An Experimental Study of Couples VCT at Three Antenatal Clinics in Dar Es Salaam

Stan Becker, Johns Hopkins University, Baltimore, Md, USA
Rose Mlay, Muhimbili University, Dar es Salaam, Tanzania
Hilary Schwandt, Johns Hopkins University, Baltimore, Md, USA

BACKGROUND

AIDS is a major epidemic with an estimated 40 million persons infected in the world and no cure in sight. Over 25 million of these infected persons are living in sub-Saharan Africa. Approximately seven out of ten people newly infected with HIV live in sub-Saharan Africa; among children under 15, the proportion is about 9 out of 10. Of all AIDS deaths since the epidemic started, 83% have been in the region. At least 95% of all AIDS orphans have been African "(UNAIDS, 2006).

Most of the transmission in Africa is via heterosexual contacts; men who have multiple partners typically bring the virus home and infect their spouses and some young women who have had premarital sex, bring HIV into the marriage. Half of those infected in sub-Saharan Africa are women. Unfortunately, anti-retroviral drugs to slow the progression of the disease have until recently not been available to many of those infected due to their high costs, entirely beyond budgets of national governments and individuals in Africa. Programs to promote condom use have had limited success. For example, in Demographic and Health Surveys from 11 African nations currently married women were asked if they had changed their sexual behavior in response to AIDS, and fewer than 15% said they had begun using condoms in all the countries, with the exception of Zimbabwe (Gardner, Blackburn and Upadhyay, 1999).

HIV in Tanzania

According to UNAIDS (2000b), among the Tanzanian population of 38 million, 1.4 million persons had HIV at the end of 2005, giving a prevalence of 8% among adults. The estimated number of orphans (under age 15) from the loss of one parent due to AIDS is 1.1 million. Among women with AIDS, nearly half are in the age group 20-29 years, the prime reproductive years. In Dar es Salaam, surveillance at antenatal sites gives seroprevalence estimates among pregnant women of 13% (U.S. Census Bureau, 2007). [We note that the seroprevalence estimate when the study began was 14%; that estimate was used in the sample size calculations.] Knowledge of HIV/AIDS is virtually universal (97% for Tanzanian women and 99% for men). Only 4% of women and 11% of men have been tested for HIV; however, nearly 70% of both sexes report they desire HIV testing. The percentages of persons already tested for HIV in Dar es Salaam are 9% for women and 16% for men.

Maternal to Child Transmission (MTCT)

Transmission of HIV from mother to infant in this setting will lead to death of the child. A synthesis of data from eight studies on pregnant women gave an overall estimate of 25% MTCT in the absence of any intervention through the time of delivery (Kourtis et al, 2001) with 10-15% more transmission via breastfeeding (Nicoll et al. 2000). Since the mid-1990s, it has been known that anti-retrovirals can prevent some MTCT transmission. Additional interventions to prevent MTCT include cesarean delivery and either no breastfeeding or exclusive breastfeeding for the first six months of life followed by abrupt weaning. Exclusive breastfeeding has a lower transmission rate than mixed feeding (Nduati et al. 2000; Coutsoudis et al. 2001). Not breastfeeding an infant to reduce MTCT carries zero risk of HIV transmission, but considerable risk of mortality from other diseases (WHO

Collaborative Study Team, 2000). For developing country settings, UNAIDS recommends that each HIV-positive woman be counseled about her options: the associated benefits and risks of different types of delivery and breastfeeding, and be left to make her own informed decisions (UNAIDS, 2000c).

With regard to anti-retrovirals, trials have shown that a single regimen of nevirapine (200 mg to women at the time of labor and 200 mg to the newborn within the first 72 hours after delivery) can decrease MTCT by nearly 50% (Guay et al 1999). Nevirapine is now becoming available in Sub Saharan Africa. Though there has been a suggestion that nevirapine be given to all women in high prevalence settings (e.g. Marseille et al, 1999), there could be serious side effects, so for appropriate use of nevirapine, a pregnant woman must know her HIV status. Thus, the importance of voluntary counseling and testing.

Voluntary Counseling and Testing (VCT)

VCT for HIV has been a part of most HIV prevention programs from the start of the epidemic. The motivation for VCT is that persons who test positive can change their sexual behaviors to prevent further spread of the disease and can notify their sexual contacts so that they in turn can know their risk, protect themselves, be tested, and so on.

Relative to a decade ago, greater emphasis is now placed on VCT for a second reason. Since antiretroviral regimens can have a greater effect and potentially extend healthy life longer the earlier after infection that they are begun, then the sooner HIV-positive persons can be identified, the better. This is also the reason for increased emphasis on the notification of sex partners (DeCock and Johnson, 1998). With regard to modification of behaviors in general populations that avail themselves of VCT, a review of 27 studies showed overall effectiveness in secondary prevention for

HIV-positive individuals, but not for primary prevention among uninfected individuals (Weinhardt et al. 1999).

Several studies have shown that VCT is cost-effective relative to other interventions (Grinstead et al. 2001, Phillips and Fernyak, 2000, Sweat et al. 2000, Varghese, Peterman and Holtgrave 1999). For example, even in populations of relatively low HIV-prevalence (i.e. the United States), VCT has been shown to be cost-effective for prevention of HIV transmission (Phillips and Fernyak, 2000). Sweat et al. (2000) working with epidemiological and cost data from Kenya and Tanzania, estimated the costs per HIV infection averted at $249 in Kenya and $346 in Tanzania. Further, VCT was more cost-effective if it was given to couples rather than individuals.

VCT for pregnant women has had added significance since nevirapine was shown to decrease MTCT by about half (Guay et al. 1999). A meta analysis of 13 studies of VCT among pregnant women in developing countries found that acceptance rates among women offered VCT were high (median 92%). However, return rates for test results were lower among HIV-positive women than among HIV-negative women in 9 of the 13 sites (Cartoux et al. 1998). One serious problem that has been identified in VCT at antenatal clinics is the reluctance of some women to test or come for their results out of fear that they might be HIV+ and their husband will find out (e.g. Temmerman et al., 1990). In fact, studies have documented that women who test positive are more likely to subsequently experience coercive sex (van der Stratten et al. 1995) and violence (Grinstead et al. 2001) than other women. However, these were the minority of women; most women had husbands who were supportive.

VCT for couples (CVCT)

An alternative to pregnant women having VCT by themselves is to have couple VCT. Studies

have consistently shown positive effects of including both marital partners in VCT. (It is possible to focus on married partners because in virtually all of sub-Saharan Africa, the vast majority of pregnancies and childbearing are within marital unions.) For example, in an observational study in Kigali, Rwanda, couples in which the male partner volunteered for testing were twice as likely to use condoms subsequently as couples in which only the woman was tested (Allen et al. 1992a). Observational studies of discordant couples in Haiti (Deschamps et al, 1996), Zaire (Kamenga et al. 1991) and Rwanda (Allen et al. 1992b) also showed that VCT directed at both partners led to greatly increased condom use (e.g. condom prevalence rose from 0% to 24% in 4 months in Port-au-Prince (Deschamps et al, 1996)). A study of 172 HIV+ women in Kenya found that women "who informed their partners about their HIV-1 seropositive status were significantly more likely to choose formula feeding over breastfeeding than women who did not inform their partners (21% versus 9%)." As noted above, the analyses of VCT by Sweat concluded that in Tanzania and Kenya, counseling for couples was more cost-effective than individual counseling.

A review of the same literature concluded: "Additional studies should be undertaken, using randomized controlled designs of the impact of CVCT on couples, especially serodiscordant ones" (Phillips and Coates 1995:121). Similarly, UNAIDS in its 'best practices' report on VCT states: "Married couples should be encouraged to go for HIV counseling together so that serodiscordant couples can be identified and counseled to help prevent transmission to the uninfected partner. Offering VCT to couples overcomes the problem of sharing test results" (UNAIDS, 2001: 23). They also pose the question that this research seeks to address: "How can VCT services associated with MTCT projects include husbands/partners and will this improve uptake and influence sexual behavior?" (UNAIDS, 2001:66).

Couples approach to reproductive health generally

In 1994 at the United Nations International Conference on Population and Development in Cairo, 180 nations reached agreement on a document that called for the integration of reproductive health services, including: family planning, infertility, STIs/AIDS, antenatal care, safe delivery and breastfeeding (United Nations, 1995). It has been recognized that the married couple may be the most appropriate unit for intervention for several of these reproductive health activities. In particular, studies with randomized designs in multiple settings have shown that involving husbands in family planning education and counseling leads to higher acceptance and continuation rates of contraception than if efforts are focused on women alone (Becker, 1996). Similarly husbands have been shown to have significant input on women's breastfeeding decisions (Sharam and Patosa, 1997) and with regard to safe motherhood, a husband's action or inaction can be crucial in cases of life-threatening pregnancy complications. Husbands' participation in antenatal care has also led to significantly better outcomes (e.g. perinatal mortality and post-natal checkups--Bhalero, et al. 1984; Mullany, Becker and Hindin, 2007). In STI treatment, partner notification, testing and treating are crucial components to minimize reinfection (Rothenberg and Potternat, 1998) and "couple-friendly" services are important to get partners to come together (Danielson et al. 1999).

Dar es Salaam and Temeke District

Dar es Salaam, the capital of Tanzania, has a population of about 3 million. Temeke is one of three districts in the city; its inhabitants are a mixture of people from various regions in Tanzania who moved into the city for the purpose of working with the government, privately, or for petty business. The district has a population of approximately one million people. The majority of the people in the Temeke district have a low income; most are employed as manual and menial workers.

The likelihood that a woman will return for subsequent antenatal visits after the first visit, if the first visit is early in her pregnancy, is relatively high in Tanzania, generally, and in Dar es Salaam, in particular. The 2004 Tanzania DHS shows that 67% of women in Tanzania had their first antenatal visit before the sixth month of gestation and most women had more than four antenatal visits (Bureau of Statistics (Tanzania) and ORCMacro, 2005: 134)

Rationale

Women have traditionally been the sole target population for antenatal care programs in developing countries. This has extended to HIV counseling and testing that is provided in antenatal clinics. VCT is a key to the prevention of HIV. Some women are reticent to be tested because of potential negative consequences if she is positive and her partner finds out. However, if she tests positive, the probability that her partner is positive is typically high (e.g. 75% or above, as reported by Keogh et al. 1994; Serwada et al, 1995). Furthermore, his support may be important in accessing nevirapine therapy that could prevent MTCT. In addition, if she is HIV-negative and he is positive, it is vital for her to know this so protective behaviors can be initiated to prevent potential transmission to both her and the fetus. Furthermore, the interventions to prevent transmission within HIV serodiscordant couples are abstinence and condoms, both of which unambiguously involve men. Thus, CVCT could have important positive effects for the entire family. Involving men has already been shown to be effective in family planning; therefore, involving couples in VCT may also prove more effective than VCT for women alone. We hypothesized that among couples with a sero-positive wife, if both partners have knowledge of their serostatus and what to do to minimize transmission to the child, it is more likely that nevirapine therapy and protective sexual behavior will

be carried out than if only the wife knows her serostatus. This study directly tests this hypothesis.

METHODS

The objective of this research was to evaluate the effectiveness of adding couple voluntary counseling and testing (CVCT) for HIV in: preventing maternal to child transmission (MTCT), increasing protective behaviors in the couple, and minimizing negative marital outcomes compared to individual voluntary counseling and testing (IVCT) in the context of antenatal care clinics in Dar es Salaam, Tanzania. The study was designed to test the following specific hypotheses:

Hypothesis 1: Offering women CVCT will not decrease their individual acceptance of VCT.

Hypothesis 2: For HIV-positive women, compared to those with IVCT, those with CVCT will have: a) improved use of nevirapine for MTCT; b) reduced sexual risk behaviors; c) lower spousal abuse and marital disruption.

Hypothesis 3: Women who consent and have CVCT are younger and of higher socio-economic status than those who do not.

Theoretical framework

Figure 1 displays the conceptual framework underlying this study. It is based on the theory of

reasoned action (Ajzen and Fishbein, 1980) which posits that background variables (left side of the figure) affect the intermediate variables of women's and men's knowledge, attitudes and beliefs about antenatal care and HIV including the fear of learning one's HIV status. These in turn influence the amount and content of couple communication about the same and the spouses' individual and joint intentions of the actions necesary to have a healthy baby; this leads most women to seek antenatal care (ANC). The figure also shows the study intervention. At ANC we offered VCT; to those consenting we randomly assigned IVCT or CVCT . In both IVCT and CVCT, if a woman tested and found out she was HIV positive, she was offered nevirapine for herself and the baby at the main delivery hospital in the area. In CVCT (only) the husband also found out about his HIV status if he consented. Protective sexual behaviors are vital to practice if either spouse is HIV+. These behaviors in conjunction with other ANC services increase the likelihood of serodiscordant couples having a healthy baby. Not shown in this simple diagram but definitely present are feedback from CVCT (and IVCT) to women's and men's knowledge, attitudes and beliefs, as well as couple communication.

Population

The target population for this study was pregnant women up to the fifth month of pregnancy, presenting for their first antenatal care visit at three antenatal clinics in Temeke, Dar es Salaam. The clinic names were: Seventh Day Adventist, Khoja and Tamya. (For women who come for their first antenatal care visit after the fifth month of pregnancy, it is more risky to have them wait for VCT until the subsequent visit with the partner, so they were not enrolled in the study, but rather offered IVCT on the day of their first visit.) Among these women, those eligible for the study were married women currently residing with their spouse. For our purposes 'married' means those with a legal

marriage, traditional marriage or those who have lived with the same partner for two years or more.

Sample size

The requisite sample size of women to enroll is dependent on the size of the differences in the criterion variables between intervention and control groups that we wished to detect with given type I and type II error probabilities. We fixed the type I error probability at 0.05 and the type II error probability at 0.20. There are four main criterion variables associated with hypotheses 1 and 2 (Table 1). The minimum sample size for this study was dictated by the last three measures for HIV-positive women since they constitute a small subgroup of all pregnant women. We postulated that only a change of at least 20 percentage points is of major importance from a policy standpoint, so we sought to detect changes of that magnitude. The usual sample size formulas for proportions in two independent samples of equal size for the intervention and control groups were applied. We inflated the numbers by the expected proportion HIV-positive (0.14). Loss to follow-up from the study either before testing or after testing positive and before the follow-up interview postpartum was assumed to be high, at 50%. The largest sample size result was 1472 which we round to 1500.

Table 1: Minimum sample size per group to detect given changes from baseline level for four criterion variables of the study

Criterion variable	Baseline level	Ref. for baseline level	Level to detect[a]	Minimum sample size required		
				HIV+ women	Women in IVCT (CVCT groups)[b]	
					Complete	With LFU
ALL WOMEN: Prop. of women testing	70%	Cartoux, 1998	90%	–	72	--
HIV+ WOMEN: Completion of nevirapine therapy	unk. (assume 50%)	—	70%	103	736	1472
Abstinence or consistent condom use since HIV test	25%	Grinstead, 2001	45%	98	700	1400
Exclusive breastfeeding or formula feeding for 1st 3 months of life	27%	Bureau of Stats. 1997	47%	100	714	1428

[a] Level to detect under alternative hypothesis specified

[b] The figures from the previous column are inflated by a factor of l/0.14 to adjust for the estimated percent seropositive and by l/0.5 to adjust for an estimated 50% drop-out.

In addition we were interested in two other outcomes for seropositive women: the proportion who have a marriage breakup and the proportion experiencing physical abuse from their husbands. Levels of these variables had been estimated for HIV-positive and HIV-negative women by Grinstead et al. (2001). We wished to determine what change in the level for HIV-positive women could be detected with the given sample sizes. Table 2 shows that with 100 HIV-positive women in each group, as specified in the last row of Table 1, it is possible to detect (assuming the same type I and type II errors) a decline in these outcomes to levels near those of HIV-negative women.

Table 2: Levels of two other outcome variables that could be detected as significantly different from reported levels for HIV+ women who did not have couple counseling (Source of reported values: Grinstead et al. 2001; Table 5)

Outcome	Reported value at follow-up for women who were:		Level that could be detected for 100 HIV+ women in this study (Table 1)
	HIV-negative	HIV-positive	
breakup of marriage	1%	19%	5%
physical abuse	6%	21%	6%

Thus the needed sample sizes were 1500 for each group. Unfortunately due to lower numbers of women attending the three clinics than expected and subsequent budget constraints, we were only able to reach a sample size of 1529 total cases.

Rapid HIV-Tests

A positive test result is not sufficient to declare that a person is HIV positive. After consultation with specialists from Uganda and laboratory staff at Muhimbili University in Tanzania,

the chosen algorithm used was the ”Bionor” test initially and if that gave a positive result then a test was run again with Abbott “Determine”. If the second result was positive, then the case was positive. If the second test was negative, then a third test (Orgenics “Doublecheck”) was done and its result constituted the tie-breaker.

Formative Research

Before study recruitment began, qualitative research was done to determine the best modalities for the study. In-depth interviews and focus groups were done with women, men and counselors at one clinic to determine the acceptability of CVCT, how to make the clinics male-friendly, how to deal with sero-discordance, and conflict in the couples. Details of this work have been reported elsewhere (Mlay, Lugine and Becker, 2007). One recommendation that was implemented in the experimental part of this study based on the formative research findings is that women in the CVCT arm be given a letter from the Medical Officer addressed to the husband inviting him to come to the clinic for the “health of the mother and baby”.

Counselor Training

Counselors from each clinic were trained in couple counseling by one of the authors (RM). UNAIDS (WHO, 1995) and the US Centers for Disease Control (2000) had detailed guidelines for counselors in HIV VCT settings generally and these were adapted to the Temeke antenatal setting; this training also drew on the results from the formative research.

Study Recruitment and Randomization

During an eligible woman’s first visit to the antenatal clinic, after usual biological tests were done, the potential study participant was asked if she would consent to be in the study including individual and couple VCT. Women who did not consent were offered IVCT.Those who gave consent were randomized to either the

intervention or control group (every other one, sequentially).

Baseline Data Collection

After a woman consented to be in the study and was randomized to a study arm, she completed a baseline questionnaire. The questionnaire was administered by a trained interviewer. Following the conceptual framework in Figure 1, the questionnaire collected information about: basic demographic, social, and economic variables (age, parity, number of living children, years of education, occupation, household possessions: radio, television, refrigerator and means of transport); knowledge of HIV transmission and prevention; and physical violence from partner in the past 12 months.

VCT

Women in the control arm were offered IVCT. Women randomized to the CVCT arm were asked if they would agree to bring their husbands with them for the next antenatal clinic visit two weeks later. For those who agreed, a letter addressed to the husband from the clinical officer in charge requesting the couple to attend the antenatal clinic together was given to the woman to give to her husband. The woman was told to return to the clinic even if her husband refused, or was unable, to come. At the next antenatal visit, if the husband did not come with the woman, she was offered IVCT.

If the couple did come together, each member had a separate counseling session. Many of the topics covered in the counseling were common to both study arms and were tailored to the situation–whether a first birth or not, any specific health problems (e.g. anemia, STI, etc) and care during pregnancy. If only one spouse consented, s/he continued with IVCT but was given a future appointment to receive the results in order to maximize confidentiality. If both consented to test, then rapid HIV tests were done, including a second test for confirmation of any positive result. If neither consented, the couple entered a comparison group in the study.

However, for 'intent-to-treat' analysis they were included with the intervention group.

For those couples in which both partners tested, we then counseled each spouse individually about his/her test results and ask for consent (or not) to share the results with the spouse. If both consented to test but not to receive results together, we continued with IVCT for each. If both consented to receive results together, then they had the counseling session together. If both tests were negative, we counseled the couple about safe sex practices so that both partners would remain negative. For sero-discordant couples, if the wife was HIV-positive and the husband was HIV-negative, we counseled them about nevirapine therapy, and the father's support for formula feeding or exclusive breastfeeding. These couples were counseled intensively. The use of abstinence or condom for the man's protection was emphasized. If the wife was HIV-negative and the husband was HIV-positive, the importance of abstinence or safe sex was stressed to protect the woman and baby. If both spouses were sero-positive, the couple was counseled about anti-retrovirals for themselves, nevirapine therapy and infant feeding options, prevention of other infections, health care availability and so on.

Information about the availability of anti-retroviral drugs was provided to all study participants who were found to be HIV-positive. Nevirapine tablets were given to the Temeke Hospital delivery ward where most women from these clinics deliver to ensure all HIV-positive women identified in this study had access to MTCT prevention treatment. A list of the HIV-positive women from this study was provided to the physician in charge at the delivery ward.

Ethical considerations

As shown in Figure 2, consent was asked at three stages in the CVCT study group: at counseling, testing, and receiving results. Women not consenting to CVCT at any time were encouraged to continue with IVCT. Though it was thought unlikely, the request for women to bring their husbands could cause a substantial

proportion of them to not return at all. We thought it would be unlikely because at the time of asking consent, women who did not consent were offered IVCT and women in Tanzania have an average of 3.9 antenatal clinic visits (Bureau of Statistics (Tanzania), 1997). In case she consented to CVCT but did not return, unless she attended another clinic, she would not have the possibility to have VCT and potential nevirapine therapy if she were HIV-positive. This would constitute an adverse outcome and if it happened too frequently, the CVCT would need to be stopped. Therefore, we monitored the percentage of women who were actually tested in the two study arms.. Ethical approval was received from the IRB of Muhimibili University College of Health Sciences and the Johns Hopkins School of Public Health. Participants were informed of the purpose of the study the procedures, risks and benefits, and gave their informed consent before participating.[1]

Analytic Methods

From clinic records, baseline questionnaires, VCT forms, and follow up forms we determined the percentages of women and couples who were in various parts of the flow diagram of Figure 2. Estimates of unconditional and conditional probabilities (from the observed proportions) were made. A crucial statistic is the proportion of women who were tested in each arm of the study. In the CVCT arm for this first test any woman who was tested is included, even if she 'crossed over' to IVCT.

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[1]*A Data Safety Monitoring Board was created to monitor the acceptance of VCT in the two study arms, since failure to accept VCT meant that pregnant women who were HIV-positive would not receive nevirapine, constituting an adverse event. Though the interim reports from hand tallies of study logs showed no significant differences between the two arms, when the computerized data were later tabulated, it was found that the hand tallies had been in error. As reported in this paper, the computerized data showed that VCT acceptance rates in the couples arm were significantly below those in the individual arm. When this was discovered, the randomization to couples VCT was discontinued, and thereafter all women were offered individual VCT. By that time, however, the study enrollment was virtually complete. The Johns Hopkins School of Public Health IRB investigated the discrepancies between the study log and computerized tabulations, and determined that these differences were due to methods of tracking individuals. The IRB approved submission of a paper for publication based on the cleaned data records.

To examine selectivity of women into the study groups, simple diagnostics were considered. Specifically in the CVCT group, tabulations of years of education, age, and other key socio-demographic variables were done for the following subgroups:

a. Women who returned with their husbands

b. Those who returned without the husband

c. Those who did not return.

Usual z and t-tests as well as ANOVA and chi-squared tests were done for each variable to assess differences between the groups outlined above.

Each HIV-positive woman (alone or in a couple) was given an appointment to return three months after the expected delivery date. She was also told of the financial incentive if she returned; more specifically, bus fare was given if she returned. At that time, a questionnaire was administered by an interviewer blinded to the woman's study group. In the interview we determined: 1) whether she and the baby completed nevirapine therapy or not; 2) whether she was still residing with her husband or not; 3) whether (or not) she experienced violence from her husband since coming to the clinic; 4) whether or not she currently was having sexual intercourse, and if so, were condoms used or not. For women who did not return, attempts were made by an interviewer to visit them in their homes.

RESULTS

The randomization was checked first by examining the differences in key variables between the IVCT and CVCT study arms (see columns 2 and 3 of Table 3). The two experimental groups are comparable except for two significant differences. Specifically, radio ownership is higher among women in the IVCT group and the proportion knowing someone who is living with HIV, or AIDS, or has died from AIDS related causes is also significantly higher in the IVCT group. We note that with the 18 tests in Table 3, the probability of two or more

showing significant results at the 0.05 level is 0.22.

Within the group randomized to CVCT, women who accepted CVCT were significantly younger and of lower parity than women who did not return (Table 4). However, women who did not return for VCT were of higher SES than women who did accept testing–i.e. they had more years of schooling and a greater proportion who lived in households that owned a television, refrigerator and car or truck. (Note these women were less likely to live in households with a radio or bicycle.)

The study results are summarized in a flow diagram (Figure 2). Among the 769 women randomized to IVCT, 710 (92%) agreed to counseling, 600(78%) to testing and 541(70%) to receive the results. Among the 760 randomized to CVCT, only 254 (33%) returned with their spouses, 115(15%) returned alone and 391 (51%) did not return at all. Of the 254 who came as couples, 119 (47%) agreed to counsel, test and receive results together. Overall in the CVCT arm, 327 (43%) tested. The diagram shows the numbers of couples where there was concordance or discordance on agreement to counsel, test and receive results together. Of the 927 women who tested, 93(10%) were HIV-positive. Only 20(22%) of the sero-positive women actually reported in the follow-up interview that they received nevirapine. Among those who tested, the proportions HIV-positive were 9.5% (57/600) in the IVCT arm and 11% (36/327) in the CVCT arm.

A comparison of the outcome indicators from the followup survey by CVCT/IVCT group is shown in Table 6. Nevirapine use was low and virtually the same in both groups. The only outcome factor that differed significantly ($p<0.05$) between the study arms was reporting use of protection for HIV transmission prevention. Also, the percentage still living with the husband was higher and the percentage experiencing domestic violence was lower among women in the CVCT arm though these differences did not reach 0.05 significance levels.. It is important to note, however, that these results could be due to a selection effect.

CONCLUSION

In this experiment of couples' VCT compared to individual VCT at three antenatal clinics in Dar es Salaam, the return rate of women with their partners was 254/760 or 33%. Since antenatal clinics are perceived as a place for women only, not men, men have to overcome individual insecurities, as well as social and cultural barriers in order to accompany their wives to the clinic. To encourage more men and women in partnership to attend VCT together, an IEC campaign about the importance of couple counseling and testing may be appropriate. Women who brought their partners were less likely to be working and less likely to be Muslim than women who did not return or returned without the husband. They were also less likely to have ever been beaten, as one might anticipate. As mentioned previously, couples VCT is not the appropriate means of HIV counseling and testing for all couples; however, it may be beneficial in certain subpopulations. Antenatal and VCT clinics may provide more effective services that produce long lasting behavior change if they are open to reorienting their design, from individual or woman centered to couple-friendly services.

There was no difference in nevirapine use by VCT study arm. We hypothesized that women would be better able to prevent MTCT with their partner's support in the couples' arm. This lack of effect may have resulted from the fact that physicians at the delivery ward dispensed the nevirapine, i.e. nevirapine was not under the woman's control.

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Table 3: Comparison of characteristics of women randomized to individual or couple VCT in experimental study in 3 antenatal clinics in Dar es Salaam, Tanzania.

Number of women	1529.00	761.00	760.00
Age (mean)	24.8	24.9	24.7
Parity (mean)	1.1	1.2	1.1
Education (mean)	7.0	7.0	7.0
Assets--Percentage with:			
Radio*	87.3	89.5	85.1
Television	35.8	36.0	35.3
Refrigerator	22.2	23.3	21.2
Bicycle	14.1	14.7	13.4
Motorcycle	3.2	3.9	2.4
Car/Truck	7.6	8.7	6.5
Percent currently working	27.5	27.9	27.0
Religion: Percent Muslim	73.8	74.8	72.8
HIV Knowledge score (mean)	5.5	5.6	5.5
Knowledge of transmission during:			
Pregnancy (%)	63.8	64.7	62.5
Breastfeeding (%)	77.6	77.8	77.4
Know someone with HIV* (%)	70.1	72.7	67.5
Know where to buy condoms (%)	80.2	81.2	79.0
Ever beaten by husband (%)	17.7	19.5	16.2
Beaten in last 6 months (%)	7.6	8.3	7.0
Scenarios with beating justified (mean out of 6)	1.7	1.7	1.6

* $p < 0.05$ for null hypothesis that all groups are from the same population.

Table 4: Comparison of characteristics of women randomized to CVCT, by their actual participation in CVCT.

Variable	Group of CVCT women					
	All CVCT women	Came with husband			Came w.o husband	Loss to follow-up
		All women	Couple had VCT together	Others who came together[a]		
Number of women	760	254	119	135	115	391
Age (mean)*	24.7	24.2	23.5	24.7	24.2	25.2
Parity (mean)	1.1	1.0	0.8	1.2	1.1	1.2
Education (mean)*	7.0	6.9	7.1	6.7	6.4	7.2
Assets–Percent with:						
Radio*	85.1	89.8	89.9	89.6	79.1	83.9
Television	35.3	32.3	26.1	37.8	29.6	38.9
Refrigerator*	21.1	20.1	15.1	24.4	7.8	25.6
Bicycle	13.4	13.8	14.3	13.3	14.8	12.8
Motorcycle	2.4	2.4	3.4	1.5	1.7	2.6
Car/Truck	6.5	4.7	5.0	4.4	7.8	7.2
% currently working	27.0	22.8	21.0	24.4	25.2	30.2
Religion: % Muslim	72.8	67.3	60.5	73.3	75.7	75.5
HIV Knowledge score (mean)	5.5	5.4	5.4	5.4	5.6	5.5
Knowledge of transmission during:						
Pregnancy (%)	62.5	57.9	58.0	57.8	68.7	63.7
Breastfeeding (%)	77.4	74.8	77.3	72.6	79.1	78.5
Know someone with HIV	67.5	65.4	63.9	66.7	61.7	70.6
Know where to buy condoms (%)	79.0	78.0	76.5	79.3	73.0	81.3
Ever beaten by husband	16.2	12.2	10.1	14.1	15.7	18.9
Beaten in last 6 months (%)*	7.0	4.0	4.2	3.7	5.2	9.5
Scenarios with beating justified (mean out of 6)*	1.6	1.5	1.5	1.4	2.2	1.6

[a] Couples came to VCT together but did not have counseling, testing, and/or receiving results of VCT as a couple.

* $p < 0.05$ for hypothesis that the three main CVCT groups are from the same population.

Table 5: Comparison of women's characteristics (percentages) at follow-up for HIV-positive women in the two randomized study arms.

Variable	VCT study arm		p-value
	Individual	Couple	
(Number of women)	(50)	(31)	--
Live with Husband	80	90	0.23
Experienced domestic violence	14	3	0.10
Use protection for HIV	61	82	0.04
Nevirapine treatment, mother	24	26	0.84
Nevirapine treatment, child	22	27	0.61

Figure 1: Conceptual framework for pregnant women seeking antenatal care (ANC) among married couples with unknown HIV status, and IVCT and CVCT interventions

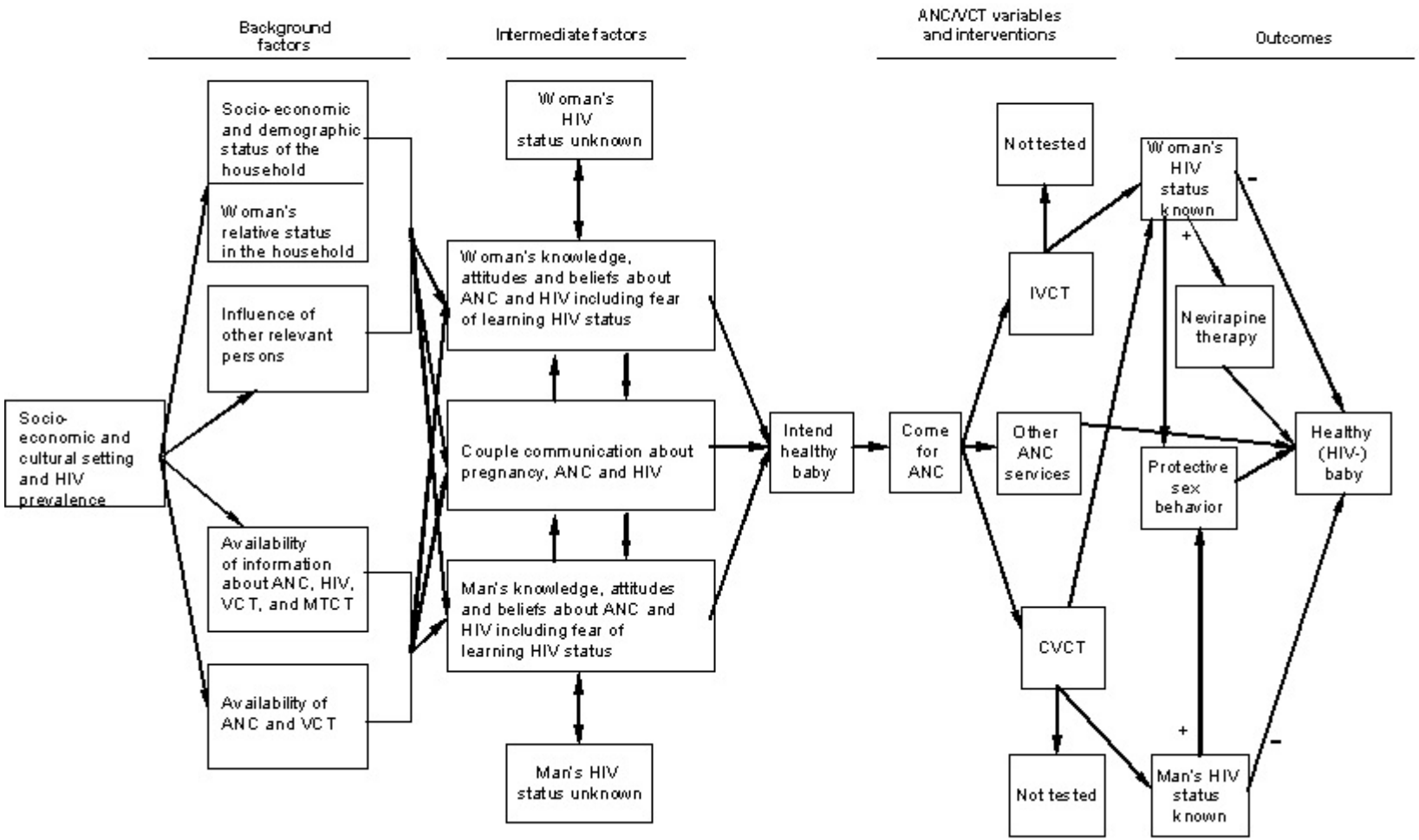

Figure 2: Flow diagram for the study