers. On the basis of the high incidence of HIV infection in people aged 16–32 years, we targeted intervention to this age group.

The study procedures and instruments were approved by the following ethical review committees: Johns Hopkins University Committee on Human Research (Thailand); Chiang Mai University Research Institute for Health Sciences (Thailand); the Ministry of Public Health (Thailand); the Medical University of South Carolina Institutional Review Board for Human Research (Tanzania); the institutional review board of Muhimbili University of Health and Allied Sciences (Tanzania); the institutional review board of the National Institute of Medical Research (Tanzania); University of California, San Francisco Committee on Human Research (Zimbabwe); and the Medical Research Council of Zimbabwe (Zimbabwe). Project Accept also has an independent data safety and monitoring board which biannually reviews project benchmarks, outcomes, and adverse events. For the analyses presented herein, only data for service use were included. Printed information sheets were provided to all clients explaining that services were being provided as part of a research study. Verbal informed consent was obtained from clients before collection of data for service use.

Randomisation and masking

At each study site, communities were paired according to similar demographic and environmental characteristics by use of community mapping results. In Tanzania and Thailand, one community from each pair was randomly selected by computer by the statistics centre (Charles University in Prague, Prague, Czech Republic) to receive SVCT (control intervention), and the other community was assigned to receive community-based VCT (CBVCT) plus access to SVCT (test intervention). To conceal allocation, each community was assigned a code before randomisation; the statistics centre then randomly assigned the codes to intervention groups but was not aware of which community was associated with each code. In Zimbabwe, the randomisation was done through a lottery in a public venue so that community members could observe. All people residing in study communities had access to VCT, either in fixed-site clinics or mobile services. Furthermore, people residing in communities assigned to receive CBVCT or SVCT could cross community boundaries to access HIV testing at CBVCT or SVCT venues, irrespective of their study group assignment. No individuals were masked to group assignment because the interventions were community based and data for service use were obtained from forms describing the services received.

Procedures

SVCT consisted of counselling before and after HIV testing and rapid blood testing for HIV infection, and was provided through fixed-site clinics located in public health facilities such as hospitals and health centres. CBVCT, described elsewhere, includes community mobilisation activities, easily accessible mobile VCT for HIV infection, and community-based support services for after testing (webappendix). Several key principles underlie our CBVCT intervention strategy. The basic premise is that individuals typically benefit from learning their HIV infection status because they have increased capacity to plan for the future, can assuage fears and concerns about their infection status, and are empowered to appropriately adjust behaviours to reduce the probability of HIV infection and transmission. Activities were done without any attempt to conceal HIV testing to destigmatise HIV testing, promote a sense of community ownership of Project Accept, and encourage collective commitment to addressing HIV
infection. Ultimately, we assumed that knowledge of infection status in large proportions of the population would lead to growing demand for VCT for HIV infection, increased disclosure and open discussion about HIV infection, reduced HIV-related stigma, and increased accessing of treatment for HIV/AIDS infection. Ultimately, we expect that these effects will reduce HIV incidence.

Data were obtained in Tanzania from March, 2006, to April, 2009, and in Zimbabwe and Thailand from January, 2006, to July, 2009. Standardised instruments and procedures were used to gather data about service use in all study sites, except in the SVCT venues in Thailand. These venues were not affiliated with the study, but, for the few venues available, the study was granted access to well maintained clinical records and data were obtained retrospectively. Once a client consented to be tested for HIV, staff completed a form about the client’s service use. In Tanzania and Zimbabwe, and in CBVCT venues in Thailand, staff recorded the date, time of day that the client entered the service venue, sex, age, testing with a partner, community of residence, report of any previous HIV test and whether the test had been done by Project Accept, specific services received (ie, counselling before the test, blood collection, counselling after the test, and receipt of test results), and the HIV test result. HIV infection was diagnosed by use of the approved national rapid testing algorithm in each country. Women were also asked if they were pregnant. In SVCT venues in Thailand, all data except for time of day of service use, pregnancy status, and repeat testing were available from clinical records. No personal identifying information was recorded. Quality assurance was regularly assessed to maintain intervention fidelity to the protocol and standardisation of the SVCT and CBVCT interventions across study sites and service venues.

Collection of data for assessments after the intervention is underway, and the primary endpoint for the completed study will be HIV incidence in people aged 18–32 years. HIV incidence is being measured in a cross-sectional probability-based sample by use of an algorithm based on the BED assay, avidity index, and CD4 cell count. However, for this report, we assessed the secondary outcome of the proportion of the target population testing for HIV infection during the intervention period. We also examined the characteristics of clients, including prevalence of HIV infection in people receiving their first HIV test from Project Accept, and the proportion of individuals repeating HIV testing with Project Accept. Details on characteristics of clients were collected on utilisation forms completed for every client receiving HIV testing in both intervention and comparison communities. People reporting previous HIV testing by Project Accept were excluded from analyses, except for clients of Thai SVCT venues for whom these data were not available.

In assessment of uptake of HIV testing, we adjusted data for Thai SVCT venues to account for repeat testing to allow the number of first-time tests to be estimated for every study site. On the basis of interviews with project staff in Thailand, we assumed that 50% of clients residing in CBVCT communities and testing in SVCT venues, and 15% of clients residing in SVCT communities and testing in SVCT venues, were repeating their test.

### Table 1: Characteristics of clients and service use

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>p value</th>
<th>Clients in CBVCT communities (n=2341)</th>
<th>Clients in SVCT communities (n=579)</th>
<th>p value</th>
<th>Clients in CBVCT communities (n=9361)</th>
<th>Clients in SVCT communities (n=2721)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>&lt;0.0001</td>
<td>22.7 (4.7)</td>
<td>23.8 (4.8)</td>
<td>&lt;0.0001</td>
<td>22.3 (5.0)</td>
<td>23.5 (5.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>&lt;0.0001</td>
<td>22.0 (19-27)</td>
<td>22.4 (20-28)</td>
<td>&lt;0.0001</td>
<td>21.6 (18-26)</td>
<td>24.0 (21-28)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>16-27</td>
<td>&lt;0.0001</td>
<td>30.0 (16%)</td>
<td>49.8 (%)</td>
<td>&lt;0.0001</td>
<td>1180 (22%)</td>
<td>49.8 (%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>18-32</td>
<td>&lt;0.0001</td>
<td>1921 (84%)</td>
<td>530 (92%)</td>
<td>&lt;0.0001</td>
<td>4257 (78%)</td>
<td>553 (92%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Women</td>
<td>0.017</td>
<td>976 (42%)</td>
<td>273 (47%)</td>
<td>0.017</td>
<td>2621 (48%)</td>
<td>277 (46%)</td>
<td>0.386</td>
</tr>
<tr>
<td>Tested as couple</td>
<td>0.011</td>
<td>54 (2%)</td>
<td>24 (4%)</td>
<td>0.011</td>
<td>223 (4%)</td>
<td>61 (10%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Women pregnant at time of test</td>
<td>&lt;0.0001</td>
<td>25 (3%)</td>
<td>27 (11%)</td>
<td>&lt;0.0001</td>
<td>75 (3%)</td>
<td>22 (8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Time of day tested</td>
<td>&lt;0.0001</td>
<td>...</td>
<td>...</td>
<td>&lt;0.0001</td>
<td>...</td>
<td>...</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Morning</td>
<td>0.0001</td>
<td>845 (36%)</td>
<td>295 (51%)</td>
<td>...</td>
<td>703 (33%)</td>
<td>242 (49%)</td>
<td>...</td>
</tr>
<tr>
<td>Midday</td>
<td>0.0001</td>
<td>1178 (50%)</td>
<td>260 (45%)</td>
<td>...</td>
<td>2758 (51%)</td>
<td>198 (40%)</td>
<td>...</td>
</tr>
<tr>
<td>Afternoon</td>
<td>&lt;0.0001</td>
<td>318 (14%)</td>
<td>24 (4%)</td>
<td>&lt;0.0001</td>
<td>1947 (36%)</td>
<td>52 (11%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HIV prevalence</td>
<td>0.0006</td>
<td>86 (4%)</td>
<td>40 (7%)</td>
<td>0.0006</td>
<td>693 (33%)</td>
<td>132 (22%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

People reporting repeat HIV testing were excluded from these analyses, except for SVCT venues in Thailand, for which repeat testing data were not available. CACT=community-based voluntary counselling and testing. SVCT=standard clinic-based voluntary counselling and testing. NA=data not available. Data were missing for 12 patients. Data were missing for 17 patients. Data were missing for 30 patients. Data were missing for 2187 patients. Data were missing for 29 patients in CBVCT communities in Zimbabwe, 110 in SVCT communities in Zimbabwe, and 3118 in CBVCT communities in Thailand. Data were missing for 181 patients.
In assessment of HIV prevalence, clients with equivocal test results were removed from analyses, and we present data for test results to which we had direct access. Some clients might have been tested for HIV infection outside of our data catchment area, but we were not able to capture these data and staff reported that such testing was rare. All study sites were rural, and high transport and opportunity costs are associated with leaving the area for HIV testing. In assessment of the proportion of individuals receiving VCT for HIV infection, we divided the number of people who had an HIV test at least once during the 3 years of the study by the total eligible population. The total population size at baseline was derived from a probability-based household sample done before the study intervention started in which we enumerated all household members in a probability-based sample of households. In assessment of the proportion of individuals repeating HIV testing, clients reporting any previous testing for HIV infection by Project Accept were counted as repeat testers for analyses.

Additional information about the study design and assessment of the primary endpoint are provided in the study protocol.

**Statistical analysis**
Analyses were done with SPSS for Windows (version 17.0). For non-parametric analyses, we used Pearson’s $\chi^2$ test for differences in characteristics of clients across strata. Source data from forms completed at the time of service use did not include detail needed for statistical analyses to account for intraclass correlation that might have been present in the community, household, or couple. Geographical location of residence was limited to whether clients lived in SVCT or CBVCT communities, and identifying information, detailed household location, and linking information to sexual partners who might also have been tested were not recorded. As a result, the p values presented might be more likely to show significant associations than if adjustments for interclass correlation had been made. A paired t-test analysis was also done to examine the mean difference in the proportion of clients tested for HIV across CBVCT and SVCT community pairs (one pair per country, two degrees of freedom). For all analyses, we judged p values of less than 0.05 to be significant.

This study is registered with ClinicalTrials.gov, number NCT00203749.

**Role of the funding source**
US National Institute of Mental Health (NIMH) funding for the project was under a cooperative agreement mechanism, allowing the NIMH project officer assigned to the study to participate in technical project activities after the award was made to the principal investigators. The NIMH project officer participated in the study as a voting member of the Project Accept steering committee, and reviewed and provided suggestions about the report before submission, but did not influence the decision to submit the report. The other funding agencies did not have any role in writing of the report. None of the funding agencies had any role in the study design, data collection, data analysis, data interpretation, or decision to submit for publication. MS had full access to all the data in the study and had the final decision to submit the report for publication.

**Results**
In all study sites, the number of people receiving their first HIV test during the study was much larger in CBVCT communities than in SVCT communities (table 1), with a difference of four times in Tanzania, about nine times in Zimbabwe, and about three times in

<table>
<thead>
<tr>
<th>Country</th>
<th>HIV test in CBVCT venues</th>
<th>HIV test in SVCT venues</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clients in CBVCT</td>
<td>Clients in SVCT</td>
</tr>
<tr>
<td></td>
<td>communities (n=6250)</td>
<td>communities (n=6733)</td>
</tr>
<tr>
<td>Total</td>
<td>2810</td>
<td>5911</td>
</tr>
<tr>
<td>First-time test</td>
<td>2323 (83%)</td>
<td>4805 (81%)</td>
</tr>
<tr>
<td>Repeat test</td>
<td>487 (17%)</td>
<td>1106 (19%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 (1%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>HIV test in CBVCT venues</th>
<th>HIV test in SVCT venues</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clients in CBVCT</td>
<td>Clients in SVCT</td>
</tr>
<tr>
<td></td>
<td>communities (n=10700)</td>
<td>communities (n=12150)</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>668</td>
</tr>
<tr>
<td>First-time test</td>
<td>18 (82%)</td>
<td>632 (95%)</td>
</tr>
<tr>
<td>Repeat test</td>
<td>4 (18%)</td>
<td>36 (5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7 (1%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7802 (69%)†</td>
</tr>
</tbody>
</table>

CBVCT=community-based voluntary counselling and testing. SVCT=standard clinic-based voluntary counselling and testing. *Repeat testing data were not available in SVCT venues in Thailand, but source data were adjusted to remove these cases from analyses: we assumed that 50% of clients residing in CBVCT communities and testing in SVCT venues, and 15% of clients residing in SVCT communities and testing in SVCT venues, were repeating their test. †9361 without removal of estimated SVCT repeat testing. ‡2721 without removal of estimated SVCT repeat testing.

Table 2: Patterns of HIV testing
Thailand. However, data for repeat testing could not be excluded for SVCT venues in Thailand so the actual difference might have been higher. Clients testing in CBVCT communities were slightly younger than were those testing in SVCT communities in all sites. Notably, the proportion of clients aged 16–17 years testing for HIV infection, although quite low, was significantly higher in CBVCT communities than in SVCT communities in all sites. In Tanzania and Zimbabwe, just more than half of clients in both CBVCT and SVCT communities were male, whereas in Thailand, just more than half of clients were female. In Tanzania and Thailand, sex had a significant effect between study groups, with a larger proportion of male clients in CBVCT communities than in SVCT communities. Few clients tested for HIV infection as couples in Tanzania and Zimbabwe, and the proportion was lower in CBVCT communities than in SVCT communities. By contrast, the proportion of clients testing as couples in Thailand was much higher than in other sites, especially in SVCT communities. Few women reported pregnancy at the time of HIV testing in all sites; the proportion was similar in CBVCT and SVCT communities in Zimbabwe, but was significantly lower in CBVCT communities than in SVCT communities in Tanzania. In both Tanzania and Zimbabwe, the time of day clients were tested differed significantly between CBVCT and SVCT communities, with clients testing later in the day in CBVCT communities (table 1).

HIV prevalence was lower in CBVCT communities than in SVCT communities in Tanzania, Zimbabwe, and Thailand, but more cases were detected in CBVCT communities than in SVCT communities because many more people were tested (952 vs 264; p=0.003; table 1). Data for first-time and repeat HIV testing from Project Accept by venue in residents of CBVCT and SVCT communities were used to calculate the proportion of clients who received their first HIV test during the study (table 2). In all study sites, the proportion of people receiving their first HIV test during the study was much larger in CBVCT communities than in SVCT communities, with a difference of about four times in Tanzania, about ten times in Zimbabwe, and three times in Thailand.

In a cross-site sensitivity analysis, we recorded a mean difference of 40–2% (95% CI 15.8–64.7; p=0.019) in the proportion of clients receiving VCT for HIV infection between CBVCT and SVCT communities. Even in this crude analysis based on data for three community pairs (one per country), the difference in uptake of VCT was significant between study groups. Few clients crossed over the randomised community boundaries to receive services in Tanzania and Zimbabwe, but in Thailand, a substantial proportion of clients in CBVCT communities opted to test in SVCT venues (about 20% of all HIV tests, excluding repeat testing).

In Tanzania, a high frequency of repeat testing was recorded during the first year of the study in clients residing in CBVCT communities, approaching 35% of all HIV tests provided by Project Accept (figure). Over time this rate dropped, and fluctuated between 15% and 20%. In Thailand and Zimbabwe, we recorded a consistent increase in repeat HIV testing over time, reaching 28% of all HIV testing by Project Accept in CBVCT venues in CBVCT communities by the end of the intervention period.

**Discussion**

Communities can be mobilised to learn their HIV infection status, including in remote rural communities with little infrastructure across different regions, epidemic settings, and cultures (panel). The numbers of clients receiving their first test for HIV infection from Project Accept in CBVCT communities was four times higher in Tanzania, ten times higher in Zimbabwe, and about three times higher in Thailand than in SVCT communities. We believe that the extremely high uptake of HIV testing in Thailand was supported by many years of national support for HIV testing, which probably has made HIV testing more acceptable and normative than in other countries. The lower, albeit still impressive, uptake in Tanzania is probably due to the more isolated nature of the communities in which the study was based. The study area in Tanzania has had restricted media exposure to HIV prevention campaigns because of limited radio service and no TV service, and little previous access to HIV testing services.

We believe that the CBVCT strategy achieved HIV testing in an average of 55% (weighted average of 15,580 of 28,240) of community residents aged 16–32 years across the three sites largely because of the multicomponent, comprehensive, and integrated nature of the intervention. Furthermore, the mobilisation component stimulated demand for HIV testing, independent of improved access alone, because the number of people residing in CBVCT communities who sought testing in SVCT venues was higher than the number of people in SVCT communities who sought testing in CBVCT venues.

![Figure: Proportion of clients residing in CBVCT communities who were receiving a repeat HIV test at CBVCT service venues](www.thelancet.com/infection)

CBVCT=community-based voluntary counselling and testing.
We recorded important differences in the characteristics of clients accessing services in CBVCT versus SVCT communities. In Tanzania, the proportion of couples and pregnant women was higher in clients testing in SVCT communities than in those testing in CBVCT communities. The proportion of pregnant women seeking testing services is increased in SVCT communities because SVCT services in Tanzania are linked to public health clinics, which are also a major source of antenatal care for women. Notably, few people residing in CBVCT communities went to SVCT venues for HIV testing, indicating that ease of access for HIV testing services has a major effect on uptake.

In Zimbabwe, the proportion of adolescents and individuals, rather than couples, testing for HIV infection was higher in CBVCT communities than in SVCT communities. SVCT venues in Zimbabwe have been criticised for not being youth friendly, which might explain the raised proportions of young people attending mobile services. The coexistence of antenatal services in SVCT venues might have contributed to the increased proportion of couples testing in SVCT communities because, in some services, men are encouraged to be tested for HIV infection when their pregnant partner is tested. Furthermore, couples might prefer to be tested away from their home community because they fear loss of confidentiality.

In Thailand, VCT has been available in all government hospitals with a small fee since 1992. All pregnant women receive VCT during antenatal care, and financial institutions require loan applicants to provide proof of negative HIV infection status. Hence, independent of the Project Accept intervention, a large proportion of the Thai population has previously been tested for HIV infection. In northern Thailand, more than 40% of people aged 18–35 years have a history of HIV testing, which might account for the much higher general frequency of testing recorded in both study groups in Thailand than in Tanzania or Zimbabwe. The proportion of women and couples testing for HIV infection was higher in SVCT communities than CBVCT communities, which, as in Tanzania, might be due to the concurrent availability of antenatal testing in Thai SVCT venues.

Against the backdrop of substantially increased HIV testing in CBVCT communities, testing as couples was rare, especially in Tanzania and Zimbabwe. When clients test for HIV infection as couples, they are more likely to reduce risk behaviour. However, couples might prefer to test for HIV infection outside of their home communities, in SVCT venues, to increase privacy.

The Project Accept trial has helped to elucidate how uptake of testing, and repeat testing, evolves over the course of the CBVCT programme. We believe that both community mobilisation and social networking dynamics promoted uptake of HIV testing in CBVCT communities. As increasing numbers of people learn their HIV serostatus, an untested person is more likely to personally know someone who has tested, instilling trust in the safety and benefits of learning their serostatus. Furthermore, by the end of the intervention period, about 28% of people testing at CBVCT venues were repeating a previous HIV test done by Project Accept. This trend towards a very high proportion of repeat testers over time is also correlated with reduced HIV case detection because case detection is associated most commonly with first-time testing. Thus, as a CBVCT programme matures, the epidemiological benefits of the programme also evolve from case detection towards behavioural reinforcement and prevention.

The data for service use were carefully obtained, and we had several layers of quality assurance to ensure that the results were accurate. However, the methodological challenges associated with measurement of complex patterns of HIV testing at the population level should not be underestimated. Although the study results should be treated with some caution, we believe that they are reliable. Information about characteristics of clients and service use was based on self-report at intake to the service venue, and clients had little reason to provide inaccurate information. The questions asked were not highly sensitive or stigmatising, and people were not discouraged from accessing services outside of the geographical community boundaries defined for the study. Everyone coming to the service venues, irrespective of where they lived, was allowed to access all services. We carefully mapped the communities before the study, and staff reported few problems in establishing whether clients resided in CBVCT, SVCT, or other communities.
We did not obtain identifying information for clients, so we were unable to record the individual pattern of repeat testing, other than by asking clients whether they had tested before, and whether Project Accept was the source of previous testing. One possible source of error is that community members might have tested for HIV infection in venues from which we did not have access to data. However, all of the study communities, both CBVCT and SVCT, were in rural areas, and access to alternative testing venues outside our data catchment was difficult. HIV testing that might have occurred outside our data catchment area would only increase the numbers of people estimated to have tested for HIV infection, and we have little reason to believe that travelling to distant VCT testing venues would occur differentially across the study groups.

The study has several other important limitations. First, cost data for the CBVCT intervention are being obtained, but are not yet available. Second, the study had missing data for some variables. In most sites, data were missing for few cases, but in Thailand, data for the time of day of services and pregnancy status were missing for many individuals in the CBVCT group, which has probably introduced a bias. In Tanzania and Zimbabwe, the study provided both CBVCT and SVCT services, increasing our ability to track uptake patterns. In Thailand, we relied on existing SVCT services not affiliated with Project Accept, which is a potential source of bias. However, we had excellent access to well maintained data for service use at these clinics, and VCT provided by governmental clinics in Thailand is of high quality and closely conforms to the same international standards applied by study-supported HIV testing services. Third, the study results are partly based on self-report for repeat testing, so some individuals might have denied that they had previously been tested for HIV infection, and clients were permitted to access HIV testing in CBVCT or SVCT venues, irrespective of their group assignment. In Tanzania and Zimbabwe, few community members crossed over the randomised community boundaries to receive services. In Thailand, about a fifth of CBVCT community members made a concerted effort to receive their HIV test in SVCT venues, implying that publicly seeking an HIV test does not appeal to all clients, whereas very few SVCT community members travelled to testing venues located in CBVCT communities. Whether these events constitute contamination of the study design will be most relevant to assessment of the primary endpoint of the study, HIV incidence.

Fourth, the main study design included matching community pairs for randomisation, and possible intraclass correlation in the community, household, and couple should ideally be adjusted for in analysis. Thus, the significance of associations should be inferred with caution. Geographical and individual data in our analysis were not sufficient to allow identification of intraclass correlation. To preserve client anonymity we opted to not obtain information at the time of service delivery which could identify clients. However, the difference in uptake of HIV testing between CBVCT and SVCT communities was substantial. The amount of intraclass correlation needed to obviate significance in this effect is highly unlikely to be present.

Bringing VCT directly to communities and linking VCT with mobilisation efforts and support services after HIV testing results in substantially greater uptake of both HIV testing and HIV case detection than does SVCT. This finding has important implications for both prevention and treatment of HIV infection in developing countries, especially in rural communities, such as those in which this study was done, which are often neglected in the provision of HIV programming because of logistical and health-system challenges. Within a short period, Project Accept mobilised large proportions of the study populations to go through the difficult process of learning their HIV infection status, proving that local communities respond to HIV epidemics with comprehensive, user-friendly services are provided.

Contributors
MS was US principal investigator for the Tanzanian site, oversaw the collection and analysis of data, and did most of the analyses. SM was US principal investigator for the Zimbabwean site, and led the quality assurance components of the intervention. DC was the US principal investigator for the Thai site, and led the assessment and measurement components of the study. MM was the study research coordinator in Tanzania, and assisted in the statistical analysis and interpretation of data. BS was the multisite data manager, merged, cleaned, and organised project data across sites, and assisted with the statistical analysis. JM was the Tanzanian principal investigator, and managed the study operations in Tanzania. SK was the project manager in Thailand, oversaw the field operations in Thailand, and managed the collection of data from SVCT clinics in Thailand. AC was the principal investigator in Zimbabwe, and managed study operations in Zimbabwe. GK-S was responsible for the multisite quality assurance of the intervention. GG was the principal investigator of the Project Accept Soweto, South Africa site, and assisted with the development and implementation of the study. LR was the principal investigator of the Project Accept Vulindlela, South Africa site, and assisted with the development and implementation of the study. MK was the Project Accept statistician, and assisted with the statistical analysis. AS was the project coordinator based in Charleston for the Tanzania site, and he assisted with statistical analysis and graphics production. TC was the US principal investigator for the South African sites, and was the chair of the Project Accept steering committee. MS, SM, DC, JM, AC, GG, LR, MK, and TC were voting members of the Project Accept executive committee, and were responsible for the design, implementation, and continuing quality assurance of the overall study. MS drafted and revised the report, and AS drafted some sections of the report. SM, DC, MM, BS, JM, SK, AC, GK-S, GG, LR, MK, and TC contributed to review and editing of the report.

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Conflicts of interest
We declare that we have no conflicts of interest.

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References