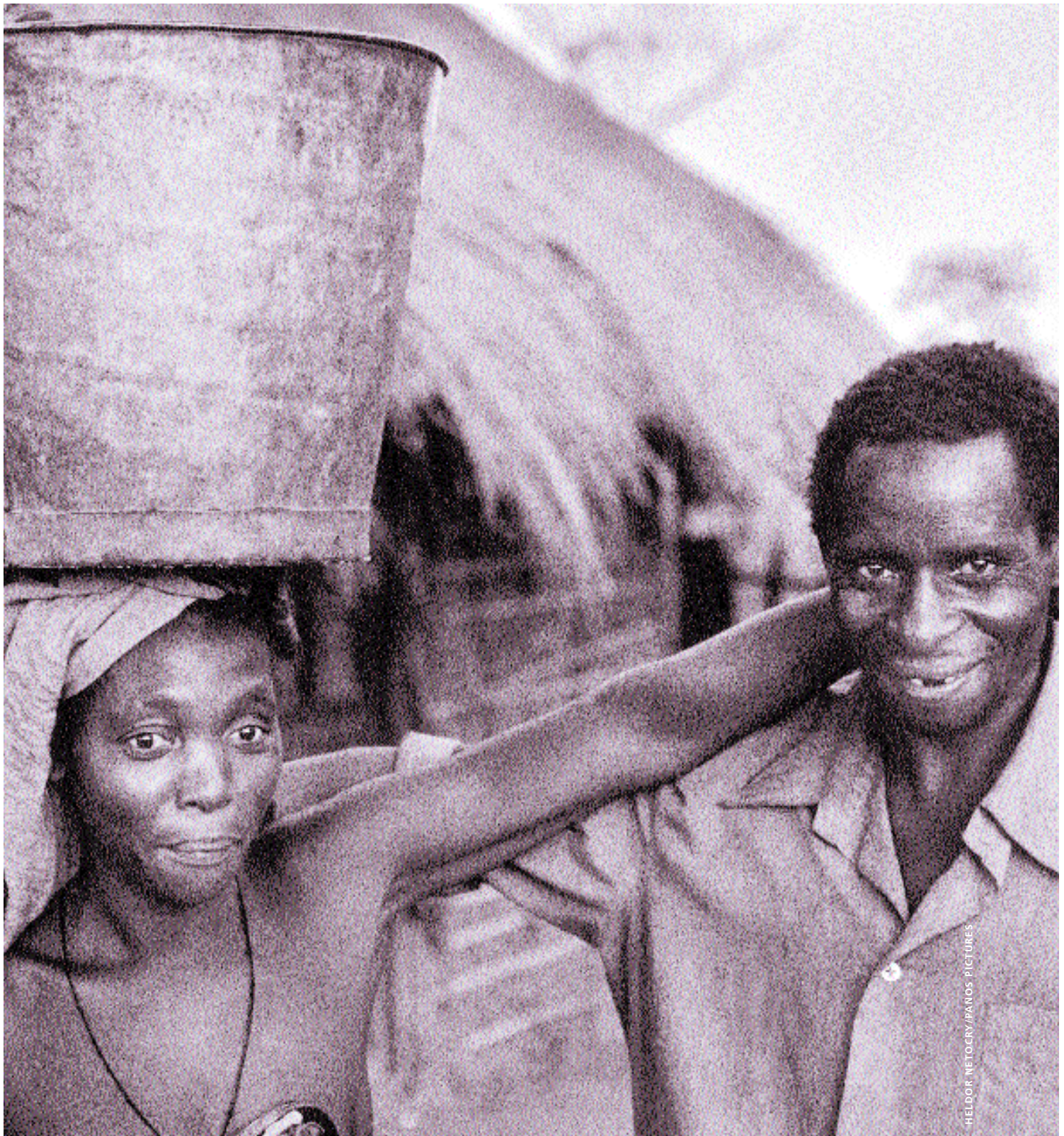


The findings of limited change in the rates of sex with any non-primary partners and a significant reduction in unprotected intercourse with these partners suggests that study participants were not just telling the investigators what they wanted to hear but rather what was really happening in their lives.



HELDOR METOCRY/PANOS PICTURES

AIDSCAP'S VOLUNTARY HIV COUNSELLING AND TESTING (VCT) PROGRAM COUNSELED AND TESTED TANZANIAN COUPLES, SUCH AS THIS ONE, IN THE FIRST RANDOMIZED CONTROLLED TRIAL OF HIV VCT.

## **VOLUNTARY HIV COUNSELLING AND TESTING IN TANZANIA**

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## VOLUNTARY HIV COUNSELLING AND TESTING IN TANZANIA

### INTRODUCTION

Until recently, voluntary HIV counselling and testing (VCT) was not fully recognized as an effective intervention for behaviour change to reduce the risk of HIV transmission in Tanzania. The inconsistency of existing data regarding the impact of VCT on behaviour and the perceived high cost and low demand for VCT programs led to limited support from the Tanzanian National AIDS Control Program (NACP) and donors working in the country.

HIV counselling and testing activities were mainly provided by nongovernmental organizations (NGOs), such as the Society for Women Against AIDS in Africa (SWAA), Walio Katika Mapambano na AIDS Tanzania (WAMATA), Pastoral Activities and Services for AIDS (PASADA), Service of Health and Development for People Living with HIV/AIDS (SHEDPHA) and others. But these activities were very limited and mainly focused on counselling HIV/AIDS patients who had been tested elsewhere and referred by caregivers or friends for psychosocial support. For others who wanted to know their HIV serostatus, access to this VCT service was very limited. The need for such a service was illustrated by many anecdotal reports of people giving blood

at blood banks or paying significant sums at private clinics and laboratories in order to learn their HIV serostatus.

In order to make programme and policy decisions for VCT, the NACP needed strong and reliable data. In October 1993, the programme was approached by Family Health International's (FHI's) AIDS Control and Prevention (AIDSCAP) Project, in collaboration with the World Health Organization's Global Programme on AIDS (WHO/GPA), with the idea of conducting a study of the efficacy of VCT programmes. Recognizing that the data from such a study would meet its information needs, the NACP agreed to provide full support and facilitated the identification of a local institution to carry out the study.

This case study describes activities related to the research project undertaken in Dar es Salaam, Tanzania, by the Muhimbili University College of Health Sciences (MUCHS), in collaboration with several international organizations as part of a multicentre randomized study of the efficacy of VCT. The project was designed with the following objectives:

- to determine the impact of VCT on behaviour change among individuals seeking VCT services

- to describe the social and psychological effects of VCT
- to determine the cost-effectiveness of the VCT intervention.

The following organizations collaborated with MUCHS in the project: FHI/AIDSCAP, the United States Agency for International Development (USAID), the Joint United Nations Programme on HIV/AIDS (UNAIDS), WHO/GPA, the Center for AIDS Prevention Studies at the University of California at San Francisco, the Kenya Association of Professional Counselors and the Queens Park Counseling Center in Trinidad.

#### **PROJECT DESCRIPTION**

**Initiation** AIDSCAP introduced the idea of conducting a study on the efficacy of VCT at a meeting of its technical working group in May 1993. Following the recommendations from this meeting, AIDSCAP held several discussions and consultations with USAID, WHO/GPA, the U.S. Centers for Disease Control and Prevention (CDC) and numerous other institutions involved in HIV/AIDS prevention. These discussions and consultations led to consensus on the importance of conducting such a study in order to better define the potential contribution of VCT to HIV/AIDS prevention in non-industrialized countries. Collaborative arrangements were made between AIDSCAP and WHO/GPA (later continued by UNAIDS and WHO) to fund and conduct a multicentre randomized study of the efficacy of VCT, with the Center for AIDS Prevention Studies at the University of California at San Francisco as the coordinating centre.

Tanzania was one of the countries selected for the study. To ensure that this research project responded to a real need for data in the country, the idea was presented to the Tanzania NACP for consideration and approval. The USAID mission in Tanzania, one of the Tanzanian government's main partners in HIV/AIDS prevention, was also consulted. Both agencies agreed that such a study was a real necessity in the country. They provided full support to the project and helped identify MUCHS as the local research institution to carry out the project in Tanzania.

**Preparation** MUCHS investigators collaborated with investigators from the other participating institutions in the development of the study protocol at a workshop in Arusha, Tanzania, in September 1994. During this workshop the investigators agreed on a core protocol for the multicentre study and a site-specific protocol for the study in Tanzania.

Following the workshop, the site-specific protocol was finalized and submitted to the NACP review board for scientific and ethical review. The study groundwork, which began after the review board had approved the protocol, included obtaining a study site (a building on the grounds of the MUCHS teaching hospital), conducting formative research, developing the research instrument and performing a pilot study.

Formative research was conducted between November 1994 and January 1995. The main goals of this research were to: (1) assess the understanding of the concept of "randomization" by members the target population and identify a culturally appropriate way to explain the concept to people in Tanzania; (2) identify the range of social, psychological and emotional

effects experienced by people receiving HIV counselling and testing in the Tanzanian context; (3) develop a concise, culturally appropriate and methodologically sensitive set of questions to measure the major variables identified for the study; (4) develop appropriate response options for each question; and, (5) test the face validity of the questions developed.

The approaches used to achieve these goals were individual interviews with service providers, individual interviews with people recently tested for HIV (HIV-positive and HIV-negative) and focus group discussions with a sample of the target population. Results from the formative research were then used in developing the study instrument and adapting the interventions, and the wording of the consent form used for the study and the advertising materials.

The counselling intervention was based on the CDC client-centred HIV preventive counselling model. Using information from the formative research, this model was tailored to be culturally appropriate, acceptable and sensitive to the needs of Tanzanians. The inclusion of a personalized risk assessment and the development of a personalized risk-reduction plan for each client further distinguished the model. Personalized risk-reduction plans were developed with each client, based on his or her level of knowledge, interpersonal situation, specific risk behaviours and readiness to change. In this counselling model, the content of the sessions and the amount of counselling received were individualized, as determined by each client's specific HIV-risk issues. Counselling sessions lasted an average of 40 minutes.

Information from the formative research was used to develop a script for the HIV health

information intervention that would be offered to the comparison group, taking into account information from the formative research.

The English-language script was translated into Swahili, and a 15-minute video was filmed at the site with a pair of local actors portraying a couple seeking information on HIV. The Tanzanian principal investigator took the role of health information officer. In the video, which was designed to provide accurate information about how HIV is transmitted and how transmission can be prevented, the couple comes to the counselling centre to discuss their concerns about HIV and AIDS. The health information officer begins by providing definitions for HIV and AIDS. He then describes ways in which HIV is and is not transmitted and ways of preventing HIV infection. Both "clients" then ask various questions about the virus and about condom use. As they leave the centre, the couple is given packs of condoms.

Following the development of the video, a three-week pilot study was conducted in April 1995. The objective of this pilot study was to test the laboratory procedures and the various counselling and testing site procedures, including those regarding client flow, informed consent, determination of eligibility, length of the interview and length of the counselling session. Based on the findings, some procedures were modified.

**Execution** The study's target population was people seeking HIV counselling and testing in Dar es Salaam, Tanzania. Participants had to be 18 years or older, planning to remain in the area for at least a year and unaware of their HIV serostatus. They were not expected to comprise a random

sample of Dar es Salaam. Participants were encouraged to come to the study with their sexual partners and to enroll as a couple. The recruitment goal was 1,600 participants: 400 individual men, 400 individual women and 400 couples.

This research project was carried out from May 1995 to March 1997. Implementation began with citywide advertising of the HIV counselling and testing site. Various publicity strategies were used, including leaflets, posters, newspaper advertisements and a community awareness campaign. Workplaces, churches, local pubs and commercial markets were targeted initially, and radio announcements were added later because the other media were not attracting enough women and couples.

Eligible participants were asked to fill out an informed consent form. The screener explained the study procedures in detail, read the consent form to the volunteer, and asked him or her to provide verbal consent. After consent was obtained, participants were given a structured face-to-face baseline questionnaire that required an average of 45 minutes to complete. The baseline questionnaire collected data on: (1) demographic characteristics; (2) self-reported sexually transmitted infection (STI) symptoms; (3) use of birth control; (4) HIV/AIDS knowledge and concerns about HIV/AIDS; (5) sexual behaviour; (6) condom attitudes and experience; (7) psychological status; and, (8) risk reduction strategies. Following the interview, each participant was asked to provide a urine sample that was frozen and stored for subsequent testing for gonorrhoea and chlamydial infection, to be used as a biological marker to corroborate self-reported behaviour.

Participants were then randomly assigned to receive either HIV counselling and testing or the health information interventions. Couples were randomized together so that both members always received the same intervention. Participants assigned to the VCT intervention met with the counsellor for counselling and to provide consent for HIV testing. Those consenting to the HIV test provided a blood sample and were asked to return two weeks later to receive the test results and appropriate post-test counselling. Those who did not feel ready for the test during their first visit scheduled additional counselling appointments.

Participants enrolling as couples were counselled together or individually, depending on their choice. To ensure accurate risk assessment, each couple member was given individual time with the counsellor. Test results were initially given individually, and then the couple was encouraged to share their results in a joint counselling session. Post-test counselling then proceeded with both members of the couple.

Participants assigned to the health information intervention watched the 15-minute video in the presence of a health information officer, who responded to their questions at the end. This was intended to be a group session; however, because clients came at different times, many video sessions were with individuals.

At the end of the baseline visit, all participants received a supply of 25 condoms and a brochure demonstrating correct condom use. They were also invited to return for additional condoms at any time.

The first all-participant follow-up visit was scheduled six months after baseline. During this visit a face-to-face questionnaire, similar to the one used at baseline, was administered

to all. They were also tested for the classic STIs and treated, as appropriate, if found positive for any STI. At this visit all participants were also offered HIV counselling and testing and asked to provide a urine sample for testing by ligase chain reaction (LCR) for *Neisseria gonorrhoeae* and for *Chlamydia trachomatis*.

All clients' six-month urine samples were tested by LCR for *N. gonorrhoeae* and *C. trachomatis* to estimate the incidence of STI among the participants. For those with a positive six-month sample, baseline urine samples were retrieved and tested by LCR. Participants with a positive test on the six-month urine sample and positive test on the baseline sample were assumed to have a prevalent case of infection. Those with a positive six-month sample, but a negative baseline sample, were considered new cases.

The second follow-up visit was scheduled 12 months after the initial baseline visit. Participants were again given a face-to-face questionnaire and offered HIV counselling and testing if they chose to be tested.

**Assuring Confidentiality** Confidentiality in this study was protected by: (1) assigning a unique identification number to each participant; (2) filing forms with participants' names in locked filing cabinets; (3) marking samples, test requests and interview forms only with identification numbers and not with names; and (4) training the staff in confidentiality procedures and having them sign a confidentiality oath.

The quality of the service was assured through careful selection and training of counsellors and close monitoring of the counselling process. Counsellors held regular, scheduled group meetings with the site manager

to share experiences and discuss difficult cases. The counselling site manager, a trained psychiatrist with extensive experience in HIV counselling, provided ongoing supervision and support to the counsellors to address their concerns. This was extremely useful in the preventing the "burnout" that often occurs in this difficult line of work.

### OUTCOMES

The recruitment phase of the study lasted for nine months, and participants were followed up for 12 months. During the initial two months of the recruitment period, advertising for the service was limited to written materials such as leaflets and posters. These attracted mainly male clients. The addition of radio advertisements significantly increased the participation of both female clients and couples. A total of 1,427 participants were enrolled in the study, comprising 500 males, 489 females and 222 couples. Seven hundred and eleven participants were assigned to receive health information, and 716 were assigned to HIV counselling and testing. The overall HIV prevalence among those assigned to receive HIV counselling and testing at baseline was 21 per cent. The HIV prevalence by gender was 13 per cent for men and 29 per cent for women.

**Impact on Behaviour Change** Data analysis was conducted in late 1997 and early 1998. Participants in the counselling and testing group were compared with those in the health information group using several behavioural variables. These included: (1) number of sex partners; (2) number of primary sex partners (defined as a spouse or spouses for married people and boyfriend or girlfriend for unmarried people);

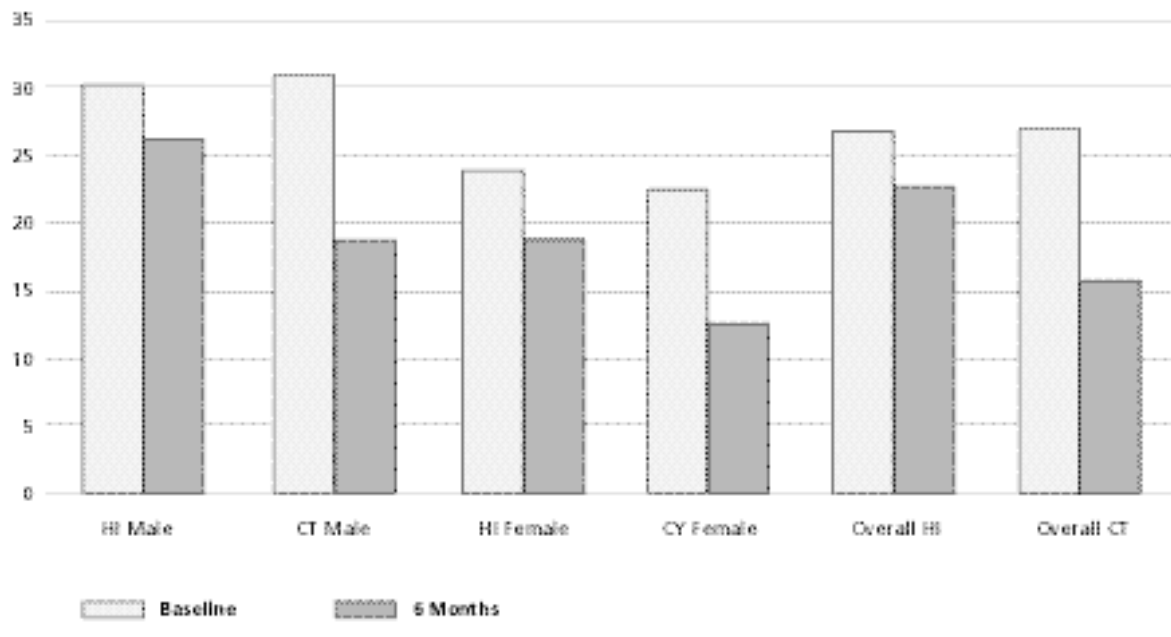
(3) number of non-primary sex partners (defined as any partner who is not the spouse(s) for married people and not the girl/boyfriend for unmarried people); (4) unprotected sex with primary partners; (5) unprotected sex with non-primary partners; and, (6) self-reported risk reduction behaviour in the last two months. This case study will focus on two primary outcomes: proportion of participants reporting sex with any non-primary partner and proportion of participants reporting unprotected sex with non-primary partners.

Following implementation of the two interventions in this study, there was a general decline in risk behaviour among the two study groups. However, individuals who received the

counselling and testing intervention showed more significantly reduced risk behaviour than did those who received health information only. For example, individuals in the counselling and testing group reported a significantly greater reduction in the percentage of unprotected intercourse with non-primary partners. As shown in Figure 1, at baseline the rates of unprotected sex were similar among the two groups. At six months, although there was a reduction in both groups, the reduction was significantly more substantial among men and women who received counselling and testing. (This case study is limited to six-month data, as the 12-month data had not yet been analyzed.) There was also a reduction in reports of

**FIGURE 1**

**Unprotected Intercourse with Non-Primary Partners Decreased Significantly More in VCT Than HI Participants**



unprotected intercourse with non-primary partners among couples in both intervention groups. The difference in the reductions between the two study groups, however, was not statistically significant.

Interestingly, the proportion of individuals reporting sex with any non-primary partners was the same in each study group. The findings of limited change in the rates of sex with any non-primary partners and a significant reduction in unprotected intercourse with these partners suggests that study participants were not just telling the investigators what they wanted to hear but rather what was really happening in their lives. In other words, what changed was not so much the number of non-primary partners, but what people did with them.

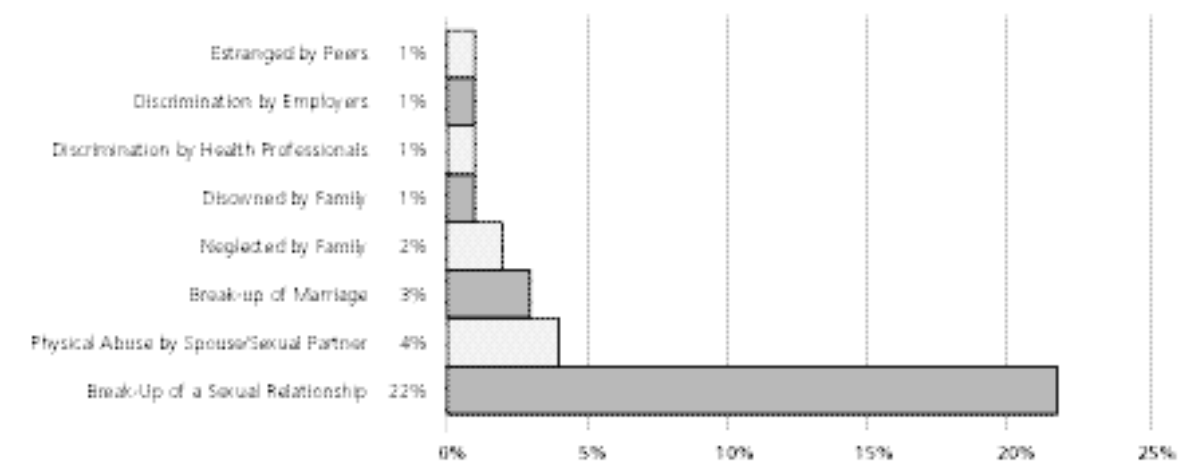
The validity of self-reported behaviour from behavioural research is often questioned. Of interest in this study is the use of STI-incidence data to test the validity of self-reported sexual behaviour among study participants.

Those who reported unprotected intercourse with non-primary partners were at least twice as likely to have contracted an STI since the study began than those who reported no unprotected intercourse with non-primary partners. This result provides evidence of the validity of the self-reported sexual risk behaviours.

With the exception of relationship breakups, negative life events such as suicide, physical violence and discrimination were rare, as shown in Figure 2. The proportion of participants reporting negative life events was similar in both groups. Among those who received counselling and testing, however, those who tested HIV-positive—particularly women—were more likely to report physical violence and breakup of marriage than were those who tested HIV-negative. As a result of their participation in the study, people also reported the occurrence of positive life events such as strengthening of relationships.

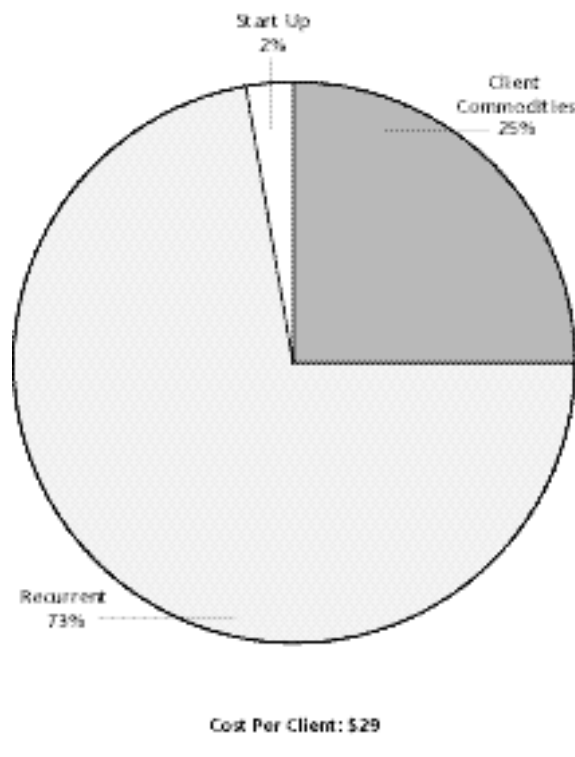
FIGURE 2

Negative Life Events Reported by Study Participants in Both Intervention Groups



**Cost Aspects of the Service** To estimate the cost of providing HIV counselling and testing, all costs related to the research aspect of this project were identified and subtracted from the total cost of the project. The cost of running the site for a year was estimated at about US\$87,000. Assuming that 3,000 clients could be seen at the site per year, the estimated cost of providing the service was \$29 per client. Recurrent costs such as rent and salaries represented more than 70 per cent of the cost.

**FIGURE 3**  
**Cost to Provide the VCT Intervention**  
**Per Client: Overview**

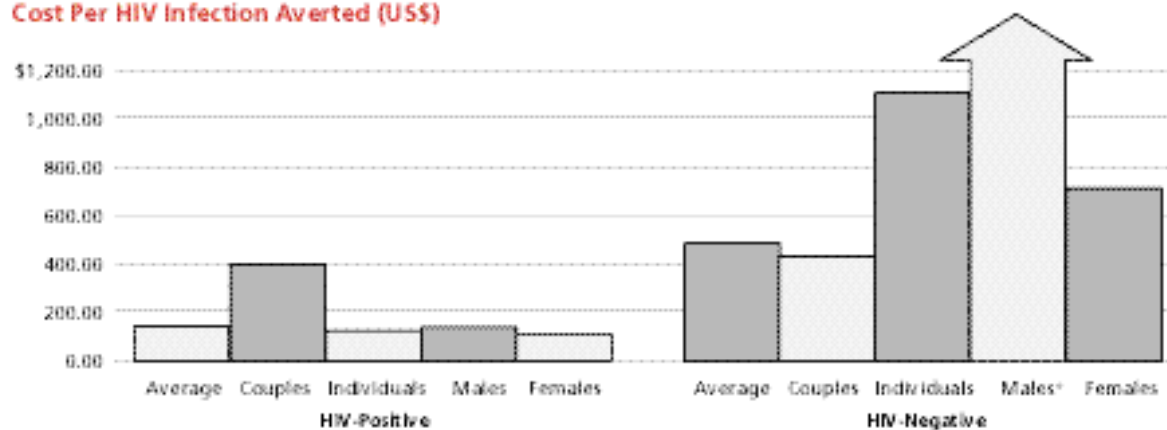


Participants' willingness to pay for the HIV counselling and testing service was explored, and more than 90 per cent reported that they would be willing to do so if asked. On average, participants reported that they would be willing to pay up to US\$5 for the service. However, it is important to note that following completion of the study, introduction of a user fee of \$3 resulted in a significant drop in the number of clients showing up at the counselling site. This number rebounded after the user fee was decreased to \$1.50, clearly suggesting that clients' willingness to pay for a service does not necessarily determine their ability to do so.

To convert behaviour-change data into health outcomes for cost-effectiveness analysis, the estimated number of HIV infections averted was calculated using a probability-based model. The baseline behaviour profile of the study participants was used to estimate the number of infections that would occur based on that profile, and the six-month behaviour profile was used to estimate the number of infections that would occur following the HIV counselling and testing intervention. The six-month figure was then subtracted from the baseline estimate to calculate the number of infections averted by the HIV counselling and testing intervention. To determine the cost per HIV infection averted, the total cost of service provision was divided by the estimated number of infections averted. The average cost per case averted was US\$303, varying from \$105 among HIV-positive women to more than \$3,000 among HIV-negative men. Figure 4 shows the cost per case averted for the different subsets of the study participants.

FIGURE 4

Cost Per HIV Infection Averted (US\$)



\* The cost of a male case averted varied to more than \$3,000.

**BEST PRACTICE CRITERIA**

This project was the first randomized trial of the efficacy of voluntary HIV counselling and testing on behaviour change to take place in non-industrialized countries. It provides the strongest evidence to date of the effectiveness of VCT as a tool to prevent transmission of HIV, and it contributes to the momentum building internationally in support of VCT programmes in non-industrialized countries.

**Relevance** Demand for VCT services is growing in most developing countries as the HIV/AIDS epidemic matures and increasing numbers of people become sick. This demand will be sustained as HIV/AIDS awareness and knowledge increase among affected populations. Providing VCT services will help support the behaviour change needed to reduce the spread of HIV and provide care and support to the growing number of people affected by the epidemic.

**Efficiency** The involvement of local collaborators from the beginning of the project significantly facilitated its implementation. Support from the NACP and the USAID mission in Tanzania was instrumental in the successful completion of the project. This project was a very positive demonstration of effective collaboration among the many organizations involved in the multi-centre study and well-coordinated partnership in meeting the study's objective in a timely manner.

**Effectiveness** The project was able to demonstrate the efficacy of VCT and its cost-effectiveness. It generated greater support for VCT services not only in Tanzania, but also in other countries in East Africa. The Tanzanian NACP is using results from this study; for example, recommendations for district-level HIV counselling and testing have been included in the Tanzania Medium-Term Plan for HIV/AIDS Prevention and Control. The NACP also has provided more support for VCT activities in Tanzania.

**Ethical Soundness** The project was implemented only after receiving clearance from the Tanzania NACP ethical review committee. Clients' participation was voluntary, and all measures were taken to ensure confidentiality. There was no report of client coercion or leak of information by the site staff. As a result, the VCT continues to achieve confidence and trust among its users, who reported feeling free to express themselves without fear for their privacy.

**Sustainability** Given the growing demand for VCT and its demonstrated cost-effectiveness as a result of this study, it is likely that the government of Tanzania and international donors working in the country will increase their support for VCT activities. The USAID mission in Tanzania has already demonstrated greater support for VCT by funding the continuation of service provision at the study site, which has become a service site at the Muhimbili University Hospital. USAID also is working with the FHI country office and MUCHS to explore ways of building on the experience gained from the counselling and testing study. According to monitoring data obtained in July 1999, the site continues to see an average of 250 clients each month.

#### **LESSONS LEARNED**

The most important lessons learned from this project include:

VCT is an effective intervention for changing risk behaviour, and it is not associated with negative life events. The results achieved in this study were made possible by the quality of the services provided at the study site. The study's client-centred counselling approach helped tailor the intervention to the needs of each client. Strict

confidentiality and the positive relationships built between counselling centre staff (especially counsellors) and their clients facilitated clients' trust and confidence in the service provided.

VCT is cost-effective. The cost of US\$303 per HIV infection averted, documented for this intervention, is well within the range of costs for other HIV-prevention interventions, such as improved syndromic management of STI in Tanzania, which was estimated at about \$250. Targeting communities with high HIV prevalence may make VCT even more cost-effective.

Although clients value VCT service and express willingness to pay for it, they do not necessarily have the means to do so. The pricing of this service must be carefully determined to ensure that people who are in most need of the service are not turned away because of their inability to pay for it.

VCT is in demand in Dar es Salaam and attracts people at relatively high risk of HIV infection, as supported by an overall HIV prevalence of 21 per cent among the VCT site's clients (compared with 14 per cent prevalence estimated in the sexually active population overall in Tanzania). After the study's recruitment period ended, many clients continued to show up for services at the site. To accommodate these clients, efforts were made to keep the centre open as a service site, with support from the USAID mission in Tanzania.

Involving local collaborators early in the project process was instrumental in ensuring a sense of ownership and in developing culturally appropriate instruments, messages and interventions for the study. For example, from the formative research conducted by the local principal investigator, locally appropriate terms

to describe concepts such as randomization (“bahati” in Swahili) and types of sexual relationships were able to be identified.

Close collaboration with the NACP and the USAID mission in Tanzania facilitated continued support for the project and rapid in-country use of the research findings to influence policy and programmes. Based on results from this study, the NACP has included VCT in its third medium-term plan (MTP III), making VCT services more accessible in Tanzania, and VCT has been identified as one of the core functions of Tanzania’s district health teams. The study findings were also used by the USAID mission in Tanzania as the basis for its continued support for the VCT site at Muhimbili University and its overall support for VCT activities in Tanzania.

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