SCIENCE TO COMMUNITY

The Voluntary HIV-1 Counseling and Testing Efficacy Study: A Randomized Controlled Trial in Three Developing Countries

Prevention #1

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Main Findings

- Voluntary counseling and testing (VCT) for HIV-1 reduces unprotected intercourse with non-primary partners among both men and women getting tested and counseled separately from their partners.
- Individuals testing positive for HIV-1 infection reduced unprotected intercourse with primary and non-primary partners to a significantly greater degree than individuals testing HIV-1 negative.
- Couples receiving voluntary counseling and testing together reduced unprotected intercourse with their enrollment partners to a greater degree than couples randomized to receive health education and information alone.
- Serodiscordant couples (in which one or both members are living with HIV-1) were significantly more likely to reduce unprotected intercourse with each other than couples in which both members were uninfected.
- HIV-1 VCT is a highly cost-effective preventive intervention in developing country settings, comparable to other proven prevention strategies such as enhanced sexually transmitted disease (STD) services and universal provision of nevirapine for pregnant women in high prevalence settings.

Background

The Voluntary HIV-1 Counseling and Testing Efficacy Study was designed to measure the efficacy of HIV VCT in developing country and resource poor settings where access to antiretrovirals and other expensive medications is difficult or impossible.[1]

What Is Special About VCT?

Even when advanced HIV therapies are not yet available in many developing countries, HIV VCT provides the following unique opportunities for individuals and couples:

- Knowledge of serostatus empowers individuals to plan and make important life decisions
- People can seek care and support
- Individuals can receive assistance in developing individualized risk reduction plans based on their serostatus and sexual relationships
- Couples can learn their serostatus together, and plan and discuss how to deal with similar or different HIV-1 infection states
- Decisions about whether to have more children or to breastfeed can be made, as can arrangements for the care and support of their current children

The Interventions

HIV VCT was based on the US Centers for Disease Control and Prevention's client-centered HIV voluntary counseling and testing model and the guidelines of the World Health Organization's Global Programme on AIDS. The content and amount of counseling the client receives are individualized and determined by their specific issues regarding HIV risk reduction. To promote cultural specificity, counselors at each site were encouraged to identify and respond to the specific cultural and environmental context of their community.

Participants were given the option of enrolling as couples or as individuals. However, individual time was given to all couple members to assure accurate risk assessment. Couples were informed prior to HIV testing of the expectation that they would share their results with their partner. These test results were given individually first, then the couple was encouraged to share their test results with each other during a joint counseling session. Post-test counseling then proceeded with both members of the couple present.

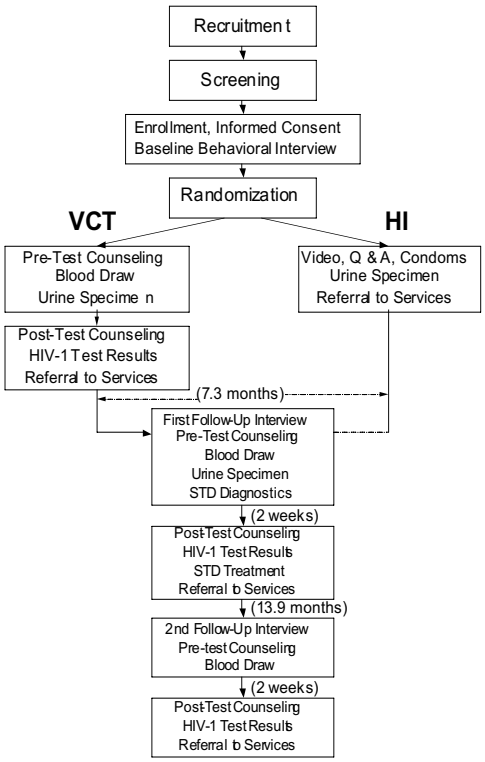
The Control Group: Health Information and Education

The Health Information and Education (HI) intervention was designed to provide accurate information about how HIV is transmitted and how transmission can be prevented through a passive, didactic method. Participants watched a 15-minute videotape including a condom demonstration and then had their questions about HIV transmission and condom use answered by

a health information officer. At the end of the session, participants received a supply of 25 condoms and a brochure describing correct condom use, and were invited to return for additional condoms at any time. A health educator or nurse with HIV education experience delivered this intervention at each site.

Study Design [1]

Sites. In Nairobi, Kenya, a freestanding clinic was established in a poor neighborhood with a high population density. The study site in Dar es Salaam was a freestanding clinic located on the grounds of Muhimbili Hospital, the national teaching hospital that is part of the University of Dar es Salaam and located in the center of the city. The site in Port-of-Spain Trinidad was a freestanding clinic established for purposes of offering an alternative to the STD clinic for VCT services.



Recruitment. Each site developed a site-specific recruitment plan combining leaflets, radio announcements, newspaper and television ads, and other media outlets. Recruiters were also sent out to solicit study participants in the community. A modest cash reimbursement was offered to all participants for each visit after the baseline visit. A total of 3120 individuals (1534 men and 1586 women) and 586 couples (1173 couple members) were recruited.

Baseline Visit. Survey, Urine Samples, Randomization to VCT or HI. Once individuals were screened, they were asked to provide informed consent and tracing information. They were administered a structured face-to-face interview (administered privately to each member of the couple with assurances of confidentiality) to assess HIV risk behaviors. Urine samples were taken and stored for later analysis, and the participant (or couple) was randomized to receive VCT or HI. Those in the HI group then received their session with the health educator and were sent home with their condom supply.

Pre-Test Counseling, Blood Draw, Post-Test Counseling. Individuals and couples assigned to VCT received pre-test counseling, had blood drawn and sent to the lab for testing for HIV-1, and were scheduled to return two weeks later for results. All participants received a supply of 25 condoms and a brochure demonstrating correct condom use.

First Follow-up. A follow-up visit occurred at an average of 7.3 months following randomization. A face-to-face behavioral survey was administered, STDs (syphilis, gonorrhea, chlamydia) were diagnosed and treated, and all participants (including those in the HI group) were offered HIV VCT. Participants provided a second urine sample that was shipped to the US to be tested using LCR for gonorrhea and chlamydia. If HIV antibodies were detected, that person's baseline sample was assayed to determine if the infection was present at baseline or had occurred in the interval between baseline and first follow-up.

Second Follow-up. A second follow-up visit occurred an average of 13.9 months following randomization, and included a repeat of the behavioral interview and STD screening. Participants who had refused HIV VCT at the first follow-up visit were again offered this service.

Selected Key Results

The participants enrolling as individuals were typically young and single (average age was 28-29 years; only 15 to 24% were currently married). Only about 30% of the men were ever married, but almost half of the women were ever married. Many had primary education (44-46%), and about the same percentage reported secondary education (40-43%); very few reported no education (2% of the men and 6-8% of the women).

Those enrolling as couples were slightly older (25-32 years of age on average) and quite likely to be currently married (62-68%), or to have been married at one time (70-74%). As with individuals, few had no education (2-7%), the majority had achieved primary education (56-62%), and some had achieved secondary education (26-32%).

How Many Were Tested and Received Their Test Results? [2]

Most individuals assigned to VCT did get tested (91 to 95%) and receive test results at baseline: 84% of the individual men and 82% of the individual women who were tested received test results. A total of 76% of the men in couples and 75% of the women in couples who were tested received test results. Of the VCT group who returned for the first follow-up, 85% were tested again; for the HI group, 94% who returned for the first follow-up were tested. (It is important to note that for nearly every study participant choosing to be tested, this was the

first time they had ever been tested.) A total of 67% of all participants who returned for the second follow-up were tested again.

How Do VCT Volunteers Compare with the General Population? [3]

We also compared persons presenting for VCT with random household probability samples in Port-of-Spain and Dar es Salaam. Individuals presenting for VCT in Tanzania and Trinidad were 3 to 4 times more likely to report unprotected intercourse with non-primary and commercial partners than population-based probability samples.

How Many Were Diagnosed with HIV-1 at Baseline? [4,5,6]

HIV-1 seropositvity varied considerably by gender and location.

- Individual men: 12% in Kenya; 8% in Tanzania; 4% in Trinidad
- Individual women: 27% in Kenya; 32% in Tanzania; 2% in Trinidad
- Men enrolling as couples: 19% in Kenya; 17% in Tanzania; 4% in Trinidad
- Women enrolling as couples: 24% in Kenya; 23% in Tanzania; 4% in Trinidad.

Did Individuals Receiving VCT Change Their Behavior? [2]

First Follow-up: The proportion of individuals reporting unprotected intercourse with non-primary partners decreased significantly more for those receiving VCT than those receiving HI:

- Men: 35% reduction in VCT vs 13% reduction in HI
- Women: 39% reduction in VCT vs 17% reduction in HI

Second Follow-up: These reductions were maintained at second-follow-up in the VCT group, and matched by the HI group after they received HIV VCT.

***Comment*:** These are the most important results of the study. Individuals receiving VCT changed their behavior and maintained those changes at a second follow-up. The initial changes were replicated in the HI group once they had access to VCT.

First Follow-up: HIV-1 infected men and women were more likely than uninfected men to reduce unprotected intercourse with primary and non-primary partners

Second Follow-up: Reductions in risk behaviors were maintained at the second follow-up and matched by those in the HI group who were diagnosed with HIV at the first follow-up.

Did Couples Receiving VCT Change Their Behavior?[2]

First Follow-up: Couples assigned to VCT reduced unprotected intercourse significantly more than couples assigned to HI.

Second Follow-up: Risk reductions documented among the VCT group were maintained; for those couple originally in the HI group that had chosen to receive VCT at the first follow-up, the same level of risk reduction was noted.

Did Couples in Which One or Both Members were Diagnosed with HIV-1 Change Their Behavior? [2]

- Couples in which one or both members were diagnosed with HIV-1 were significantly more likely to reduce unprotected intercourse with each other than couples in which both members were HIV-negative.
- These changes were maintained at the second follow-up and matched by couples receiving HIV-1 diagnoses at the first follow-up.

***Comment*:** Transmission rates among serodiscordant couples are quite high in most places in sub-Saharan Africa, even when people know that they are living with HIV. The difficulty is that this information is frequently not shared with the partner. A couples counseling strategy allows the disclosure and discussion of risk reduction to take place in a neutral environment with a counselor who can negotiate through the difficulties of disclosing such sensitive information.

Freestanding Clinic
Dar es Salaam

Did People Tell Others That They Had HIV?[7]

In contrast to other studies, we found high rates of disclosure. 70% of those enrolling as individuals and 91% of those enrolling as couples revealed their serostatus to their sexual partner(s).

***Comment*:** The right kind of counseling can encourage disclosure.

Did Bad Things Happen to People Who Disclosed That They Had HIV?[7]

Rates of negative life events were rare; 25% reported break-up of a relationship (30% for men, 20% for women). A total of 4% of the HIV-negative individuals and 8% of the HIV-positive individuals reported physical abuse (6% for women and 2% for men).

***Comment*:** Rates of physical abuse were higher for the HIV-infected persons, but not so high as to discourage the use of HIV VCT.

Which HIV-1 Infected Persons Were Likely to Continue High Risk Behaviors?[8]

We used univariate and multivariate analyses to identify demographic, cognitive, health, and relationship variables associated with continued sexual risk behavior among HIV-1 infected individuals.

- Women were more likely to continue unprotected vaginal intercourse with primary partners if they were married, involved in newer relationships, had more economic resources, perceived greater difficulty in negotiating condom use, or reported more conflicts in their relationship.
- Men who were married, involved in newer relationships, reported fewer HIV-associated symptoms, consumed alcohol prior to sex, or had less concern about the consequences of being HIV-1 infected were more likely to continue unprotected intercourse after diagnosis.

***Comment*:** This analysis is essential to identifying interventions for increasing the efficacy of VCT. Skills building in condom use negotiation, relationship conflict resolution and reducing alcohol use should be considered for subsequent interventions. In addition, programs are need that focus on men who test HIV-positive but show little compunction for subsequent behavior change.

Is HIV-1 VCT Cost-Effective?[9]

- HIV-1 VCT was estimated to avert 1104 infections in Kenya and 895 infections in Tanzania during the one-year following the intervention.
- The cost per HIV-1 infection averted was $249 in Kenya and $346 in Tanzania.
- The cost per disability adjusted life year saved (DALY) was $12.77 in Kenya and $17.78 in Tanzania.
- The intervention was most cost effective for HIV-1 infected individuals and for those who received HIV VCT as a couple.
- VCT is as cost effective as enhancement of STD services and universal provision of nevirapine for pregnant women in high prevalence countries.

***Comment*:** Demonstrating the cost-effectiveness of HIV-1 VCT is essential. The resources for HIV prevention in the developing world are far from what they should be. Studies like this point to the possible: if we were willing to spend the funds, this is what we could achieve.

Recommendations

This study reinforces the benefits and cost-effectiveness of HIV-1 VCT as part of a comprehensive package of prevention strategies for the developing world. Expert panels and plentiful data support the potential of a variety of strategies for preventing the spread of HIV-1. To that armamentarium should be added voluntary counseling and testing for HIV-1.

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Materials Available

Intervention, training materials and surveys are available on the CAPS web site: www.caps.ucsf.edu/projects/c&tindex.html.

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