Early detection of HIV infection in discordant heterosexual couples in Africa
Susan Allen and the Rwanda/Zambia HIV Research Group

Objective: The early infection period is of interest for studies of pathogenesis. Early detection is also critical as an endpoint in clinical trials of prevention interventions. Strategies to increase identification of new infections include shorter testing intervals and antigen detection methods.

Methods: HIV discordant couples are enrolled though a couples' VCT center and followed at 3-month intervals. The HIV negative partner is serologically tested with rapid HIV tests (Abbott Determine and Trinity Biotech Capillus), and plasma set aside for weekly p24Ag screening (Beckman-Coulter). Antibody positive patients are counseled and additional samples taken of blood and genital fluids from both partners. Antibody negative individuals that are p24Ag+ are called in for repeat testing and sample collection. The p24Ag is considered positive at 3x the calculated cutoff for the EIA run.

Results: The seroconversion rate in counseled HIV discordant Zambian couples is 7-8/100 PY. Of 106 seroconvertors identified in 30 months of the study, 24 (23%) were p24Ag+. Six of these were antibody positive with two rapid tests at the time p24Ag was detected, the remaining 18 were antibody negative. All 18 were antibody positive when they returned for repeat testing and sample collection, but only 1 of the 18 was still p24Ag+ at re-draw.

Conclusions: In a cohort with a seroconversion rate of approximately 2% per 3-month interval, one quarter of new infections can be identified during the early, p24Ag+ phase. The main obstacle to detection is the short duration of the antigen positive window, rather than the sensitivity of the antigen test. Because increasing the frequency of study visits would result in decreased retention, the best strategy for obtaining study samples in early infection is more frequent batching of p24Ag testing and same-day invitations for re-draw.

Prioritizing ART selection in Rwanda.
Jane Atkinson, Kayitesi Kayitenkore, Brigitte Bekan, Etienne Karita and the Rwanda/Zambia HIV Research Group

Objectives: Currently within sub-Sahara Africa there are 25 million HIV positive people of which approximately 15% qualify for antiretroviral treatment (ART) according to guidelines commonly used in the area. Funding agencies are increasingly providing ART to meet this need. However, how can countries and projects within these countries handle the rush for treatment? We review the systems put in place in Rwanda to meet the objective of "effective and ethical selection of patients for ART within resource constraints."

Methods: Several methodologies have been proposed for prioritised selection of ART patients from a large potentially eligible population, including 'first come first served', 'first diagnosed HIV positive first served', 'clinical stage' and 'CD4 count'. Using a combination of these, Projet San Francisco developed its own system adapted to Rwandan circumstances and ethical considerations. This system is based on the Ministry of Health's national guidelines, which outline the clinical and immunological criteria for starting a)stage IV, b) stage III with CD<350, and c) CD4<200. They also outline the need for a selection committee to review all potential patients.

Results: The system has 9 stages: 1) staff training; 2) patient staging by nurses; 3) Co-trimoxazole adherence assessment; 4) file review by doctor; 5) discussion with client about ART; 6) laboratory tests; 7) presentation of clients' file at selection committee. If selected 8) client and a support partner are given

precommencement counselling with the option to refuse. Only then is the final stage reached: 9) commencement of treatment. To maintain quality, 1 doctor and 2 nurses can commence a maximum of 5 clients per week.

Conclusions: Systems must be put in place to show in a transparent way who is selected and who isn't. Projects and centres must start slowly so as to not get overwhelmed. Support must be proved to the clients and staff.

Clinical Efficacy of Generic Antiretroviral Therapy
Joyce Au and the Rwanda/Zambia HIV Research Group

Objective: Little research has been published on generic antiretroviral (ARV) drugs. Thus, this study aims to evaluate their clinical efficacy.

Methods: The six month progress of HIV patients initiated on ARV is compared to that of those who did not receive ARV since it was just before ARV became available. All patients were with the HIV research group, Project San Francisco, in Kigali, Rwanda, and all had advanced HIV disease at World Health Organization (WHO) stage III or IV at baseline. The primary measures of outcome were the WHO stage and mortality. Other measures were body mass index (BMI), hematocrit, CD4 count, adherence, and change of drug regimen.

Results: With respect to individual change in WHO stage, 84% in the ARV group experienced improvement, compared to only 55% in the control group (Fisher test, $p<0.05$). Generic ARV also reduced the mortality rate from 21% in the control group to 4% in the ARV group (Fisher test, $p<0.05$). The six-month increases in BMI and hematocrit were also greater in the ARV group than the control group (both Satterwaite t-tests, $p<0.05$). Within the ARV group, the average CD4 count rose from 116 to 220 in six months (paired t-test, $p<0.05$), and adherence was high with only 0.22% doses missed. Only 3 out of 56 ARV patients had side effects that prompted a change in the drug regimen.

Conclusion: Generic ARV drugs are efficacious in reducing morbidity and mortality, with high levels of patient compliance and drug tolerance. Thus, they offer a viable and affordable option for developing countries in Africa where the need for HIV treatment is tremendous. Given the infrastructure such as that at Project San Francisco, generic ARV programs can be implemented and expanded with a sustainable future.

Knowledge, Attitude, And Behavior Of Hiv Patients On Antiretroviral Therapy
Joyce Au and the Rwanda/Zambia HIV Research Group

Objective: Given the recent advent of antiretroviral (ARV) therapy, this study aims to explore the knowledge, attitude, and behavior of HIV patients on ARV therapy.

Methods: Interviews were conducted with HIV patients on ARV at the research site, Project San Francisco, in Kigali, Rwanda. A standardized survey was then designed and administered.

Results: Some of the many findings were as follows. 97% knew the significance of a CD4 count - some even described it as "the soldiers that guard your health". 100% stated that they could not miss even one dose of ARV ever – it was "like never forgetting to eat". With regards to obstacles in accepting ARV

therapy, 76% patients feared that the ARV would increase their appetites while they would not have enough to eat. Since starting on ARV therapy, 82% became more willing to discuss about HIV and encourage others to be tested. Over 80% patients regained the ability to run the household and work a job. 98% also reported maintaining or increasing the frequency of safe sex with condoms.

Conclusion: Our patients demonstrate a high level of knowledge on ARV, a pragmatic attitude, an open outlook on HIV, and conscientious behavior. This study uniquely highlights issues specific to developing countries in Africa, such as the dilemma to accepting treatment posed by the scarcity of food. Also, the pre-treatment counseling at Project San Francisco is effective and instills responsibility in patients so as to optimize the sustainability and future of ARV. Furthermore, ARV contributes to an open atmosphere where people are more encouraged to get tested for HIV and thus address the HIV epidemic. Beyond in health, generic ARV programs have a beneficial impact on the overall well-being of the individual and the community.

Integrating nutritional care and support and to the standard care of people living with HIV/AIDS: Case of Projet San Francisco, Rwanda
Brigitte Bekan and the Rwanda/Zambia HIV Research Group

Objective: Nutrition status is proven to influence the progression of HIV and poor nutrition has been linked to decreased immunity. People living with HIV/AIDS (PLWHA) in Africa are challenged by poor nutrition prevailing in many countries. Furthermore their declining health put them at a higher malnutrition risk. Building a model of nutritional care and support within the standard care is therefore crucial to avoid the cycle combining malnutrition, immunity, and infection.

Methods: Due to resource constraint, we set priorities and defined selection criteria for our food distribution program. Food supplement was provided to individual on Antiretroviral or tuberculosis treatment, and individuals with critically low Body Mass Index (BMI) <18 for women and <17.5 for men. We took into consideration “food sharing” by providing enough food for five- member families.

Results: We enrolled 208 individuals: 68% are on Antiretroviral treatment, 27% had low BMI (62% of which were HIV negative) and 3% were treated for tuberculosis. After 3 months, we recorded less recent illnesses compare to the three months prior to enrollment (25 vs. 85): 5 Upper Respiratory Infection Vs. 7, 11 cases of asthenia vs. 27, and acute diarrhea vs. 14. In addition, there was a noticeable increase in individual BMI, the mean raising from 20.59 to 20.69, and the number of daily meals has gone up from 2.015 to 2.256.

Conclusion: The preliminary data shows a clear positive effect of food supplementation on all aspects of recipients’ health and well-being. Challenges to the food program include “food-sharing”, cost for transport, the inadequacy between supplement and local food pattern. A food supplementation coupled to income-generating activities can substantially improve the health and quality of life of PLWHA.

Taking it to the Streets: Mobile Units for Couples Voluntary Counseling and Testing
Deborah Casanova and the Rwanda/Zambia HIV Research Group

Objectives: Couples’ VCT (CVCT) decreases HIV incidence between partners by >50%/year, however <1% of African couples have been tested together. In addition to fixed CVCT sites, mobile units (MU) enhance

supply of CVCT by bringing the service into communities. This study considers various factors in determining the success of MUs to increase CVCT uptake in Rwanda and Zambia.

Methods: MUs were implemented concurrently in Kigali and Lusaka from July 2004-January 2005 where CVCT was not previously available. Political and community Influential Network Leaders (INLs) identified MU locations for CVCT. MUs were held at each location twice a week for one month. Influential Network Agents (INAs) were trained to invite couples to fixed CVCT and MU sites. The number of couples tested and additional observations were recorded.

Results: In Kigali, MUs were held at 3 schools, 1 private clinic, 1 PLWHA association, and 1 district office from July 2004-January 2005 where 366 couples were tested. The highest average of couples tested was at the private clinic (14.8). Most sites were located at least 3kms away from the fixed site. In Lusaka, MUs were held at 1 school, 3 private clinics, 3 churches and 1 community center where 22 couples were tested. The highest average of couples tested was at the private health clinic (1.4). All Lusaka MU sites were located within 3kms of the fixed site.

Conclusions: Successful MU sites depend on the participation from community and political/administrative leaders as well as the type of site. In Kigali, the most successful MU benefited from strong INL involvement and additional leaders at the grassroots level. In Lusaka, bringing services closer to the community through MUs has not been successful. Additional political/administrative and grassroots leaders have not been fully utilized in promoting MUs and these sites may not be far enough away from the fixed site.

Too Many Jobs, Too Few Doctors: Problems and Possible Solutions for Government Health Institutions Sharing Clinically Trained Officials with HIV/AIDS Research Centres
Elwyn Chomba, Jennifer Albertini, and the Rwanda/Zambia HIV Research Group

Objectives: The increased funding for HIV/AIDS research in developing countries has created a wealth of research opportunities for physicians, many of who are working for the Ministry of Health. Such positions offer higher wages than the government agencies can offer. These high wages have created a situation, which results in an extreme variation in salaries, and therefore a high turnover rate and training costs to both government institutions and international HIV/AIDS research centres. As a result, the need to share a limited number of clinically trained physicians between the government institutions and the HIV/AIDS research centres becomes a critical issue.

Methods: Key informant interviews and literature reviews form the basis of this study. Research centres receive funding from international, national and bilateral donors. These organizations set up centres in developing countries and hire local clinical staff, many of whom were previously government employees.

Results: The siphoning off of skilled government workers has left a dearth in government health systems worldwide. Training leading to advanced degrees has been provided to more than 20 physicians affiliated with an HIV research project in Zambia to support an even distribution of human resources. Several of these researchers sponsored by this project now collaborate with the research project part-time while maintaining their responsibilities at government hospitals and health centres. This ensures technology transfer and allows civil servants to earn more without leaving government. Unfortunately, several other organizations have hired the few physicians available full time, which depletes government institutions even further.

Conclusions: Research projects must work closely with Ministries of Health to ensure that research and care mandates are mutually reinforced, and in particular to protect government against debilitating 'brain

drains' caused by a burgeoning NGO sector. International organizations must examine the impact they have on local government health systems and salary scales.

Knowledge of Couple's VCT, willingness and obstacles to get tested : Results from household survey reflecting the impact of Community based Promotion Program in Kigali/Rwanda
Freya De Clercq, Francois Katangulia, and the Rwanda/Zambia HIV Research Group

Objectives: In Africa, > 60% of new HIV infections are acquired from a spouse or cohabiting partner. Yet <1% of African couples utilize Couples' Voluntary HIV Counseling & Testing (CVCT) services. This study investigates the population's knowledge of CVCT services in Kigali, Rwanda- an African capital with a high prevalence of HIV.

Methods: "Influence Network Agents"(INAs) were trained to invite and mobilize couples in their community for CVCT. A household survey was conducted with one adult per household. 400 women and 400 men were interviewed, including 200 from the INA neighborhood and 600 from 3 neighborhoods where INAs had not worked.

Results: Over 84% of the population interviewed knew where to get tested; 90% of the cohabiting couples and 77% of singles or non-cohabiting couples. >93% knew about CVCT services and >95% approved of the idea to getting tested with the partner. INAs felt that obstacles to testing were primarily logistical (time, cost). In contrast, survey respondents cited fear of the partner (41,7%), fear of stigma (29,9%) and finance (14,1%). The population cited the radio (59%), religious leaders (21,8%) and grass-root leaders/INAs/teachers (19%) as the primary means of mobilization for couples' testing. Residents in the INA neighborhood were more likely to know about CVCT than those in the other 3 neighborhoods.

Conclusions: Results indicate a great familiarity with VCT services amongst couples in Kigali. Although the vast majority approved of the idea to get tested together, stigma and fear of the partner were cited as main impediment to get tested. Community based promotional strategies has proven to be the most efficient mean to tackle those issues. A further integration and mobilization of community leaders with the INAs would increase the demand for CVCT and overcome stigma by spreading out the right message on HIV/AIDS prevention in their communities.

Establishment of Quality Control Procedures for HIV Rapid Testing in Lusaka, Zambia
Shannon Emery and the Zambia/Rwanda HIV Research Project

Objective: Results of EIA testing as external quality control for HIV rapid tests at a couples' Voluntary HIV testing and counseling center are presented.

Methods: From March 2002 to February 2005, plasma collected from couples was screened with Abbott Determine and confirmed with Trinity Biotech Capillus. Plasma with indeterminate or invalid results and a random sample of 1% positive or negative samples were sent to the Zambia blood bank for quality control confirmation using the Murex HIV Ag/Ab Combination Enzyme Immunoassay (EIA). Clients with discrepant or invalid results were asked to return for retesting one month later.

Result: Of the 639 samples sent for EIA confirmation, 188 specimens had indeterminate (N=56) or invalid (N=132) HIV rapid tests results. Eleven percent of the specimens tested with Determine and EIA yielded different results. 20/48 samples with different Determine and EIA results were resolved with

repeat blood draw and/or testing and the Determine result was correct 65% of the time. Of the 329 specimens tested with Capillus and EIA, 10% resulted in discrepant results. 10/34 were resolved and Capillus was correct 60% of the time. If EIA is used as gold standard, the sensitivity and specificity of the Determine test and the Capillus test were both 92% and 87%.

Conclusion: External is necessary for voluntary HIV testing programs that depend on rapid HIV testing. Training and continuous monitoring of the quality control of both rapid tests and confirmatory EIA are essential to ensuring accurate and reliable results. Although EIA is often viewed as a 'gold standard', it is technically more complex than rapid tests and often results in more errors. Further testing of samples that have different results with rapid tests and ELISA is required in order to ensure comprehensive quality control.

Increases in HIV Prevalence and Prior Testing at a Couples' Voluntary Counseling and Testing and Research Center in Lusaka, Zambia

Amanda Fraser-Bell, Susan Allen, and the Rwanda/Zambia HIV Research Group

Introduction: The Zambia-Emory HIV Research Project (ZEHRP) in Lusaka, Zambia has provided couples' voluntary counseling and testing (CVCT) for HIV since April 1994. Recently, HIV prevalence and self report of prior testing have increased.

Methods: HIV prevalence and prior testing are described for 7774 couples attending ZEHRP CVCT between January 2002 and February 2005. Data are compared with over 10,000 couples tested from 1995-2000 and 665 couples tested at two antenatal clinics in 2001. All clients received HIV results, counseling, and condom skills training as a couple.

Results: From 1995-2000, 57% of couples were concordant negative (--), 20% discordant (+-), and 23% concordant positive (++). At two antenatal clinics in 2001, 3-8% of women reported previous HIV testing.

From 2002-2005, the proportion of concordant positive, discordant, and concordant negative couples changed from 28% (++), 20% (+-), and 52% (--) in 2002 to 36% (++), 18% (+-), and 46% (--) in 2005. The proportion of clients previously tested at non-ZEHRP clinics increased from 9% of women and 7% of men in 2002, to 28% of women and 17% of men in 2005. The proportion of couples with both partners previously tested increased from 4% to 14%, and the proportion with neither partner previously tested decreased from 87% to 62%. Many women reported previously testing at antenatal clinics. ARV programs opened at nearby government clinics in quarter four of 2004, and the proportion of couples with at least one HIV+ partner increased from 53% to 58% during that time.

Conclusions: At ZEHRP, the proportion of clients previously tested for HIV has steadily increased in the last 3 years. This corresponds with the introduction of PMTCT and VCT programs, and confirms that these services are encouraging individuals to test with their spouses. Although most HIV-positive individuals are asymptomatic at VCT, simple symptom-based ARV referral procedures are needed.

Differing Results of a Rapid HIV Testing Algorithm in Couples' Testing Centers in Two African Cities with Different Clades of HIV

Shila Glass and the Zambia/Rwanda HIV Research Group

Objective: To evaluate the results of a rapid HIV testing algorithm based on a combination of Abbott Determine HIV-1/2, Trinity Biotech Capillus HIV-1/HIV-2, and
Trinity Biotech Uni-Gold HIV in Kigali, Rwanda (predominately clade A) and Lusaka, Zambia (clade C). Among HIV discordant couples, the likelihood of early infection is high in the uninfected partner, necessitating a more sensitive testing algorithm.

Methods: From August 2004 – February 2005 couples were screened with Determine, and those with both partners Determine negative were not further tested. Couples with one or both partners positive or indeterminate with Determine were tested with Capillus and Uni-Gold. Results for each test were interpreted as negative (-), positive (+), or indeterminate (I). Results given were based on >=2 tests with the same result.

Results: In Rwanda, 80% of the 4637 couples tested had two Determine (-) partners. Of 1820 samples tested further: 57.0% were (+) and 33.6% were (-) with all three rapid tests. Of the remaining 170 samples with indeterminate or discrepant results, 68% were Determine (+) or (I) and Capillus and Uni-Gold (-) and 23% were a combination of discrepant test results including 21 clients counseled as (-) and 18 as (I). In Zambia, 43.6% of the 686 couples tested were two Determine (-) partners. Of the 772 samples tested further: 80.7 % were (+) and 17.6% were (-) with all three rapid tests. Only 1.7% of samples had discrepant or (I) test results: 7 were counseled as (-), 5 as (I) and 3 as (+).

Conclusion: A third 'tiebreaker' rapid test allowed definitive same-day results to be provided to >99% of clients and reduced the number of indeterminate results given to 0.20% and 0.36% of clients in Rwanda and Zambia respectively. More discrepant results were seen between tests in Rwanda, where clade A predominates.

What the better half is thinking: perceptions of risk, beliefs about HIV, and couple communication in Rwandan husbands and wives

Kathy Hageman and the Rwanda/Zambia HIV Research Group

Objectives: To investigate dynamics of partnership dyad that influence risk of HIV, this analysis assesses couples' communication and agreement/disagreement regarding sexual behavior, attitudes, beliefs, and HIV risk factors.

Methods: In 1988, 1,458 women recruited from an antenatal sample were offered VCT and enrolled in a prospective study. At the 36-month follow-up visit women's partners were invited to participate. 779 males enrolled, one-third had previously been tested for HIV. Men and women separately completed a 158-question survey, assessing knowledge, attitudes, and beliefs regarding sexual behavior and HIV.

Results: Of the 779 couples, 67% were concordant negative, 19% were concordant positive, and 14% were HIV discordant. All couples were married or cohabitating for an average of 11 years. The majority of couples were monogamous and Catholic. Men reported more years of schooling than women, and two-thirds of women earned no income of their own. Men and women were very knowledgeable about HIV transmission, prevention, and natural history of disease. Women were more pessimistic than men about the likelihood of finding an HIV vaccine or cure in the next 5 years (53% vs 44% no). Women were more likely than men to think that men were unfaithful (50% vs 20%) and could not stop themselves (56% vs 46%). Men were more likely than women to believe that sex without a condom was necessary to maintain health of both partners and the developing fetus (73% vs 55%). 52% of women and 35% of men thought they were at risk for AIDS, with 43% of couples agreeing on risk perception.

Conclusions: Responses indicated limited communication within couples about HIV related beliefs and risk perception. Couples' counseling strategies should include bringing important beliefs into the open during the pre and post-test counseling session in order to facilitate an effective risk reduction plan.

A Family Planning Intervention to Promote Future Planning in HIV Infected Zambian Couples
Faith Henderson and the Zambia/Rwanda HIV Research Group

Objectives: Two interventions were developed to help HIV infected couples plan for their future needs while preventing unplanned pregnancies. Couples randomized to the motivational intervention visited the financial advisor to plan for the consequences of their illness and death.

Methods: Our 3 couples' VCT centers in Lusaka identified eligible discordant/concordant HIV positive couples. Randomization occurred to one of four arms via video: control, method intervention, motivational intervention, or both interventions. The method intervention promotes user independent methods as a more effective contraception. The motivational intervention encourages future planning actions such as naming a guardian and making a will. Couples randomized to the motivational intervention or both interventions made appointments with the financial advisor to discuss their future planning needs.

Results: Since July 2002, 1,037 couples have been randomized. Of the 630 couples randomized to motivational or both interventions, 37% attended a meeting with the financial advisor after randomization. Before randomization, very little difference existed between the different arms. Three months after randomization, couples randomized to motivational or both interventions reported naming a guardian (45%) and to have husband or wife write a will (32%, 26% respectively). They also reported planning for their children's school fees (generation of new income = 50%; spending less on alcohol = 85%). Couples in motivational, both, and method interventions reported planning for school fees by reallocating income (90%).

Conclusions: The motivational intervention prompts couples to visit the financial advisor to plan for their future family needs. By couples addressing their future issues together, their decisions can help reduce the family consequences of parental illness and death such as ensuring their children's welfare and not contributing to the AIDS orphan population.

A Quantitative evaluation of the impact of religious leaders in the promotion of Couples Voluntary Counselling and Testing in Lusaka, Zambia
Helen Ji and the Rwanda/Zambia HIV Research Group

Background: Influence Network Leaders (INL) and Influence Network Agent (INA) are ZEHRP community leaders utilized in promotion of couples VCT (CVCT). They represent four categories of leadership: Health, private sector, NGO/CBO, religious sector. Because Zambia is a religious nation with 80% of its population claiming to be Christian, the relationship between religious leaders and their communities in promoting CVCT will be examined.

Method: Data was collected from eligible couples, invited couples, and INLs/INAs between June 2004 and February 2005.

Results: Only 70/2377 couples who sought testing (3%) heard about CVCT from a religious official. Of 67 INLs affiliated with our project, 38 were religious leaders, 15 of who saw that role as most important. These religious INLs were not more likely to previously test alone (11%) or with spouse (8%) than INLs as a whole. 199/372 (53%) of INAs were religious leaders, 97 of whom gave their religious role more importance than any other leadership role. INAs were more likely than INLs to test either alone (37%) or with spouse (28%), with similar proportions in religious INAs and other INAs. Of 56,400 invitations given by 376 INAs, 23% were preceded by public endorsement from an INL or another community leader. Of those, only 1413 (11%) were delivered by religious leaders. 7% of invitations were delivered by an INA to fellow church members and 4% were delivered at a church/mosque.

Conclusion: Zambia is a very religious country and many influential people identify themselves as religious leaders. Although churches are a place where couples are found together, and pastors preach about HIV prevention, systematic efforts to use church networks to promote CVCT have not been successful. The low number of INLs who reported having themselves been tested with their spouse confirms they are not leading by example.

A comparison HIV and syphilis seroprevalence among clients of couples' voluntary counseling and testing centres in two Zambian cities

William Kanweka, Mubiana Inambao, Susan Allen, and the Rwanda/Zambia HIV Research Group

Background: Couples' voluntary counseling and testing (CVCT) is a proven intervention in preventing HIV and STI transmission in married/cohabiting couples. In July 2004 two CVCT centres were opened in Kitwe and Ndola, Zambia. These two cities are located 56 Km from each other and are similar in terms of size, ethnicity and local economy. Adult HIV prevalence is estimated at about 25% in both cities.

Objective: To compare HIV and syphilis seroprevalence among CVCT clients in Kitwe and Ndola.

Methods: Kitwe and Ndola CVCT centres offer same day HIV counseling and testing using a two rapid test algorithm. Qualitative syphilis testing (RPR) and treatment are also offered. Data covering the period July 2004 to March 2005 were analyzed using SAS software.

Results: 1188 couples at least 16 years were tested (480 in Kitwe and 708 in Ndola). Female HIV seroprevalence was 21.67% in Kitwe compared to 29.40% in Ndola (p 0.0142). Male HIV seroprevalence was 22.71% in Kitwe compared to 27.63% in Ndola (p 0.0776). Female syphilis seroprevalence was 13.33% in Kitwe compared to 17.61% in Ndola (p0.0536) while male seroprevalence was 11.88% compared to 21.00% respectively ($p<0.0001$). In Kitwe 8.54% of the couples were HIV discordant compared to 16.48% in Ndola (p 0.0005) while 17.71% of couples in Kitwe were concordant positive compared to 20.03% in Ndola. The mean age for males in Kitwe was 41.66 years compared to 38.38 in Ndola ($p<0.0001$) while the mean age for females in Kitwe was 34.04 compared to 30.90 in Ndola ($p< 0.0001$).

Conclusion: Female HIV seroprevalence was significantly higher in Ndola compared to Kitwe while male syphilis seroprevalence was significantly higher in Ndola compared to Kitwe. These differences may be due to the significantly younger age of the Ndola clients. CVCT promotion therefore should include strategies that target younger couples.

Similarities and Differences Between Cohabiting And Non Cohabiting Couples Seeking Voluntary HIV Counseling And Testing Services In Kigali, Rwanda

Etienne Karita, Gurkiran Sardar, Susan Ju, Deborah Casanova, Freya de Clercq, Kayitesi Kayitenkore, Erin Shutes, Susan Allen

Introduction: Voluntary HIV counseling and testing (VCT) has been shown to be an effective strategy to reduce the incidence of HIV in cohabiting couples. This strategy needs to be extended to young boys and girls before marriage.

Methods: Influential network agents (INAs) were trained to invite couples for VCT in Kigali, Rwanda. Predictors of seropositivity in males and females were analysed in both cohabiting and non-cohabiting couples.

Results: Between January 2003 and January 2005, we tested 10,341 married couples and 3,520 boyfriends/girlfriend couples. Fourty percent of cohabiting couples and twenty five percent of non-cohabiting couples were invited by INAs. The mean age for males and females was 36.1 and 29.8 years in cohabiting couples, and 27.9 and 24.2 years in non-cohabiting couples. Over 40% of individuals in cohabiting couples had previously been tested for HIV, whereas 27% of boyfriends/girlfriends knew their HIV status prior to coming to our VCT sites. The HIV prevalence rate among males and females was similar in cohabiting couples (18.4% vs 17.3%), and it was higher in females than in males in non cohabiting couples (11.7% vs 6.7%). The proportion of couples with discordant HIV test results was respectively 14.1% and 13.6%. Among cohabiting couples, invitation by INAs was associated with a lower likelihood of being HIV positive in both males and females (OR 0.8), whereas it was associated with a higher likelihood of being HIV positive in non cohabiting couples (OR 1.4). Having been tested before coming to our VCT sites was a strong predictor of seropositivity in cohabiting couples but not in non cohabiting couples.

Conclusions: In settings with high HIV prevalence rates, VCT services should also target young boys and girls as couples before marriage. INAs were able to identify young adults with a high risk of being HIV positive.

Efficacy and toxicity of generic antiretroviral treatment in HIV-1 infected adults in Kigali/Rwanda

K.Kayitenkore, J.Atkinson, J. Mugabekazi, B. Bekan, C. Rutanga, Etienne Karita, Susan Allen, Projet San Francisco and the Rwanda/Zambia HIV Research Group

Objectives: Generic antiretroviral treatment presented as a fixed dose combination has been available since 2003 in Rwanda. The recommended first line treatment was D4T- 3TC-NVP. A previous study had shown the efficacy of this regimen over a six-month period. We aimed at assessing the efficacy of the regimen over a 12-month period and wanted to report on the adverse events encountered during the same lapse of time.

Methods: Projet San Francisco is a NGO based in Kigali since 1986. In August 2003 we started our first patients on a generic fixed combination antiretroviral treatment. We have now more than a 100 patients receiving antiretroviral treatment at our clinic. We reviewed patient's files and assessed CD4 count progression over a 12-month period as well as the numbers and types of adverse events.

Findings: The mean increase in CD4 count was 172 cells/microliters over a year. 28% of the patients reported symptoms related to peripheral neuropathy. 4 % of the patients developed cutaneous reactions related to Nevirapine and were switched to an effavirenz-containing regimen.

Conclusions: Generic antiretroviral treatment presented as a fixed combination containing D4t-3TC-NVP has shown to be effective over a 12-month period. Since 2004, the Rwanda government has been providing another regimen containing AZT-3TC-NVP in a fixed combination. In view of the high level of D4T related peripheral neuropathy, we have decided to switch from the D4T-3TC-NVP fixed combination to the AZT-3TC-NVP fixed combination as first line treatment.

Screening And Enrollment In Two Cohort Studies With Different Procedures And Benefits In Lusaka, Zambia.

Jean-Baptiste Ntamwemezi and the Rwanda/Zambia HIV Research Group

Objectives: The HIV heterosexual transmission (HT) study provides counseling and condom skills to prevent HIV transmission, whereas the family planning (FP) study provides family planning counseling and contraceptive methods. Both studies recruit from Voluntary Counseling and Testing (CVCT) centers and participants are followed at the same research site.

Methods: HT study participants receive outpatient health care at the project clinic and participants come at 3-month intervals. Per visit reimbursement is $5. FP study participants receive reproductive health care at the research clinic. Women in the FP study return quarterly while their male partners return annually. Per visit reimbursement is $7. Identical medical and laboratory data collection procedures are used in the two studies. FP participants complete one additional behavioral assessment tool.

Results: Between June 2002 and January 2005, a total of 7679 couples were tested in Lusaka. 1098 discordant couples were eligible for the HT study whereas 762 were eligible for FP study. 731 (67%) discordant eligible couples were enrolled a mean of 15.1 days after screening. 518/762 (68%) couples were eligible for the of whom 518 (68%) were enrolled a mean of 14.7 days after screening. The median (12 days for HT and 11 for FP) and ranges (1-92 for HT and 1-87 for FP) were similar and the mode (days) was the same for both studies.

Conclusion: The enrollment rate for the two studies was similar, indicating that the different benefits and procedures associated with each study did not significantly affect couples' decisions to participate. While a broad range of outpatient services is a appreciated as a benefit for HT participants, it is costly in personnel time and medication. A higher per visit reimbursement with health care limited to reproductive health resulted in similar enrollment rates.

Health Providers' Dilemma and Reproductive Health Needs of African HIV Sero-discordant Couples, Kigali, Rwanda

Julie Rufagari and the Rwanda/Zambia HIV Research Group

Objective: Discordant couples have a reproductive health need that differs from that of non-infected couples. Service providers in this case have to meet discordant couples' needs for family planning while bearing in mind the need to protect the negative partner. Seroconversion and unwanted pregnancies are the major outcomes of contraceptive failure within these couples.

Methods: All eligible couples in our studies receive family planning services, which include regular counseling, condom distribution and condom skills training to ensure consistent use. During follow-up visits couples are asked about the consistency of condom use and other contraceptive methods in their

relationship. An HIV test determines whether or not the negative partner has seroconverted. Pregnancies are confirmed by a urine pregnancy test.

Results: Amongst the discordant couples, half had a negative male partner and half had a negative female partner. The length of follow-up varied from 0-87 month visits with an average of 15 months. Forty-four women (5.7%) became pregnant and thirty-four of the negative partners (4.4%) had seroconverted. Two of these pregnancies occurred after the negative partner had seroconverted. Sixty percent of the couples with a partner who had seroconverted versus only 30% of the entire cohort reported inconsistent condom use. During follow-up 44% of all discordant couples reported using only condoms. Of the 44 women who became pregnant, 4 had used only condoms and 4-reported inconsistent condom use.

Conclusion: The health provider's dilemma in offering family planning service among discordant couples in Rwanda can be overcome by applying systematic counseling on condom use in addition to all other methods of contraception. Furthermore, increasing access to condoms and instructing couples regarding proper and consistent condom use is effective in preventing unwanted pregnancies and seroconversion.

Unmet need for contraception among HIV discordant couples
Julie Rufagari and the Rwanda/Zambia HIV Research Group

Introduction: Cultural beliefs can be an impediment to the utilization of family planning services. African couples' use of contraception and other family planning services is also affected by their knowledge on available methods and their access to services. The unmet need for family planning affects particularly couples that have accomplished their reproductive goal and those willing for health related reasons to have control of their reproductive life. Couples affected by HIV in Africa are the most likely to set a reproductive goal and need access to modern contraceptives.

Methods: We administered to all couples coming to be enrolled in our studies a set of questions about their reproductive goals, their contraception knowledge, and the past and current use of modern contraception methods.

Results: Between Feb2003 and Feb2005 a total of 830 HIV discordant couples were enrolled into this study. Over 95% of women knew at least 2 modern contraceptive methods, but only 30% had used or were currently using any contraceptive method. Of those who used contraception in the past, 75% stopped because of desire for pregnancy or side effects. More than 60% of women who never used a contraceptive method did so because of misconceptions about the side effects.

Conclusion: Despite a good knowledge of contraception methods among HIV positive women, very few of them use modern contraceptives to family planning service due to their misconceptions about the side effects of these methods. HIV counseling should include discussion of user-independent contraception and reassurance about side effects.

What Influences Couples to Get Tested at Couples VCT Centers in Kigali, Rwanda and Lusaka, Zambia
Gurkiran Sardar and the Rwanda-Zambia HIV Research Group.

Objectives: Couples Voluntary Counseling and Testing (CVCT) is an effective HIV prevention strategy for couples who represent the largest risk group in Africa. 10-20% of couples have one HIV+ and one HIV- partner. These discordant couples benefit from joint counseling and are eligible for clinical trials of HIV prevention strategies. A comparison of CVCT promotional strategies in two African capitals is presented.

Methods: Promotion of CVCT at 6 CVCT centers in Kigali, Rwanda and Lusaka, Zambia included distribution of written invitations by Influence Network Agents (INAs), who were supported by public endorsements from Influence Network Leaders (INLs) and senior government officials. Information was gathered from tested couples regarding how they heard about CVCT.

Results: Between May 2004 and January 2005, 9,335 couples were tested in Kigali, and 2,109 couples were tested in Lusaka. In Kigali, 32% of couples tested were invited by INAs and 68% were walk-ins. In Lusaka, 70% of couples tested were invited and 30% were walk-ins. In Lusaka, the primary way in which couples had heard of CVCT was through INAs (71%), followed by radio (27%), TV (17%), posters (12%), friends (14%), and previously tested couples (7%). In Rwanda, the primary way in which couples heard of CVCT was through couples who had been previously tested (51%), followed by radio announcements (41%), INAs (36%), posters (32%), and friends (13%).

Conclusion: The same promotional activities yielded very different results in the two cities. One-on-one contact with an INA is an effective means of promoting CVCT in both Kigali and Lusaka. The hoped for 'snowball effect' only occurred in Kigali, with tested couples referring many friends for CVCT. Radio was also a more effective strategy in Kigali, where there is only one local language. In Lusaka, 5 major language groups and 72 dialects are represented in a large number of radio stations.

Recruitment and retention of an HIV discordant couple cohort in Kigali, Rwanda in preparation for vaccine efficacy trials

Erin Shutes, Etienne Karita, Kayitesi Kayitesi, Nzeera Ketter, Crispin Kambili, and Susan Allen

Objectives: The Global HIV/AIDS Vaccine Enterprise identified "expanding access to large, well-defined populations of uninfected people at high risk of HIV infection" as a gap in the clinical trials capacity of developing countries. An estimated, 25.4 million people in Africa were living with HIV at the end of 2004. Cohabiting couples in Africa are the largest HIV risk group in the world. In Kigali, Rwanda, we have enrolled 800+ discordant couples (one partner HIV infected, one HIV uninfected) in preparation for HIV prevention trials.

Methods: Projet San Francisco maintains three Couples' Voluntary Counselling and Testing (CVCT) Centers. HIV discordant couples, who have cohabitated for the last twelve months and live in Kigali are offered enrollment into a heterosexual transmission of HIV study. Follow-up is quarterly; study benefits include free family medical care and prescriptions, family planning, ARV screening and treatment and ongoing counseling.

Results: In 2004, PSF CVCT Centers tested 9770 couples. 513 (5.3%) discordant couples were invited to enroll in the follow-up study. 401 (78%) chose to screen and were enrolled. The majority of couples not enrolled were determined to be false couples by community workers and enrollment of truly eligible couples is 93%. The HIV incidence rate is 4% per year and retention is >90% at 12 months.

Conclusions: The establishment and retention of a well-defined, high-risk cohort in preparation for vaccine efficacy trials is possible in developing countries. A run-in design, using an existing cohort

provides an accurate assessment of HIV incidence and allows the recruitment of volunteers with good follow-up and compliance. Further, the opportunity to determine contraceptive acceptability, an inclusion criteria of vaccine trial,s is critical in countries like Rwanda, where up to 75% of eligible women are pregnant or breastfeeding. The limiting factor to the development of such cohorts is the commitment of funding.

Patterns of contraception choice to prevent unplanned pregnancies among HIV infected couples in a Family planning study in Zambia

Bellington Vwalika and the Rwanda/Zambia HIV Research Group

Background: Access to user-independent family planning methods is improving in Africa. The total fertility rate in Zambia is 6.1. This is a concern for couples with HIV who must plan for their families if they fall ill or die.

Methods: HIV concordant positive or discordant couples were recruited through our VCT centres in Lusaka and enrolled in a trial of family planning promotion interventions. Video messages were used in four study arms: method-focused, motivational, both, or neither (control). The methods video promoted user independent contraception while the motivational video encouraged planning activities such as will writing, naming a guardian, and making a financial plan. The control video addressed hand washing and malaria prevention. Videos were presented to couples in groups and followed by one-on one counseling with scripted messages to reinforce the videos. Couples were then offered their choice of family planning method.

Results: Fewer than 7% of 1037 couples randomized did not select any contraceptive method after the video sessions. Couples who viewed the methods video were 3-4 times as likely to choose IUD than those who did not (6-8% vs 2%). Selection of tubal ligation (2-3%), implant (9-15%), depo-provera (38%-44%) and oral contraception (34-38%) was similar in all groups. Kaplan-Meier analysis showed a significantly lower pregnancy incidence in the intervention groups compared with the control group (log rank and Wilcoxon rank sum tests $p<0.05$). The impact of method and motivational interventions on patterns of contraceptive switching and attrition will be compared. Condom use in discordant couples did not differ among the different method users and non-users.

Conclusions: Many couples with HIV wish to limit fertility. Interventions that encourage user-independent contraceptive use can assist with prevention of unplanned pregnancies. Many clinical trials exclude pregnant women; effective contraceptive promotion can contribute to reduced dropout due to pregnancy.

Enrollment of HIV discordant couples for HIV prevention trials

Cheswa Vwalika and the Rwanda/Zambia HIV Research Group

Objective: Cohabiting couples with one HIV+ and one HIV- partner ("discordant couples") are the largest risk group in Africa. They are also ideal participants for clinical trials of prevention strategies for heterosexual transmission, including reduction of the 'contagion' of the HIV+ partner as well as reduction of 'vulnerability' of the HIV- partner.

Methods: Recruitment of HIV discordant couples is a challenge. Fewer than 1% of African couples have been tested together. The recent increase in VCT services prompted by PMTCT programs and ARV

services have resulted in more individuals seeking testing, but past experience shows that more than half of married individuals who are tested alone share their results with their spouse. We provide Couples' VCT services and used a variety of community-based strategies to promote the services.

Results: From 2002-early 2005, 1388 discordant couples (794 with HIV- men and HIV+ women and 594 with HIV+ men and HIV- women) were identified at the CVCT center. Of those, 1098 (79%) met eligibility criteria for enrollment and 743 (68%) of those were enrolled. 114 seroconvertors (70 women and 44 men) have been identified during followup. As of Feb 8, 2005, 618 couples are actively enrolled.

	Male:Female HIV results					**Discordant couples**								
	++	--	-+	+-		**Eligible**			**Enrolled**	**Cohort size**	**Seroconversion**			
						+-	-+	Total			F	M	Total	
2002														
Q1	89	40	39	24		24	38	62	12	218	4	3	7	
Q2	126	233	44	34		34	41	75	30	287	4	1	5	
Q3	185	379	84	57		48	64	112	56	343	3	1	4	
Q4	219	477	92	56		40	73	113	118	444	4	4	8	
2003														
Q1	295	564	122	77		71	99	170	111	532	4	6	10	
Q2	177	279	50	44		39	42	81	84	582	8	3	11	
Q3	144	205	32	36		32	27	59	59	596	7	7	14	
Q4	168	244	54	47		34	34	68	53	600	7	4	11	
2004														
Q1	161	236	56	47		40	38	78	48	606	9	5	14	
Q2	134	166	42	26		24	32	56	43	591	5	1	6	
Q3	261	366	85	59		40	60	100	49	605	8	2	10	
Q4	313	346	64	66		45	37	82	39	600	4	4	8	
2005														
-Feb 8	99	142	30	21		18	24	42	41	**618***	3	3	6	

Conclusions: It is possible to recruit and retain sufficient numbers of HIV discordant couples for Phase II-b clinical trials. Phase III trials will require substantial expansion of CVCT services.