

1. INTRODUCTION TO REVISED APPLICATION: We have substantially revised our proposal for development and piloting of a home-based couples intervention for pregnant women and their male partners in Kenya. In the original proposal, the reviewers noted a high level of innovation, felt the objectives were significant, and reflected that the research would be implemented within a strong scientific environment. However, they expressed several concerns, which we have now addressed. We have edited throughout and have indicated changed paragraphs with lines in the right margin in the application.

Explanation of how the intervention and analyses will differ for HIV-positive and HIV-negative women: The reviewers recognized the importance of including both HIV-positive and HIV-negative women and male partners in this study, but requested further information about how the differing needs of these groups would be addressed. Recent literature has emphasized the benefits of couple-based HIV interventions for couples of all serostatus combinations.¹ In our intervention, the offer of Couple HIV Counseling and Testing (CHCT) and healthy pregnancy messaging will be the same for all couples, and additional content related to PMTCT and HIV care will be provided to couples in which one or both partners are HIV-positive. An important innovation of our approach will be that the couple will be offered CHCT and the woman will be re-tested for HIV along with her male partner, even if she has already been tested at the clinic, as a method of ensuring safe disclosure and enhancing couple communication. We now better describe how intervention content will take into account the couple's HIV serostatus (see Section C.4) and have clarified which outcomes will be examined for which target groups in the analyses (Table 3).

Clarification on how the intervention may change couple relationship factors: We have provided support from the literature to more clearly explain how the intervention might affect change in couple relationship factors. Studies indicate that the CHCT process in itself may have positive effects on couple communication and other relationship variables.^{2,3} CHCT, which includes support for HIV status disclosure, allows pregnant couples to be open and talk about an issue that is of importance to their relationship, their own health, as well as the health of their unborn baby. The addition of maternal and child health content for the couple in our intervention model will provide another area of joint concern, communication, and action.

Plan for how intervention fidelity will be assessed: We have further described our process evaluation methods, based on our team's experience evaluating complex interventions.^{4,5} These include a form which will be completed by lay health workers at each couple home visit, including health topics addressed, services provided (e.g., CHCT), referrals and linkages made to other services, and issues for follow-up. Data from these forms, along with documented observations by supervisors, will be used to assess intervention fidelity.

Details on data from male partners and dyadic analyses: We have clarified that women who consent to be randomized will be asked for permission and contact information for male partners. Interviewers will conduct individual follow-up interviews with each woman and her male partner three months after the birth, regardless of study arm. The extent to which men can be contacted and participate in these interviews will be an important finding of this study, which can inform the design of a larger trial. We have revised the study design to omit follow-up interviews for male partners of women who refuse randomization (as contacting their partner may be unacceptable to these women for the same reasons). We will, however, collect data from these women at baseline on male partner characteristics. Although our sample size is small and precludes some types of analyses, we have now described exploratory dyadic analyses using data from both members of the couple.

Increased effort and time on the ground by team members: Within the limitations of the R34 budget, we increased the level of effort for key team members, including additional time in Kenya for Dr. Janet Turan (PI).

Articulation of the unique contribution of this study: Distinct from other male partner involvement and PMTCT studies being conducted in sub-Saharan Africa, this study is based on an interdependence model of communal couple coping and behavior change⁶ and our own formative research, which indicate that a couple-focused approach is needed. Specifically, these suggest that adopting healthy behaviors related to PMTCT and maternal and child health requires involvement of both members of a couple. Approaches that simply tell pregnant women to bring male partners to a clinic may be less effective than those that actively encourage and facilitate couple communication and joint decision-making on health issues in the safety of one's home.^{7,8}

Other issues and summary: We have added information about how our team's rich understanding of Kenyan culture—including Dr. Kwena's research with couples in Nyanza—guides our research and will inform the intervention development process. We have clarified our sample size rationale, recruitment and randomization procedures, and key measures that we will focus on in our analyses. We believe that this revised study, with a clearer focus on how the intervention will operate for different types of couples and elucidation of the theoretically-informed mechanisms through which we expect to impact couple motivation and behavior, will provide more robust scientific knowledge, with important potential benefits for maternal and child health.

2. SPECIFIC AIMS

Despite the potential for anti-retroviral therapy (ART) to improve maternal health and reduce mother-to-child transmission of HIV to as low as 1%,^{9,10} HIV-related maternal deaths and HIV infection among infants remain unacceptably high across sub-Saharan Africa.¹¹ This is particularly true in Kenya, where antenatal care attendance is high¹² but crucial drop-offs occur in uptake of and adherence to key maternal and child health (MCH) and prevention of mother-to-child transmission (PMTCT) services.¹³ Maternal mortality in Kenya is 488 deaths per 100,000 live births,¹² far higher than national¹⁴ and global¹⁵ targets. The rate of mother-to-child transmission of HIV is 15%,¹⁶ despite goals to reduce this to less than 5% by 2015.¹⁷ An estimated 42% of HIV-positive pregnant women are not receiving ART.¹⁶ Weak health systems contribute to insufficient service coverage, but many barriers to MCH and PMTCT lie beyond the clinic—in the partner, family, and community factors that shape women's use of health facilities and their health care decisions.^{18,19}

Throughout sub-Saharan Africa, many women refuse antenatal HIV testing and do not adhere to PMTCT regimens because they fear negative consequences of HIV for their relationship with their male partner.¹⁹⁻²¹ Our research in Kenya has shown that fears of HIV-related stigma from male partners—and related lack of disclosure—serve as critical barriers to pregnant women's utilization of HIV testing, maternity care, and PMTCT services.^{22,23,24} Men can play a crucial decision-making and supportive role for PMTCT,^{25,26} but male partners in Kenya are poorly engaged in the PMTCT process and less than half have ever been tested for HIV themselves.¹² Positive involvement of both members of the couple in health during pregnancy and PMTCT has the potential to improve women's access to resources, contribute to better health decisions, and increase healthcare utilization.¹⁹ In addition, although many women and partners may feel "safe" after an initial HIV-negative test result at the clinic,²⁷ pregnant women in Africa face continuing and high risk of HIV acquisition during pregnancy and postpartum.^{28,29} To meet international goals to eliminate new HIV infections among children and reduce HIV-related maternal mortality,^{17,30} it is crucial to develop and test strategies that reach both HIV-positive and HIV-negative pregnant women and their male partners.

The objective of this application is to develop and pilot-test a feasible and acceptable intervention that reaches both HIV-negative and HIV-positive pregnant women and male partners, and results in increases in safe HIV testing and disclosure within pregnant couples; leading to increased utilization of available health services and better health outcomes. We propose to adapt an existing evidence-based intervention, Couples HIV Counseling and Testing (CHCT),^{31,32} and integrate it into home visits for maternal and child health delivered by pairs of lay health workers (one male and one female) in rural Nyanza Province, Kenya. Based on our preliminary studies, many pregnant women prefer to repeat HIV counseling and testing as a couple in the home, without revealing the result of the woman's initial HIV test at the clinic. After intervention adaptation activities, we propose to conduct a pilot-test in which we will recruit pregnant women at two antenatal care (ANC) clinics after initial HIV testing, collect baseline data, and then randomize those who are willing to either the couples home visit or the standard care arms of the study. We propose these specific aims:

Aim 1: To further explore the acceptability of a home-based couples intervention among pregnant women and male partners, by extending our prior findings from qualitative research with HIV-positive pregnant women and partners, to now include pregnant women who test HIV-negative at ANC clinics and their male partners,

Aim 2: To use our preliminary findings to refine a home-based couples intervention model for HIV-positive, HIV-negative, and serodiscordant pregnant couples, including both CHCT and maternal and child health content, through a collaborative process with local stakeholders.

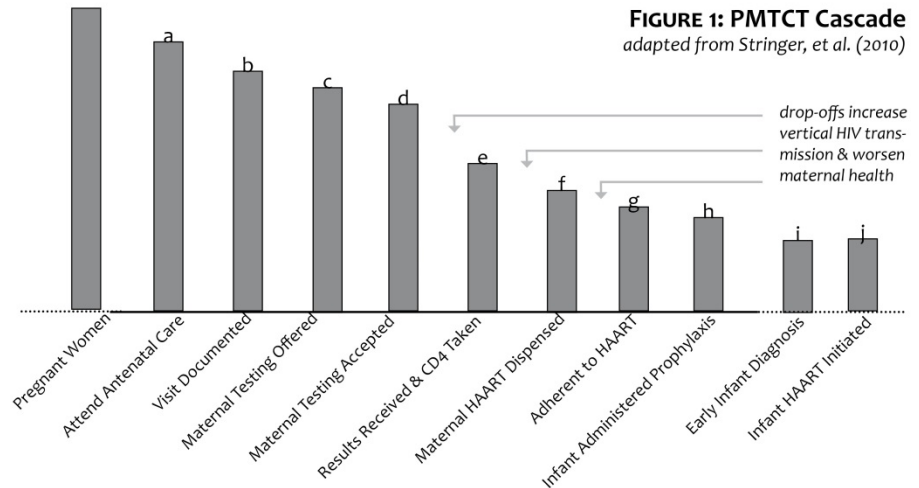
Aim 3: To conduct a randomized pilot study of the home-based couples intervention, in which we will a) assess the acceptability and feasibility of the intervention and research methods; and b) preliminary assess effects on acceptance of CHCT, repeat HIV testing during pregnancy, and use of maternal child health, PMTCT, and HIV services by pregnant women and male partners.

This intervention based on couple relationship theory has the potential to increase couple HIV testing and mutual disclosure, and thus increase uptake of and adherence to essential health services by pregnant women and their male partners in sub-Saharan Africa. In addition to addressing the important HIV prevention needs of pregnant couples of all serostatus combinations, delivering our intervention to all types of pregnant couples in the study communities (not just those who have tested HIV-positive) will ensure that the home visits are not a source of stigma in themselves. Based on the findings of this pilot study, we will develop an R01 application to assess the effectiveness of our intervention in a larger randomized controlled trial (RCT). If found to be effective, this intervention will contribute to reaching key global public health goals, including elimination of mother-to-child transmission of HIV and reduction of HIV-related maternal deaths.³⁰

3. RESEARCH STRATEGY

A. SIGNIFICANCE

A.1. New strategies are needed to promote linkage to and retention in PMTCT and HIV treatment for pregnant women. Despite the advent of ART for treatment of maternal HIV disease and prevention of mother-to-child transmission,⁹ HIV prevalence among mothers and infants in sub-Saharan Africa remains persistently high.³³ Globally, only 15-30% of pregnant women complete the series of steps required for efficacious PMTCT,³⁴ leading experts to call this the “PMTCT cascade”³⁵ (Fig. 1). While rates of antenatal HIV testing have been increasing over time in Kenya – 83% of pregnant women were tested in 2010 – less than half of women testing HIV-positive (43%) received the most effective regimens to reduce vertical transmission of HIV.³⁶ Among those who do access PMTCT, rates of subsequent drop-out are also high.^{13,37,38} It has been noted that fixing the PMTCT coverage problem could prevent as many infant HIV deaths as would more effective drug regimens.³⁵ Evidence-based interventions that reduce drop-offs in the PMTCT cascade are urgently needed to ensure maternal health and eliminate vertical HIV transmission.



A.2. Fears and experiences of HIV-related stigma, discrimination, and violence are key barriers to completion of the PMTCT cascade in sub-Saharan Africa. Fears of stigma, discrimination, and violence are common themes in narratives of pregnant women affected by HIV.^{39,40} Studies in sub-Saharan Africa suggest that these social factors are among the most important barriers to pregnant women’s acceptance of HIV testing during antenatal care and to their participation in programs for PMTCT.^{39,41-53} Theoretical frameworks indicate that different dimensions of stigma—anticipated stigma, perceived community stigma, enacted stigma (discrimination), and self-stigma—adversely affect quality of life, healthcare access, and health outcomes for persons living with HIV,⁵⁴⁻⁵⁶ and some research suggests that stigma from close persons may have a significant impact.⁵⁷ Our research in Kenya has found that fears and experiences of stigma from a male partner decrease antenatal HIV testing, linkage to HIV care, and uptake of skilled childbirth services.^{22,23,24,58} A recent systematic review suggests that stigma, violence, and discrimination hinder PMTCT uptake even despite the introduction of more efficacious regimens and improved guidelines in sub-Saharan Africa.⁵⁹

A.3. Lack of disclosure of HIV testing and HIV test results to male partners is a significant barrier to health service utilization by pregnant women. Disclosure of HIV status can have important benefits, including gaining access to social support, lowering risk of HIV transmission to partners, obtaining more appropriate medical treatment, decreasing stress, and creating closer relationships with others.⁶⁰ In a recent systematic review of studies in sub-Saharan Africa, partner non-disclosure was associated with poor PMTCT uptake in a majority of both quantitative (6 of 9) and qualitative (17 of 24) studies.⁵⁹ For many HIV-positive pregnant women, lack of disclosure to partners has drastic health implications: It limits their ability to link and adhere to HIV care for their own health; it poses a risk for sexual transmission of HIV if the male partner is still HIV-negative;⁶¹⁻⁶⁴ and it increases the odds of non-optimal adherence to PMTCT interventions⁶⁵ and vertical transmission of HIV.⁶⁶ Evidence from South Africa suggests that the average time gap between obtaining an HIV-positive test result and disclosing the result to a sex partner is as high as 16 months.⁶⁷ In a recent study in Kenya, only about 50% of HIV-positive women tested antenatally disclosed to their partner during pregnancy⁶⁸ and in Cote D’Ivoire only 46% of such women had disclosed to their partner within 2 years.⁶⁹ As countries such as Kenya move toward an emphasis on lifelong ART treatment for all HIV-positive women as early as possible in pregnancy (Option B+),⁷⁰ timely disclosure and linkage to HIV care become even more relevant.

A.4. Pregnant women testing HIV-negative and their male partners are a high-risk group for incident infection. Women who initially test HIV-negative and their male partners are a crucial group to include in interventions. Often, pregnant women and partners feel “safe” after an initial HIV-negative test result at the ANC clinic.²⁷ Yet, this group is at high risk of becoming HIV-infected during late pregnancy and breastfeeding.²⁸ A recent modeling study predicted that transmission from mothers seroconverting after their

first ANC visit will represent 34% of MTCT by 2014.²⁹ As HIV transmission risk increases by more than two-fold during pregnancy,²⁸ uninfected women and their male partners are at heightened risk of incident infection.

A.5. Despite recognition that male partners play a major role in uptake of services by pregnant women, most PMTCT programs focus on pregnant women alone. When male partners are uninvolved in HIV testing and antenatal care, women are less likely to accept ART,⁷¹⁻⁷³ deliver in a health facility,²⁶ or adhere to recommended care.⁷⁴ It is thus unsurprising that scholars globally have advocated for engaging men in PMTCT.^{71,75-77} Yet, current antenatal HIV testing strategies generally reach out to women only,^{23,78-80} making it immensely challenging for men to become involved in PMTCT. This is compounded by gender norms that limit men's ability to involve themselves in pregnancy and infant care and label ANC clinics as "female spaces."⁸¹⁻⁸³ Our research⁸⁴ and that of others^{85,86} shows that men themselves desire more involvement in PMTCT and antenatal services, but may not be reached by traditional clinic-based efforts. Innovative methods are necessary to make sure that male partner involvement occurs in a safe and supportive way.⁸⁷

A.6 Couples HIV counseling and testing, an evidence-based intervention, offers potential to engage men and women, but has been underutilized in the PMTCT context. Based on increased evidence of the need to include both pregnant women and their male partners in PMTCT, programs across Africa have increasingly called for couples HIV counseling and testing (CHCT). Yet, most CHCT programs are implemented in a clinic setting, making it unlikely that pregnant women and male partners will utilize them. Existing studies show that few pregnant women who are tested for HIV in ANC clinics bring their male partners for subsequent HIV testing: 10% in Zambia,⁸⁸ 12.5% in Tanzania,⁸⁹ 16% in Kenya.⁶³ Program data from over 20,000 antenatal clients in Uganda revealed that although 62% of pregnant women were tested for HIV, only 2% of their male partners accepted HIV testing.⁹⁰ A 2012 WHO-commissioned report⁹¹ stated that "no couple-specific interventions have been developed expressly to improve PMTCT uptake" thereby underscoring the need for a couples-based approach. Although one intervention in Kenya suggested that home-based strategies may improve male uptake of HIV testing,⁹² no studies to our knowledge have examined the effect of home-based couples visits on PMTCT uptake or maternal and child health outcomes.

We propose to develop and pilot-test a home-based intervention to facilitate safe HIV testing and disclosure within pregnant couples in order to increase use of PMTCT and family health services. Our proposed study focuses on couple relationship theory and factors, determinants of the decision to participate in CHCT, and on measuring PMTCT and MCH utilization outcomes. It will advance the evidence base by piloting the intervention in a small RCT, which will provide data for testing the intervention in a larger trial. If this strategy is successful, pregnant women and male partners will engage in family health, PMTCT, and HIV treatment services, with important implications for maternal, paternal, and infant health.

B. INNOVATION

Our strategy is innovative in the following ways: It focuses on **couples** instead of women alone; it applies couples **theory** to an evidenced-based intervention; it uses a **home-based** strategy to target difficult-to-reach populations; and it **integrates** HIV services with other maternal and child health services for pregnant couples of different HIV serostatus combinations.

Recent literature and WHO guidance have called for a renewed emphasis on couples to enhance PMTCT and HIV prevention efforts.^{61,91,93-97} However, there are few couple interventions for pregnant women and male partners in low resource settings.⁹⁸ In a systematic review conducted by members of our team, we found no published interventions targeting pregnant couples for HIV testing and subsequent linkage to care.⁹⁴ Another recent systematic review on male involvement in PMTCT identified only one study in Tanzania.⁹⁹ Our proposed study fills this gap by targeting expectant mothers and fathers as a couple. Distinct from existing programs like mothers2mothers¹⁰⁰ and mentor mothers,¹⁰¹ our intervention will be conducted by a pair of lay health workers (one male and one female) who engage both partners in the promotion of family health. Couple-focused interventions have been identified as an effective way of identifying couples for engagement in a range of HIV treatment and prevention interventions, including PMTCT and ART programs.^{1,7,8}

The proposed study would be among the first research to use a theoretical framework based on an interdependence model of communal couple coping and behavior change⁶ to inform intervention development for PMTCT-related and maternal health outcomes. Extensive research has shown that couple relationship factors are associated with health behavior change,^{102,103} including: smoking cessation,¹⁰⁴ arthritic care,¹⁰⁵ survival after cardiac trauma,¹⁰⁶ and overall mortality.¹⁰⁷ Similar associations have been found in HIV research, where partner dynamics influence both prevention and treatment adherence.¹⁰⁸ Yet, couples-based theories

are only just beginning to be applied to HIV-related health behavior in sub-Saharan Africa. Qualitative research from Uganda and Zambia has shown that an interdependence model of communal couple coping and behavior change can help explain why serodiscordant couples recruited as dyads into HIV trials are more successful at initiating and maintaining behavior change.⁹⁵

We propose a **home-based** approach to reach both pregnant women and male partners in a space that is safe, convenient, inexpensive, and less stigmatizing than men accompanying a woman to the ANC clinic. Although home-based HIV counseling and testing has proven to be feasible and acceptable in Kenya,¹⁰⁹⁻¹¹¹ few interventions have had a special focus on pregnant women and partners. A recent study in Kenya achieved high acceptance rates for home-based HIV counseling and testing (82% of around 25,000 people), yet among couples who tested, less than half were tested together as a couple.¹¹² Acceptability studies by our team⁸⁴ and others¹¹³ suggest that home-based couples counseling and testing is a desirable approach in East Africa. Nevertheless, most current strategies for couple counseling and testing require both partners to come to the clinic, thereby reaching only a minority of couples. Our home-based approach will reach more male partners, which has benefits for their own health and concomitant benefits for pregnant woman and the unborn infant.

Finally, our intervention responds to the growing demand for PMTCT and HIV services to be **integrated** within existing Maternal and Child Health (MCH) services.^{30,114} Home visits will be designed for all pregnant couples (regardless of woman's initial HIV test result at the ANC clinic) and will include topics important for maternal, paternal, and child health during pregnancy and postpartum. CHCT will be just one component of this comprehensive approach to MCH. This approach capitalizes on men's heightened concern for family health during pregnancy,¹¹⁵ and is more likely to engage men than an approach that focuses solely on HIV-related health. Our preliminary research suggests that this integrated approach will also ensure that home visits are not a source of stigma in themselves.

C. APPROACH

C.1. Conceptual Framework

The conceptual framework for the proposed research draws upon Lewis et al.'s Interdependence Model of Health Behavior Change (Fig 2).⁶ The Interdependence Model extends beyond an individual-based understanding of health behavior change (e.g., health belief, self-efficacy) by positing that both partners influence one another's health decisions and behaviors.¹¹⁶ It hypothesizes that by influencing the couple as a unit, interventions can make lasting impacts on health behaviors.

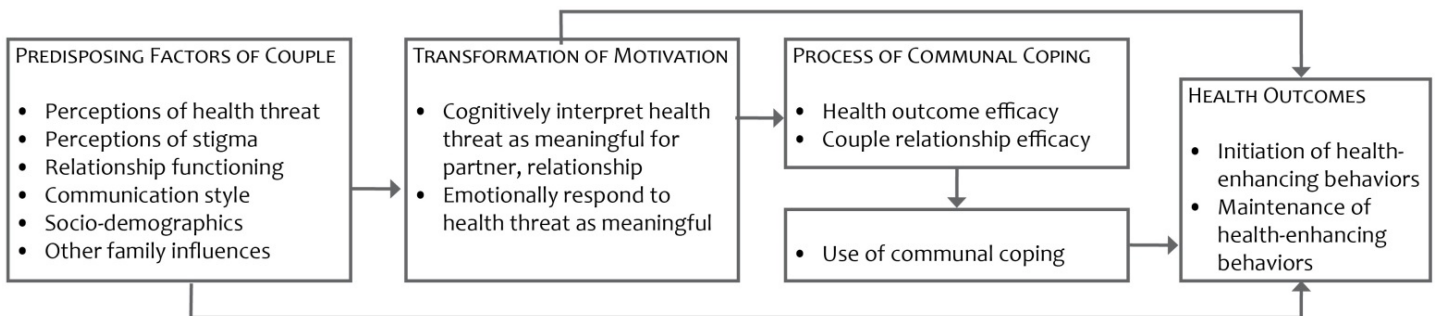


FIGURE 2. Interdependence model of couple communal coping and behavior change. Lewis et al. (2006)

Several aspects of this model can be used to understand how couples initiate and maintain healthy behaviors:

- Predisposing characteristics of couples include both intrinsic qualities (e.g., socio-demographic such as age, education, marital status) and variables that have the potential to be modified through intervention (e.g., perception of health threat; couple communication). We will adapt this part of the model to include specific aspects of the Kenyan cultural setting elucidated in our preliminary studies, including the influence of extended family members and the type of union (including polygamous unions).¹¹⁷
- Transformation of motivation helps couples move from a self-centered understanding of a health issue to a relationship-centered perspective.⁶ This process occurs when health issues are interpreted as having significance for the relationship or family, rather than simply for oneself.¹¹⁸
- Communal coping is when couples make a joint assessment of a health threat and have a shared vision for managing that threat.¹¹⁹ It is influenced by outcome efficacy, or the couple's belief that a solution can be found to the health challenge, and couple relationship efficacy. Communal coping includes enhanced communication, joint decision making, working together to try new behaviors.

C.2. Preliminary Studies

The Maternity in Migori and AIDS Stigma (MAMAS) Study: Our investigative team conducted the MAMAS Study, a prospective mixed methods investigation of the effects of HIV-related stigma on pregnant women's use of health services in rural Nyanza Province, Kenya (PI: Turan, NIMH K01 Award, 2007-2012). Findings from MAMAS (n=1,777) suggest that pregnant women in this setting both fear and experience HIV stigma from male partners, creating an important barrier to uptake of MCH and HIV services. Prior to an offer of HIV testing at an ANC clinic, rates of anticipated HIV stigma among pregnant women were high: 32% anticipated break-up of their marriage/relationship; 26% anticipated physical abuse from their partner. Women who anticipated male partner stigma were more than twice as likely to refuse HIV testing, after adjusting for other individual-level predictors (OR=2.10, 95% CI: 1.15-3.85, p=0.016).²³ Women with higher perceptions of HIV-related stigma at baseline were subsequently less likely to deliver in a health facility with a skilled attendant, even after adjusting for other known predictors of health facility delivery (AOR=0.44, 95% CI:0.22-0.88).²² We found that only 58% of HIV-positive women had disclosed their HIV status to anyone by 4-8 weeks after the birth, with a mere 31% having disclosed to their male partner. **HIV-positive women in the MAMAS Study who had disclosed to a male partner had 3.0 times higher odds of having taken medications for PMTCT (95% CI: 1.2-7.4) and 2.6 times higher odds of giving birth in a health facility (95% CI: 1.2-5.4), as compared to HIV-positive women who had not disclosed.**¹²⁰ In addition to the importance of these findings in informing our intervention approach, MAMAS demonstrates the ability of our team to recruit and follow both HIV-positive and HIV-negative pregnant women in this rural Kenyan setting.

During the final phase of MAMAS, we conducted qualitative research with HIV-positive pregnant women, male partners, and service providers to inform content and delivery of an intervention.⁸⁴ Participants indicated a strong desire to be tested for HIV together as a couple, even if one or both of them had already been tested separately. They believed this approach was likely to reduce conflict, improve understanding, and promote trust. Home visits were supported as a way to reduce costs and initial fears of visiting a health facility, and to reach male partners. One pregnant woman explained: "It is a good approach when your partner fears going to the health facility because other people will see him. I think when it's at home it's better, because you will be the two of you only". Despite these benefits, participants mentioned things to be careful about regarding home visits, such as negative reactions of male partners to an unannounced visitor and community gossip. Measures recommended by participants to reduce these risks included training health workers on confidentiality and ensuring that male partners are notified before the home visits. They also suggested that the program should be promoted in the community as health visits for all pregnant women and not just for HIV-infected women.

The Gender-Based Violence (GBV) Study: Based on preliminary findings from MAMAS, in 2010-11 we conducted a study aiming to address gender-based violence (GBV) in rural Nyanza, with a special focus on pregnant women. We conducted formative qualitative research and found that many pregnant women fear and suffer from psychological, physical, and sexual violence related to HIV-status disclosure.¹²¹ Findings also indicated that health workers are an appropriate resource for assessing pregnant women's risk of violence, providing counseling, and referring women to support resources.¹²² We developed and piloted GBV services at a rural ANC clinic in Nyanza Province, including culturally appropriate training materials, risk assessment tools, and referral protocols,¹²³ which will be used to train the staff in this proposed study. The GBV Study also helped us pilot an approach for collaborating with local stakeholders to design targeted interventions. We propose to use a similar series of stakeholder meetings to develop and refine the proposed intervention.

Fishermen Couples Studies: Zachary Kwena (co-investigator) has conducted a series of HIV-related studies in Kenya¹²⁴⁻¹²⁶ and has extensive knowledge of culture and gender in Nyanza, necessary for the successful completion of this project. In a cross-sectional study of mobility and sexual concurrent partnerships in Nyanza Province,¹²⁷ he conducted interviews, HIV testing, and facilitated disclosure with 545 fisherman couples. Among the identified married couples (defined as any two people of the opposite sex who live together in a sanctioned union as husband and wife for at least three months), the study refusal rate was only 7.7% and the non-contact rate was 1.5%. The results indicated that even in this relatively mobile population, the majority of couples did not report traveling and spending a night away from home in the past month (65%). The couples proposed to be recruited for the current study will be living in less mobile rural farming communities.

Community-Based Couples VCT in South Africa: Lynae Darbes (co-investigator) is a psychologist with expertise in couples research and designing and testing culturally relevant couples' interventions.^{94,128-133} She leads an ongoing RCT of a community-based intervention to increase CHCT in South Africa (R01 MH 086346). The intervention draws upon couples theory and aims to provide couples with relationship skills (e.g.,

communication skills). Dr. Darbes is also co-investigator of an RCT aiming to increase testing for HIV among HIV-negative pregnant women by increasing partner involvement in Uganda (R01 HD070767 Homby, PI).

Other Studies on PMTCT and Couple Engagement in MCH: Our team has recently conducted a cluster-randomized trial to examine the effects of integration of ANC and HIV treatment services on PMTCT uptake and MCH outcomes in Nyanza (the Study of HIV and Antenatal Integration in Pregnancy (SHAIP) Trial).¹³⁴ In addition, Dr. Turan has also conducted intervention studies aiming to promote involvement of both partners of a couple in MCH and reproductive health during pregnancy in different settings globally, including intervention studies in Turkey and Eritrea.¹³⁵⁻¹³⁸ These studies will help to inform strategies for couple engagement and MCH content of the intervention.

C.3. The Setting

Nyanza Province has the highest HIV prevalence in Kenya, with approximately 14% of adults 15-49 years of age testing HIV-positive.¹³⁹ Maternal mortality in the province is 669 per 100,000 live births,¹⁴⁰ or more than four times the national target.¹⁴ The proposed research will take place in southern part of Nyanza, bordering Tanzania and Lake Victoria (Fig. 4). We propose to conduct the study in two communities where our team has worked for over two decades: Migori District is a poor area mainly composed of ethnic Luos, while the other is a somewhat better off community in Rongo District with residents from both the Luo and Kisii ethnic groups.

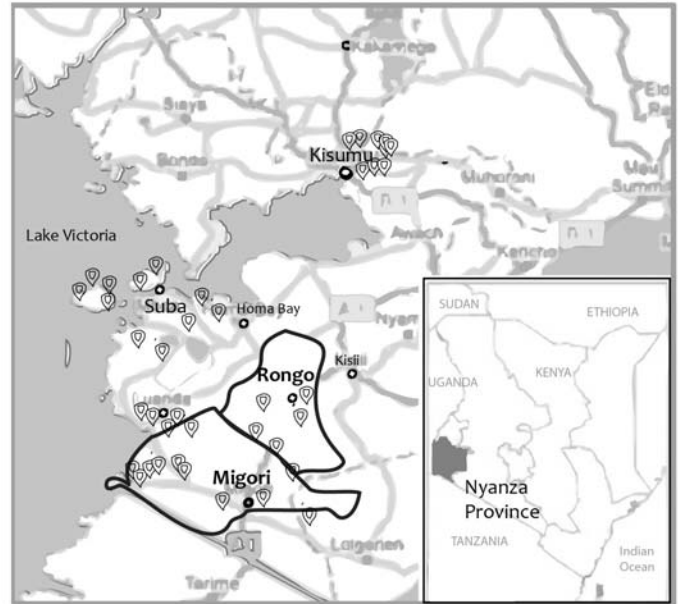


FIGURE 3. Study Setting and FACES Clinics

This setting has several characteristics that make it a priority area for interventions among pregnant women and male partners. In addition to high HIV prevalence among pregnant women (18%) and high rates of MTCT (7-10%),¹⁴¹ our team's preliminary data indicate that only 50% of HIV-positive pregnant women enroll in HIV care and treatment.^{120,142}

This study will be conducted at health care facilities supported by Family AIDS Care and Education Services (FACES).¹⁴³ FACES is funded by PEPFAR-Centers for Disease Control (CDC PS001913-01) to support scale-up of HIV prevention, care, and treatment services in Nyanza. FACES is a collaboration between Kenyan Ministry of Health (MoH), Kenya Medical Research Institute, and University of California, San Francisco (see letters of support). FACES supports the MoH in providing comprehensive HIV services (including PMTCT) at 134 sites in Nyanza. FACES also provides CHCT services and engages couples in research studies as a site for the Partners PrEP Study.¹⁴⁴ Our research strategy takes advantage of FACES infrastructure and aims to address needs noted by patients and staff in Nyanza. Our investigative team has a long track record of conducting multiple program and policy-relevant HIV intervention studies within FACES. These factors will facilitate the rapid scale-up of our intervention, should it be found to be effective.

C4. The Intervention: Home-based Couples Intervention

The proposed intervention is home-based couples visits (two home visits during pregnancy; one postpartum) delivered by FACES lay health workers, one male and one female, including three components, as detailed below. Intervention content will be adapted for different serostatus couples (see Figure 4).

a. Couple HIV Counseling and Testing (CHCT) including mutual disclosure of HIV status. Developed in Rwanda and Zambia, this strategy has been implemented in many sub-Saharan African settings and has been shown to increase male involvement and linkage to care.^{71,89,93,94,145,146} The CDC has published a CHCT Training Curriculum, which includes modules for mutual disclosure for discordant and concordant couples.¹⁴⁷ Assistance with disclosure allows a couple to discuss HIV test results and strategies in a safe and supportive setting,¹⁴⁸ and training sessions include techniques to encourage communication between partners.¹⁴⁹ This existing CHCT curriculum will be supplemented by training materials for community-based HIV counseling and testing developed in Uganda,¹⁵⁰ that have been adapted for use in Kenya.¹¹⁰

b. HIV Linkage to Care. As the intervention is home-based, it will be crucial for lay health workers to actively link couples to existing HIV care and treatment. Similar to existing outreach services already implemented by FACES, lay health workers will provide referral letters and provide information about HIV care and treatment.

c. Maternal, child, and family health information. The content of home visits will build on our team’s prior experience in engaging couples in pregnancy and postpartum services.^{137,151} Along with general family health promotion (e.g., importance of antenatal care, delivery at a health facility, immunizations, safe infant feeding, infant development, and family planning), this component will be an opportunity for couples to ask questions about the pregnancy, labor, and delivery. Lay health workers will provide information about existing health services and help couples develop strategies for appropriate utilization of these services.

	Concordant HIV +	Discordant	Concordant HIV -
a Couples HIV counseling & testing	<ul style="list-style-type: none"> present results and contain emotions encourage mutual support PMTCT steps 	<ul style="list-style-type: none"> reinforce accuracy of results dispel misbeliefs; address blame concerns discuss need to protect uninfected partner PMTCT steps (adherence, breastfeeding, early infant diagnosis) 	<ul style="list-style-type: none"> establish commitments to remain uninfected focus on trust, bonding re-testing late pregnancy
b HIV linkage to care	<ul style="list-style-type: none"> discuss disclosure clarify basics of ART and PMTCT 	<ul style="list-style-type: none"> provide referral letter describe FACES services 	
c Maternal Child Health	<ul style="list-style-type: none"> antenatal care visits plans for facility delivery 	<ul style="list-style-type: none"> questions about pregnancy, labor, delivery immunizations & infant feeding 	<ul style="list-style-type: none"> family planning postnatal visits

FIGURE 4. Intervention Components by Serostatus

FACES employs a cadre of lay health workers based at peripheral health facilities. Lay health workers, many of whom are also HIV clinic patients, deliver family-centered services for counseling, testing, and HIV care and run patient support groups. Lay health workers are trained and supervised by FACES coordinators in each district. The lay health worker curriculum includes CHCT. These workers are already doing home visiting for HIV-positive clients who miss clinic visits. With a relatively small investment in additional training, these workers can be leveraged to reach pregnant couples through a home-based approach.

Our team’s research in this setting suggests that 87% of pregnant women live with their male partner.¹⁵² Thus, home visits should be a good approach to reach our target population. Recognizing that some pregnant women may live in extended family households where privacy is difficult to maintain,¹⁵³ in each community we will identify a location for couple sessions that participants may choose if privacy cannot be assured in the home (such as the home of the local community health worker). Lay health workers will visit all participating households again 2-4 weeks later, as well as 6 weeks after the expected delivery date (EDD) of the baby.

We propose to use the Interdependence Model of Health Behavior Change as a theoretical starting point to understand the mechanisms through which couples interventions might affect health behavior outcomes (Fig. 5). We hypothesize that couple home visits by lay health workers will facilitate a “transformation of motivation” which will make couples more likely to accept and undergo CHCT. The CHCT process, which includes mutual HIV status disclosure, will then bolster communal coping related to HIV, during which couples communicate and build efficacy to address HIV prevention and treatment together. The Interdependence Model suggests that communal coping will help couples make health-related decisions jointly and mutually support one another’s goals around MCH, PMTCT uptake, linkage to HIV care and treatment. Home-based couples visits will aid the couple in developing efficacy to engage in timely use of key health services.

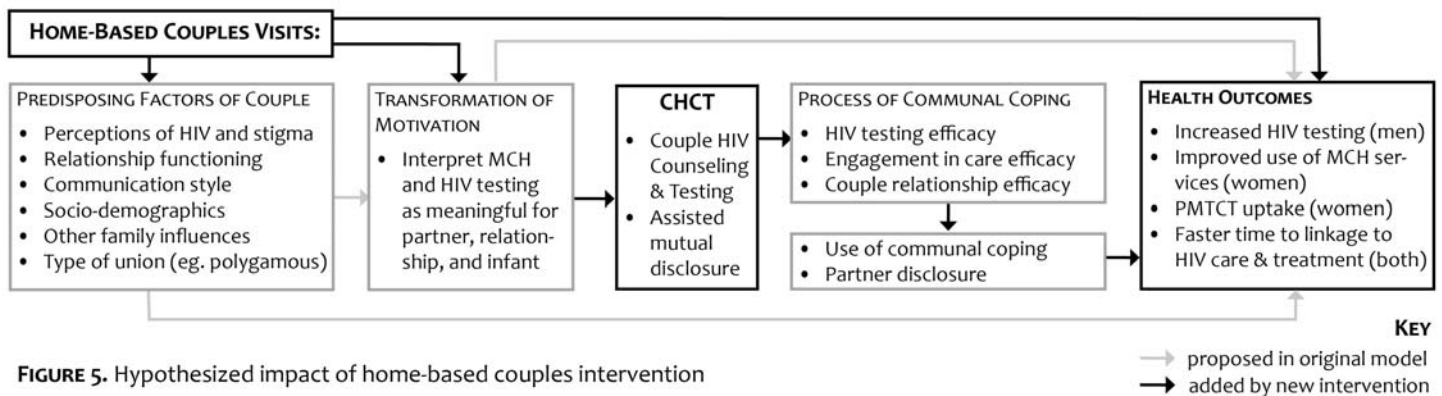


FIGURE 5. Hypothesized impact of home-based couples intervention

C.5 Research Design and Methods

Overview of research design for Aims 1, 2, and 3: To accomplish Aim 1, to further explore the acceptability of a home-based couples intervention among pregnant women and their male partners, we will conduct qualitative interviews with pregnant women who test HIV-negative at the ANC clinic and their male partners.

We will analyze the qualitative data to extract key themes and lessons, and integrate the findings with our previous qualitative research with HIV-positive pregnant women and their male partners. In Aim 2, we will work with local stakeholders to review the findings from both sets of qualitative interviews, critically examine existing home visit and CHCT protocols, and develop specific materials for the intervention. To achieve Aim 3, we will conduct a pilot test of the home-based couples intervention in two communities. We will recruit pregnant women at two ANC clinics, collect baseline data, and randomize those who are willing to either the home-based couple intervention (estimated n=61) or the standard care arm (estimated n=61). We will interview randomized study participants (both women and men) three months after expected infant delivery date to ascertain rates of CHCT, repeat HIV testing during pregnancy, and uptake of maternal child health, PMTCT, and HIV services by pregnant women and male partners.

Methods for Aim 1: During the MAMAS Study, we used qualitative methods to garner input on HIV status disclosure and couple home visits among HIV-positive pregnant women, male partners, and health workers. For this study, we propose to collect additional qualitative data from pregnant women who test HIV-negative and male partners.

Sampling and recruitment for Aim 1:

- **HIV-negative pregnant women:** At each ANC clinic, 10 women who have tested HIV-negative will be asked to participate in a one-on-one qualitative interview (5 who have disclosed their HIV test result to their male partner and 5 who have not disclosed), for a total of 20 interviews. Women will be invited to participate in an interview at the health facility or at a later date/place of their choosing.
- **Male partners of HIV-negative pregnant women:** We will recruit 10 male partners at each of the two sites, for a total of 20 interviews. Half of males interviewed will be the partners of the same HIV-negative women interviewed in order to compare and contrast perspectives on this issue within couples. Pregnant women identified as HIV-negative will be asked if a researcher may contact their male partner regarding an interview on maternal and child health issues, including HIV. These men will be contacted by a researcher through contact information provided by the woman and will be invited to participate in an interview in a private location at a date/place of his choosing.

Theme	Topics	TABLE 1. AIM 1 INTERVIEW TOPICS
Male involvement	(1) opinions and experiences regarding male partner involvement in pregnancy, birth, ANC and antenatal HIV testing	
Couple and family relationships	(2) views on couple communication, trust, relationship satisfaction (3) role of extended family members (including co-wives in polygamous unions) in health seeking behavior during pregnancy	
HIV Testing and Disclosure	(4) perceptions of HIV risk after an initial HIV-negative test in pregnancy; re-testing (5) views and experiences regarding HIV testing and status disclosure within a couple (6) barriers and facilitators for couple HIV counseling and testing	
Health Care Utilization	(7) barriers to utilization of health care services for pregnant women and partners	
Home Visits	(8) perceived advantages and disadvantages of home visits for couples (9) types of information, counseling, and services that could be provided during a home visit to couples (10) discussion of service delivery options, including how best to conduct home visits without unwanted disclosure or stigmatization	

Study procedures for Aim 1: In-depth interviews will be led by experienced qualitative interviewers in the local language (Luo, Kiswahili, or English) using interview guides developed by the research team. Topics to be explored in the interviews will elucidate ways to make a home visits for couples acceptable and feasible for this population (see Table 1). These interviews will also be an opportunity to collect data for adapting couple relationship measures already used by members of our team in South Africa (see Table 3).

Data management and analysis for Aim 1: Qualitative in-depth interviews will be audio-recorded using digital recorders and the audio files will be password-protected and uploaded to the computer. These files will first be transcribed directly in the language of the interview into Microsoft Word files and then will be translated into English in separate Word files by an experienced tri-lingual (English, Luo, and Swahili) transcriptionist. Ten percent of the transcripts will be randomly selected for checking by another translator and discrepancies will be resolved through discussions with senior members of the research team who are fluent in both languages.

Analysis will draw from a framework approach to coding, in which key conceptual domains are derived from both the existing literature and the qualitative data gathered for the study.¹⁵⁴ Our team has used this approach in prior qualitative studies in this setting,^{22,121-123} and found it a useful way to ensure the analytical process is replicable and the findings representative of the data. NVivo qualitative data analysis software will be used as a tool for coding and analysis. As a first step, a preliminary coding scheme will be developed by the investigative

team and field researchers based on the literature and topics included in the interview guides. This coding scheme will be applied to a sample of initial transcripts by two analysts, who will refine it with input from the investigative team. Numeric identifiers will be assigned in such a way that analysts can match and compare responses within couples. In the next step, transcripts will be reviewed again and a more detailed, second-level coding structure will be developed. The second-level codes are built inductively from the data, allowing the voices of participants to emerge. Finally, a third step of analysis will aim to develop conceptual networks that illustrate relationships between codes, and to compare dyadic responses from partners within a couple. A detailed analytical report will interpret key findings of the coding scheme, using direct quotations to illustrate themes and second-level codes. The analytical report will provide fodder for qualitative papers, allow for structured modification of the intervention, and can be shared with stakeholders during Aim 2 activities.

Expected outcomes and alternative strategies for Aim 1: The data collected in Aim 1 will complement the qualitative data we have already collected during MAMAS, and provide us with comprehensive knowledge of the context, challenges, and best strategies for implementing a couple home visit intervention for both HIV-negative and HIV-positive pregnant couples. This will be the starting point for our work in Aim 2. One potential problem could be lack of local community acceptance of the research, resulting in low rates of participation in the interviews. However, strong pre-existing relationships with communities will facilitate entry into the communities. In addition to pre-study initiation meetings at FACES health facilities, we will meet with community leaders and representatives of community groups prior to beginning recruitment for Aim 1. Another potential problem could occur if study participants are unwilling to share information on sensitive topics, due to fears of breaches of confidentiality. To avoid this problem, male and female partners will be interviewed separately, we will employ trained qualitative researchers experienced in interviewing on sensitive topics, and we will provide them with extensive training in how to maintain confidentiality. Our experience with qualitative research conducted in Nyanza Province, Kenya^{22,53,121,155} will help our team implement these strategies.

Methods for Aim 2: In Aim 2, we will work with FACES staff, community members, and other stakeholders in three phases to review the two sets of qualitative findings, critically examine and decide together on needed modifications to existing protocols for home visits and CHCT, and create manuals and data collection instruments for our intervention. Stakeholders will include representatives of: FACES, the District Ministry of Health Teams, the health facilities located in the study communities, the local administration, village elders, church leaders, HIV patient support groups, and local community-based organizations (especially women's organizations). We will do this through a series of stakeholder meetings led by Dr. Turan and Dr. Kwena, followed by the establishment of smaller working groups for the creation of the specific intervention materials. This stakeholder method was used successfully by Dr. Turan and her team in Nyanza in the GBV Study.¹²³

Phase 1: At an initial stakeholder meeting, the findings from the qualitative research conducted will be presented and discussed. Members of the research team will present the qualitative research findings and ask the participants to provide feedback on representativeness, and discuss implications for culturally relevant intervention strategies. Options for having the most feasible and acceptable home visits will be explored in light of the data, including what other messages and services to include in the home visits, and optimal characteristics for those who will be doing the home visits (gender, training, counseling skills, experience, etc.).

Phase 2: A second smaller stakeholder meeting will be held to review existing protocols for CHCT and home-based HIV counseling and testing being used by FACES in Kenya, and suggest modifications needed to create a strategy for pregnancy-related couple home visits. In addition, materials from maternal and child health-focused home visit programs in sub-Saharan Africa^{101,156} will be reviewed. The outcome of this second meeting will be a targeted plan for implementing the intervention based on buy-in from key partners.

Phase 3: In Phase 3, the research team will work in consultation with the stakeholders mentioned above to develop training modules, manuals, standard operating procedures, and data collection instruments for the pilot test of the intervention to be conducted during Aim 3.

Methods for Aim 3: In Aim 3, we will conduct a pilot study of the modified intervention at two ANC clinics. This pilot study will allow us to assess the acceptability and feasibility of the intervention and research methods. The pilot study will also provide preliminary data on short-term effects of the intervention on CHCT uptake, HIV retesting during pregnancy, PMTCT and MCH health service use. It is anticipated that this pilot data will provide sufficient information to allow us to test the intervention in a conclusive trial in the near future. The pilot will use a randomized, controlled design (Fig. 6).

Start-up activities for Aim 3: We will train lay health workers in informed consent processes, privacy and confidentiality protections, community sensitization strategies, maternal, paternal, and child health messages,

CHCT techniques for couples with different serostatus combinations, and protocols for GBV risk assessment and support. All health workers at study health facilities will also receive training on GBV risk assessment, counseling, and supported referrals from protocols developed during the GBV Study (See Human Subjects).

Study population and sample size for Aim 3:

The target populations are pregnant women identified in the two ANC facilities and their male partners. The vast majority (87%) of women presenting for first ANC visits in Kenya are in the 2nd and 3rd trimesters of pregnancy,¹² but given the importance of early initiation of ART for maternal health and PMTCT,⁶⁶ we will enroll women as early as possible. We will select women at 36 weeks of pregnancy or less, to have time to deliver at least one home visit during pregnancy. Other inclusion criteria are: (a) 18 years of age or older (b) has been offered HIV testing at ANC, (c) is currently living with a male partner, (d) has not yet participated in couple HIV testing during this pregnancy. Male partners are the person identified by the pregnant woman as her primary male partner and should also be 18 years of age or older.

Based on clinic registers, we estimate that each clinic will have an average of 10 eligible HIV-positive women per month (for a total of 120 women in 6 months). We are confident that we will identify an equal number of HIV-negative women (n=120) in the same time period. We will recruit HIV-negative women in

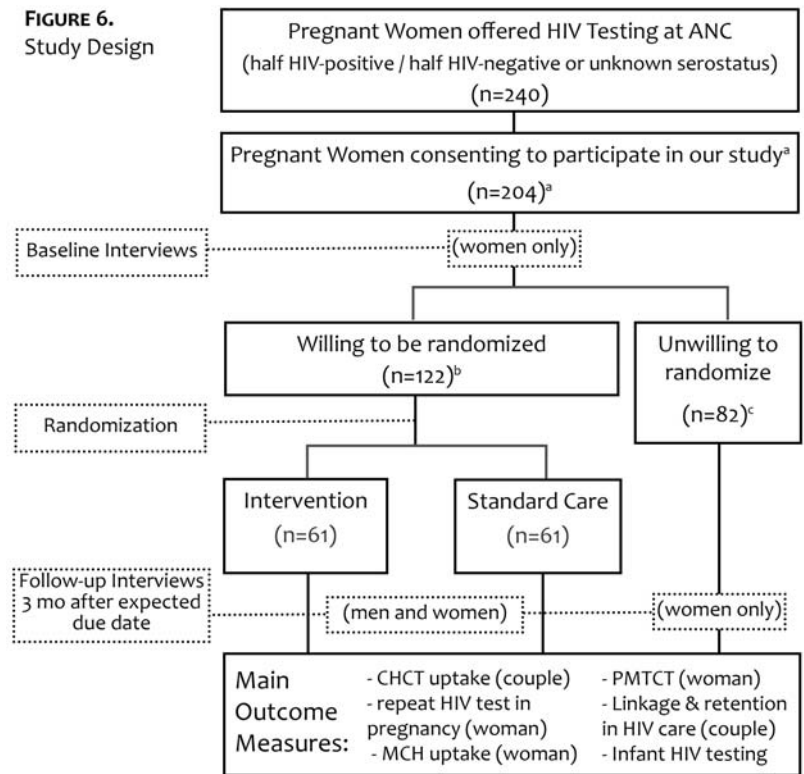
equal numbers to HIV-positive women each month, to ensure that these two groups are balanced over time. In prior studies, our team has achieved participation rates of over 90% (among HIV-positive and HIV-negative pregnant women), and thus estimate a conservative 85% participation rate in baseline interviews (n=204). However, we recognize that the proportion of women who agree to participate in the intervention portion of the study (after the baseline interview) may be lower, at somewhere between 50-70%. As shown in Figure 6, if 60% of these women will agree to be randomized, over a period of 6 months 122 women will be randomized to intervention or control arms (n=61 per arm, around half of which will be HIV-positive at baseline). If we experience 20% loss-to-follow-up (although we anticipate lower loss-to-follow-up due based on prior studies), we will still have approximately 50 couples in each randomized group for analysis. Given the short-term and pilot nature of this R34 study, we have chosen a sample size attainable in a 6-month period.

Recruitment and enrollment for Aim 3: Pregnant women who meet study inclusion criteria will be asked if they would like to participate in a study about approaches for supporting pregnant couples on family health issues (including HIV) during pregnancy and postpartum. If interested, informed consent will be obtained for a baseline interview, which will be followed by a separate consent process for the randomization.

Obtaining informed consent for Aim 3: A lay health worker will consent eligible women after they have been offered HIV testing during an ANC visit (these workers routinely conduct post-test counseling at these sites). The informed consent process will be built into a private post-ANC-visit counseling session conducted for all women, regardless of HIV status. This session will also include screening and referrals for GBV based on our team's existing protocols.¹²³ All participants will be asked to provide informed consent for data abstraction from their medical records. Male partners will be recruited into the study and asked to provide informed consent for study participation at time of first contact (at time of first intervention home visit or follow-up interview) by being introduced to a study on family health during pregnancy concerning health of mothers, fathers, and infants.

Randomization for Aim 3: We will ask all women attending ANC clinics to participate in the study until we have achieved a sample size of 204 women (half HIV-positive and half HIV-negative/unknown) who agree to participate in the study. After a baseline interview, we will ask women if they would be willing to be randomized

FIGURE 6.
Study Design



^aWe estimate 85% participation, based on our previous studies in this setting

^bBased on estimates that 50-70% of women will agree to randomization, this example shows 60%

^cAs 30-50% of women may prefer not to be randomized, this example shows 40%

to one of two approaches for helping to increase couple engagement in maternal and child health (including being offered CHCT). Those who agree will be randomized to the intervention (home visits) or control arm (standard care). Women who decline randomization will be offered support for disclosing their HIV test result on their own (including disclosure tips, support group participation, and referrals) and will be asked a few questions about why they declined randomization. A woman who consents to randomization will receive a sealed envelope labeled with her newly assigned study ID number, which will contain her random assignment. Random assignments will be computer generated and will be stratified by clinic and HIV status to assure approximately equal numbers of women in each study arm and in each HIV status group in any given time period. We expect to have around 60 couples in each study arm (30 in which the woman is HIV-positive at baseline and 30 in which the woman is HIV-negative at baseline).

Study arms for Aim 3: If a woman has been randomized to the intervention arm, a lay health worker will obtain detailed locator information (including cell phone contacts) and consult with the woman about optimal times for a home visit. The woman will be given a letter for her male partner to inform him about the upcoming visit, given that our preliminary research revealed that notifying the male partner beforehand is important.⁸⁴ As described above, the intervention arm will consist of three home visits conducted by one female and one male lay health worker. The standard care arm will offer standard clinic-based services, including the option for women and partners to return to the clinic for male partner HIV testing or CHCT (although our past clinical experience in this setting suggests uptake of these services is low).

Data collection and measures for Aim 3: Factors to be assessed for Aim 3 are presented in Table 3 below.

TABLE 3. Factors to be Assessed in Aim 3 Data Collection

	Factors to be assessed	Study measurements	Assessment group
INTERMEDIATE OUTCOMES	Couple HIV testing	CHCT uptake *	All
	Antenatal HIV testing	Re-testing for HIV during pregnancy *	HIV-negative women
HEALTHCARE UTILIZATION OUTCOMES	Use of family health services	Number of ANC visits during pregnancy * Childbirth with a skilled attendant (Y/N) Postnatal check-up for woman and infant *	All
	Use of PMTCT interventions	Mother's use of ARVs for PMTCT * Prophylactic ARVs for the infant * Appropriate infant feeding practices	HIV-positive women
	Woman's linkage and retention in care	Woman's time to linkage in HIV care * Woman's enrollment in HIV care (Y/N) * Number of HIV visits completed *	HIV-positive women
	Male partner linkage with and retention in care	Male partner's time to linkage in HIV care * Male partner's enrollment in HIV care (Y/N) * Number of HIV visits completed *	HIV-positive men
	Infant HIV testing	Date and result of infant HIV test *	HIV-exposed infants
POTENTIAL MEDIATORS AND MODERATORS	Disclosure of HIV testing and status	Reports of disclosure to others from both partners ¹⁵⁷	All
	Couple relationship dynamics	Sexual Communication Self-Efficacy ¹²⁹ Sexual Relationship Power Scale ¹⁵⁸ Relationship satisfaction and trust Joint decision-making	All
	Perceptions of HIV-related stigma	Anticipated stigma and perceived community stigma scales ¹⁵⁹	All
	Experiences of HIV-related stigma	HASI-P scales of enacted stigma and self stigma ¹⁶⁰	HIV-positive women and men
	Social consequences	Positive and Negative Life Events measures ¹⁶¹	All
PROCESS MEASURES	Intimate partner violence	Measures used in MAMAS	All
	Study Participation	% willing to be randomized, reasons for non-willingness	All women with baseline interviews
	Intervention participation	Number of couple home visits completed	Couples in intervention arm
	Intervention content received	Topics covered, services delivered, referrals made during couple visits	Couples in intervention arm
Acceptability	Satisfaction with intervention components, intervention content, and mode of delivery	Couples in intervention arm	

* Measures to be confirmed through medical records and/or couple visit form

Data will be utilized from four sources:

- *Brief baseline questionnaires* with all study participants (including those who subsequently refuse the randomization) will be conducted with women (at the ANC clinic) and participating male partners (at the time of the first home or clinic visit). These questionnaires will assess baseline measures, including socio-demographic characteristics of both women and male partners, couple relationship measures, and stigma.
- A *couple visit form* will be filled by lay health workers at each home visit. The form will include information on topics covered, CHCT uptake and result, assessments of negative life events, including GBV (conducted with women and men individually),¹⁶¹ other services provided, and process measures. This form, along with records of observations of visits by supervisors, will be used to assess intervention fidelity.
- *Follow-up questionnaires* with women and male partners will occur 3 months after the expected due date (EDD) of the baby on process and outcome measures, as well as mediating and moderating factors. These questionnaires will be administered during research visits by gender-matched independent interviewers.
- *Medical records*: FACES uses an electronic medical record system called Open Medical Record System (OpenMRS[®]). Normally, a short form is completed for each woman identified as HIV-positive in the ANC clinic; we will extend this form to include all women offered HIV testing in ANC. Subsequently data from all patient visits are entered into the OpenMRS system. This database will provide baseline data and objective (non self-report) data on healthcare utilization and health outcomes for all women in the study.

Data management and analysis plans for Aim 3: Data from the baseline interviews, the couple visit form, as well as the 3-month follow-up interview data, will be entered into secure Access databases. Procedures to promote data quality will include range and logical checks built into the data entry program, double entry, and running additional error checks. OpenMRS[®] data routinely undergo a variety of quality control procedures. In preliminary analyses, we will describe demographic characteristics of women and male partners using one-way frequency tables, as well as univariate descriptive statistics for primary outcomes and potential mediators/moderators of interest. To examine acceptability of the research and of being randomized, we will analyze baseline interview data to determine rates of and factors associated with randomization refusal. To examine acceptability and feasibility of the intervention itself, we will examine process indicators (see Table 3).

Although this pilot study is not powered to be a true test of the effectiveness of the intervention, the data will provide preliminary estimates of levels and variability in key outcome measures (e.g., uptake of CHCT, utilization of PMTCT and HIV services) and mediators/moderators of interest (e.g., couple relationship measures). These will help us to determine and refine measures to be used in a larger trial. Given that we will have baseline and follow-up data for both partners of the couple, we will be able to conduct exploratory dyadic analyses, including examination of how similar/different partners are within couples in terms of our mediating and moderating variables. We will use approaches that allow us to both compare couples to each other, as well as to examine actor and partner influences within couples.¹⁶² For example, the former analysis will allow us to examine whether couples who have more positive relationship factors, or less HIV stigma are more likely to have positive outcomes, as well as to explore whether couples who differ on hypothesized variables of interest are less likely to have positive outcomes. The latter approach will allow for the exploration of whether gender impacts outcomes, or whether, for example, a women's likelihood of participating in MCH services is associated with her male partner's experience of HIV stigma or his communication.¹⁶³ Although power will be limited due to sample size, we have successfully utilized these methods before in comparable samples.¹³⁰

Potential Risks and Alternative Strategies for Aim 3: The evidence suggests that antenatal couples HIV counseling interventions do not result in increases in adverse social events in sub-Saharan Africa.¹⁶⁴ In Zambia women participating in antenatal couple counseling did not experience more adverse social events associated with HIV disclosure (separation/divorce, forced to leave the home, violence) than women counseled alone.⁸⁸ In a randomized study in Tanzania, HIV-positive women in the couples voluntary testing and counseling arm had lower levels of marital dissolution and violence after testing.⁹³ In discordant relationship where the woman is HIV-positive, the woman would most likely be safer having test results shared in front of a trained counselor as opposed to disclosing to her partner alone or not disclosing and risking his finding out later.⁹³

Nevertheless, due to potential risks, it is clear that home-based strategies need to be carefully designed. Considerations include how to inform the community about upcoming home visits, how to approach the home without causing unwanted disclosure, how to explain the need for privacy to other family members or neighbors, what package of information and services to offer, and how to handle potential couple conflict that may arise. Informed by our team's extensive work in couples-based approaches and our formative research, we will institute comprehensive protections for risks associated with GBV to ensure safety of our study participants (see Human Subjects). Women will be given a letter to take home to inform their male partner

Bibliography:

1. Medley A, Baggaley R, Bachanas P, Cohen M, Shaffer N, Lo YR. Maximizing the impact of HIV prevention efforts: Interventions for couples. *AIDS Care*. May 8 2013.
2. Desgrees-du-Lou A, Orne-Gliemann J. Couple-centred testing and counselling for HIV serodiscordant heterosexual couples in sub-Saharan Africa. *Reprod Health Matters*. Nov 2008;16(32):151-161.
3. Jones DL, Peltzer K, Villar-Loubet O, et al. Reducing the risk of HIV infection during pregnancy among South African women: a randomized controlled trial. *AIDS Care*. 2013;25(6):702-709. PMC3665743.
4. Hargreaves J, Hatcher A, Strange V, et al. Process evaluation of the Intervention with Microfinance for AIDS and Gender Equity (IMAGE) in rural South Africa. *Health Educ. Res.* Oct 1 2010;25(1):27-40.
5. Hatcher A, de Wet J, Bonell CP, et al. Promoting critical consciousness and social mobilization in HIV/AIDS programmes: lessons and curricular tools from a South African intervention. *Health Educ. Res.* Oct 21 2011;26(3):542-555.
6. Lewis MA, McBride CM, Pollak KI, Puleo E, Butterfield RM, Emmons KM. Understanding health behavior change among couples: an interdependence and communal coping approach. *Soc. Sci. Med.* Mar 2006;62(6):1369-1380.
7. El-Bassel N, Remien RH. Couple-based HIV prevention and treatment: state of science, gaps, and future directions. *Family and HIV/AIDS*: Springer; 2012:153-172.
8. El-Bassel N, Wechsberg WM. Couple-based behavioral HIV interventions: Placing HIV risk-reduction responsibility and agency on the female and male dyad. *Couple and Family Psychology: Research and Practice*. 2012;1(2):94.
9. Lehman DA, John-Stewart GC, Overbaugh J. Antiretroviral strategies to prevent mother-to-child transmission of HIV: striking a balance between efficacy, feasibility, and resistance. *PLoS Med.* Oct 2009;6(10):e1000169.
10. Mofenson LM. Protecting the next generation—Eliminating perinatal HIV-1 infection. *N. Engl. J. Med.* 2010;362(24):2316-2318.
11. UNAIDS WHO. *UNAIDS report on the global AIDS epidemic*. Geneva, Switzerland: UNAIDS;2010.
12. Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya], ORC Macro. Kenya Demographic & Health Survey 2008-2009. Calverton, Maryland: KNBS and ICF Macro; 2010.
13. Ferguson L, Lewis J, Grant AD, et al. Patient attrition between diagnosis with HIV in pregnancy-related services and long-term HIV care and treatment services in Kenya: a retrospective study. *J. Acquir. Immune Defic. Syndr.* Jul 1 2012;60(3):e90-97.
14. Ministry of Public Health and Sanitation, Ministry of Medical Services. *National Reproductive Health Strategy, 2009–2015*. Nairobi: Republic of Kenya, ;2009.
15. United Nations. *United Nations Millennium Declaration. A/RES/55/2*. New York: United Nations General Assembly;2000.
16. UNAIDS. 2013 progress report on the global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. 2013; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20130625_progress_global_plan_en.pdf. Accessed 30 August, 2013.
17. UNAIDS. *Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive*. Geneva,: Joint United Nations Programme on HIV/AIDS (UNAIDS),;2011.
18. Turan JM, Nyblade L. HIV-related Stigma as a Barrier to Achievement of Global PMTCT and Maternal Health Goals: A Review of the Evidence. *AIDS Behav.* Sep 2013;17(7):2528-2539. PMC Not applicable to Public Access Policy.
19. Bajunirwe F, Muzoora M. Barriers to the implementation of programs for the prevention of mother-to-child transmission of HIV: a cross-sectional survey in rural and urban Uganda. *AIDS Res Ther.* Oct 28 2005;2:10.
20. Tchendjou PT, Koki PN, Eboko F, et al. Factors associated with history of HIV testing among pregnant women and their partners in Cameroon: baseline data from a Behavioral Intervention Trial (ANRS 12127 Prenahtest). *J. Acquir. Immune Defic. Syndr.* Jul 1 2011;57 Suppl 1:S9-15.
21. Maman S, Moodley D, Groves AK. Defining male support during and after pregnancy from the perspective of HIV-positive and HIV-negative women in Durban, South Africa. *J Midwifery Womens Health.* Jul 2011;56(4):325-331. PMC3137135.

22. Turan JM, Hatcher AH, Medema-Wijnveen J, et al. The role of HIV-related stigma in utilization of skilled childbirth services in rural Kenya: a prospective mixed-methods study. *PLoS Med.* 2012;9(8):e1001295. PMC3424253.
23. Turan JM, Bukusi EA, Onono M, Holzemer WL, Miller S, Cohen CR. HIV/AIDS stigma and refusal of HIV testing among pregnant women in rural Kenya: results from the MAMAS Study. *AIDS Behav.* Aug 2011;15(6):1111-1120. PMC3127002.
24. Hatcher AM, Turan JM, Leslie HH, et al. Predictors of Linkage to Care Following Community-Based HIV Counseling and Testing in Rural Kenya. *AIDS Behav.* Oct 22 2011 PMC3590795.
25. Aluisio A, Richardson BA, Bosire R, John-Stewart G, Mbori-Ngacha D, Farquhar C. Male antenatal attendance and HIV testing are associated with decreased infant HIV infection and increased HIV-free survival. *J. Acquir. Immune Defic. Syndr.* Jan 2011;56(1):76-82. PMC3005193.
26. Albrecht S, Semrau K, Kasonde P, et al. Predictors of nonadherence to single-dose nevirapine therapy for the prevention of mother-to-child HIV transmission. *J. Acquir. Immune Defic. Syndr.* Jan 1 2006;41(1):114-118.
27. Rujumba J, Neema S, Byamugisha R, Tylleskar T, Tumwine JK, Heggenhougen HK. "Telling my husband I have HIV is too heavy to come out of my mouth": pregnant women's disclosure experiences and support needs following antenatal HIV testing in eastern Uganda. *J Int AIDS Soc.* 2012;15(2):17429.
28. Mugo NR, Heffron R, Donnell D, et al. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS.* Sep 24 2011;25(15):1887-1895.
29. Johnson LF, Stinson K, Newell ML, et al. The contribution of maternal HIV seroconversion during late pregnancy and breastfeeding to mother-to-child transmission of HIV. *J. Acquir. Immune Defic. Syndr.* Apr 1 2012;59(4):417-425. PMC3378499.
30. WHO, UNICEF. *GLOBAL MONITORING FRAMEWORK AND STRATEGY for the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (EMTCT)*. Geneva, Switzerland: World Health Organization;2012.
31. Mulogo EM, Abdulaziz AS, Guerra R, Baine SO. Facility and home based HIV Counseling and Testing: a comparative analysis of uptake of services by rural communities in southwestern Uganda. *BMC health services research.* Mar 4 2011;11(1):54.
32. Amolloh M MA, Owuor P, Audi B, Sewe M, Muttai H, Laserson KF, Ackers M. Factors Associated With Early Uptake of HIV Care and Treatment Services After Testing HIV-Positive during Home-Based Testing and Counseling (HBTC) in Rural Western Kenya. *Abstract presented at the 18th Annual Conference on Retroviruses and Opportunistic Infections (CROI)*. 2011.
33. World Health Organization, UNAIDS, UNICEF. *Towards Universal Access : Scaling up priority HIV/AIDS interventions in the health sector : Progress report 2009*. Geneva, Switzerland: World Health Organization;2009.
34. Padian NS, McCoy SI, Karim SSA, et al. HIV prevention transformed: the new prevention research agenda. *The Lancet.* 2011;378(9787):269-278.
35. Stringer EM, Ekouevi DK, Coetzee D, et al. Coverage of nevirapine-based services to prevent mother-to-child HIV transmission in 4 African countries. *JAMA.* Jul 21 2010;304(3):293-302.
36. WHO, UNAIDS, UNICEF. *Global HIV/AIDS Response: Epidemic update and health sector progress towards Universal Access: Progress report 2011*. Geneva, Switzerland: WHO;2011.
37. Stringer EM, Chi BH, Chintu N, et al. Monitoring effectiveness of programmes to prevent mother-to-child HIV transmission in lower-income countries. *Bull. World Health Organ.* Jan 2008;86(1):57-62.
38. Manzi M, Zachariah R, Teck R, et al. High acceptability of voluntary counselling and HIV-testing but unacceptable loss to follow up in a prevention of mother-to-child HIV transmission programme in rural Malawi: scaling-up requires a different way of acting. *Trop. Med. Int. Health.* Dec 2005;10(12):1242-1250.
39. Bond V, Chase E, Aggleton P. Stigma, HIV/AIDS and prevention of mother-to-child transmission in Zambia. *Eval. Program Plann.* Nov 2002;25(4):347-356.
40. Thorsen VC, Sundby J, Martinson F. Potential initiators of HIV-related stigmatization: ethical and programmatic challenges for PMTCT programs. *Dev World Bioeth.* Apr 2008;8(1):43-50.
41. Painter TM, Diaby KL, Matia DM, et al. Women's reasons for not participating in follow up visits before starting short course antiretroviral prophylaxis for prevention of mother to child transmission of HIV: qualitative interview study. *BMJ.* Sep 4 2004;329(7465):543.

42. Pool R, Nyanzi S, Whitworth JA. Attitudes to voluntary counselling and testing for HIV among pregnant women in rural south-west Uganda. *AIDS Care*. Oct 2001;13(5):605-615.
43. Forsyth B, Visser M, Makin JD, De Villiers A, Jeffery B, Serithi. Disclosure of HIV status among South African women: factors that impede disclosure and subsequent repercussions. Paper presented at: XVI International AIDS Conference 2006; Toronto, Canada.
44. Ekouevi DK, Leroy V, Viho A, et al. Acceptability and uptake of a package to prevent mother-to-child transmission using rapid HIV testing in Abidjan, Cote d'Ivoire. *AIDS*. Mar 5 2004;18(4):697-700.
45. Medley A, Garcia-Moreno C, McGill S, Maman S. Rates, barriers and outcomes of HIV serostatus disclosure among women in developing countries: implications for prevention of mother-to-child transmission programmes. *Bull. World Health Organ*. Apr 2004;82(4):299-307.
46. Etiebet MA, Fransman D, Forsyth B, Coetzee N, Hussey G. Integrating prevention of mother-to-child HIV transmission into antenatal care: learning from the experiences of women in South Africa. *AIDS Care*. Jan 2004;16(1):37-46.
47. Nyblade L, MacQuarrie K. *Can we measure HIV/AIDS stigma and discrimination? Current knowledge about quantifying stigma in developing countries*. Washington, DC: The Policy Project, ICRW, USAID;2006.
48. Painter TM, Diaby KL, Matia DM, et al. Sociodemographic factors associated with participation by HIV-1-positive pregnant women in an intervention to prevent mother-to-child transmission of HIV in Cote d'Ivoire. *Int. J. STD AIDS*. Mar 2005;16(3):237-242.
49. Kilewo C, Massawe A, Lyamuya E, et al. HIV counseling and testing of pregnant women in sub-Saharan Africa: experiences from a study on prevention of mother-to-child HIV-1 transmission in Dar es Salaam, Tanzania. *J. Acquir. Immune Defic. Syndr*. Dec 15 2001;28(5):458-462.
50. Larsson EC, Waiswa P, Thorson A, et al. Low uptake of HIV testing during antenatal care: a population-based study from eastern Uganda. *AIDS*. Sep 10 2009;23(14):1924-1926.
51. Bwirire LD, Fitzgerald M, Zachariah R, et al. Reasons for loss to follow-up among mothers registered in a prevention-of-mother-to-child transmission program in rural Malawi. *Trans. R. Soc. Trop. Med. Hyg*. Dec 2008;102(12):1195-1200.
52. Turan JM, Nylade L, Monfiston P. *Stigma and Discrimination: Key Barriers to Achieving Global Goals for Maternal Health and Elimination of New Child HIV Infections*. Washington, DC: The Health Policy Project;2012.
53. Turan JM, Miller S, Bukusi EA, Sande J, Cohen CR. HIV/AIDS and maternity care in Kenya: how fears of stigma and discrimination affect uptake and provision of labor and delivery services. *AIDS Care*. Sep 2008;20(8):938-945.
54. Steward WT, Herek GM, Ramakrishna J, et al. HIV-related stigma: adapting a theoretical framework for use in India. *Soc. Sci. Med*. Oct 2008;67(8):1225-1235.
55. Earnshaw VA, Chaudoir SR. From conceptualizing to measuring HIV stigma: a review of HIV stigma mechanism measures. *AIDS Behav*. Dec 2009;13(6):1160-1177.
56. Holzemer WL, Human S, Arudo J, et al. Exploring HIV stigma and quality of life for persons living with HIV infection. *J. Assoc. Nurses AIDS Care*. May-Jun 2009;20(3):161-168.
57. Brickley DB, Le Dung Hanh D, Nguyet LT, Mandel JS, Giang le T, Sohn AH. Community, family, and partner-related stigma experienced by pregnant and postpartum women with HIV in Ho Chi Minh City, Vietnam. *AIDS Behav*. Dec 2009;13(6):1197-1204.
58. Medema-Wijnveen JS, Onono M, Bukusi EA, Miller S, Cohen CR, Turan JM. How Perceptions of HIV-Related Stigma Affect Decision-Making Regarding Childbirth in Rural Kenya. *PLoS One*. 2012;7(12):e51492. PMC3520801.
59. Gourlay A, Birdthistle I, Mburu G, Iorpenda K, Wringe A. *Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: a systematic review*2013.
60. Greene K, Derlega VJ, Yep GA, Petronio S. *Privacy and Disclosure of HIV in Interpersonal Relationships: A Sourcebook for Researchers and Practitioners*. Mahwah, New Jersey; : Lawrence Erlbaum Associates, Publishers; 2003.
61. Desgrees-du-Lou A, Brou H, Traore AT, Djohan G, Becquet R, Leroy V. From prenatal HIV testing of the mother to prevention of sexual HIV transmission within the couple. *Soc. Sci. Med*. Sep 2009;69(6):892-899.
62. Orne-Gliemann J, Desgrees-Du-Lou A. The involvement of men within prenatal HIV counselling and testing. Facts, constraints and hopes. *AIDS*. Nov 30 2008;22(18):2555-2557.

63. Katz DA, Kiarie JN, John-Stewart GC, Richardson BA, John FN, Farquhar C. HIV testing men in the antenatal setting: understanding male non-disclosure. *Int. J. STD AIDS*. Nov 2009;20(11):765-767.
64. Bond VA. "It is not an easy decision on HIV, especially in Zambia": opting for silence, limited disclosure and implicit understanding to retain a wider identity. *AIDS Care*. 2010;22 Suppl 1:6-13.
65. Jasseron C, Mandelbrot L, Dollfus C, et al. Non-disclosure of a pregnant woman's HIV status to her partner is associated with non-optimal prevention of mother-to-child transmission. *AIDS Behav*. Feb 2013;17(2):488-497.
66. Myer L. Initiating antiretroviral therapy in pregnancy: the importance of timing. *J. Acquir. Immune Defic. Syndr*. Oct 1 2011;58(2):125-126.
67. Wong LH, Rooyen HV, Modiba P, et al. Test and tell: correlates and consequences of testing and disclosure of HIV status in South Africa (HPTN 043 Project Accept). *J. Acquir. Immune Defic. Syndr*. Feb 1 2009;50(2):215-222. PMC2729272.
68. Roxby AC, Matemo D, Drake AL, et al. Pregnant women and disclosure to sexual partners after testing HIV-1-seropositive during antenatal care. *Aids Patient Care STDS*. Jan 2013;27(1):33-37. PMC3545327.
69. Brou H, Djohan G, Becquet R, et al. When do HIV-infected women disclose their HIV status to their male partner and why? A study in a PMTCT programme, Abidjan. *PLoS Med*. Dec 2007;4(12):e342.
70. National AIDS and STI Control Programme (NASCOP). *GUIDELINES FOR PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) OF HIV/AIDS IN KENYA*. Nairobi, Kenya: Ministry of Health, Government of Kenya;2012.
71. Farquhar C, Kiarie JN, Richardson BA, et al. Antenatal couple counseling increases uptake of interventions to prevent HIV-1 transmission. *J. Acquir. Immune Defic. Syndr*. Dec 15 2004;37(5):1620-1626.
72. Kiarie JN, Kreiss JK, Richardson BA, John-Stewart GC. Compliance with antiretroviral regimens to prevent perinatal HIV-1 transmission in Kenya. *AIDS*. 2003;17(1):65-71.
73. Peltzer K, Mlambo M, Phaswana-Mafuya N, Ladzani R. Determinants of adherence to a single-dose nevirapine regimen for the prevention of mother-to-child HIV transmission in Gert Sibande district in South Africa. *Acta Paediatr*. May 2010;99(5):699-704.
74. Nassali M, Nakanjako D, Kyabayinze D, Beyeza J, Okoth A, Mutyaba T. Access to HIV/AIDS care for mothers and children in sub-Saharan Africa: adherence to the postnatal PMTCT program. *AIDS Care*. 2009/09/01 2009;21(9):1124-1131.
75. Duff P, Kipp W, Wild TC, Rubaale T, Okech-Ojony J. Barriers to accessing highly active antiretroviral therapy by HIV-positive women attending an antenatal clinic in a regional hospital in western Uganda. *J Int AIDS Soc*. 2010;13:37.
76. Delva W, Yard E, Luchters S, et al. A Safe Motherhood project in Kenya: assessment of antenatal attendance, service provision and implications for PMTCT. *Trop. Med. Int. Health*. May 2010;15(5):584-591.
77. Chinkonde JR, Sundby J, de Paoli M, Thorsen VC. The difficulty with responding to policy changes for HIV and infant feeding in Malawi. *Int Breastfeed J*. 2010;5:11.
78. Katz DA, Kiarie JN, John-Stewart GC, Richardson BA, John FN, Farquhar C. Male perspectives on incorporating men into antenatal HIV counseling and testing. *PLoS One*. 2009;4(11):e7602.
79. Kebaabetswe PM. Barriers to participation in the prevention of mother-to-child HIV transmission program in Gaborone, Botswana a qualitative approach. *AIDS Care*. Mar 2007;19(3):355-360.
80. WHO. *Programming for Male Involvement in Reproductive Health, Report of the Meeting of WHO Regional Advisors in Reproductive Health, WHO/PAHO, Washington DC USA, 5-7 September 2001*. Geneva, Switzerland: WHO Department of Reproductive Health and Research;2002.
81. Falnes EF, Moland KM, Tylleskar T, de Paoli MM, Msuya SE, Engebretsen IM. "It is her responsibility": partner involvement in prevention of mother to child transmission of HIV programmes, northern Tanzania. *J Int AIDS Soc*. 2011;14(1):21. PMC3108267.
82. Byamugisha R, Tumwine J, Semiyaga N, Tylleskar T. Determinants of male involvement in the prevention of mother-to-child transmission of HIV programme in Eastern Uganda: a cross-sectional survey. *Reproductive Health*. 2010;7(1):12.
83. Kwambai TK, Dellicour S, Desai M, et al. Perspectives of men on antenatal and delivery care service utilisation in rural western Kenya: a qualitative study. *BMC Pregnancy Childbirth*. 2013;13:134. PMC3691751.

84. Walcott M, Hatcher A, Kwena Z, Turan JM. Acceptability and feasibility of approaches to facilitated HIV disclosure for pregnant women and partners in rural Kenya: A qualitative study. Under Review.
85. Duff P, Rubaale T, Kipp W. Married men's perceptions of barriers for HIV-positive pregnant women accessing highly active antiretroviral therapy in rural Uganda. *Int J Womens Health*. 2012;4:227-233.
86. Koo K, Makin JD, Forsyth BW. Where are the men? Targeting male partners in preventing mother-to-child HIV transmission. *AIDS Care*. Jan 2013;25(1):43-48.
87. Medley AM, Kennedy CE, Lunyolo S, Sweat MD. Disclosure outcomes, coping strategies, and life changes among women living with HIV in Uganda. *Qual. Health Res*. Dec 2009;19(12):1744-1754.
88. Semrau K, Kuhn L, Vwalika C, et al. Women in couples antenatal HIV counseling and testing are not more likely to report adverse social events. *AIDS*. Mar 24 2005;19(6):603-609.
89. Msuya SE, Mbizvo EM, Hussain A, Uriyo J, Sam NE, Stray-Pedersen B. Low male partner participation in antenatal HIV counselling and testing in northern Tanzania: implications for preventive programs. *AIDS Care*. Jul 2008;20(6):700-709.
90. Kizito D, Woodburn PW, Kesande B, et al. Uptake of HIV and syphilis testing of pregnant women and their male partners in a programme for prevention of mother-to-child HIV transmission in Uganda. *Trop. Med. Int. Health*. May 2008;13(5):680-682. PMC2592475.
91. World Health Organization. *GUIDANCE ON COUPLES HIV TESTING AND COUNSELLING INCLUDING ANTIRETROVIRAL THERAPY FOR TREATMENT AND PREVENTION IN SERODISCORDANT COUPLES*. Geneva, Switzerland: WHO, ;April 2012.
92. Onyango OA, Grace JS, James K, et al. Home visits during pregnancy enhance male partner HIV counselling and testing in Kenya: a randomized clinical trial. *AIDS*. Aug 12 2013.
93. Becker S, Mlay R, Schwandt HM, Lyamuya E. Comparing Couples' and Individual Voluntary Counseling and Testing for HIV at Antenatal Clinics in Tanzania: A Randomized Trial. *AIDS Behav*. Sep 10 2009.
94. Burton J, Darbes LA, Operario D. Couples-focused behavioral interventions for prevention of HIV: systematic review of the state of evidence. *AIDS Behav*. Feb 2010;14(1):1-10. PMC3640442.
95. Montgomery CM, Watts C, Pool R. HIV and dyadic intervention: an interdependence and communal coping analysis. *PLoS One*. 2012;7(7):e40661. PMC3395677.
96. Orne-Gliemann J, Tchendjou PT, Miric M, et al. Couple-oriented prenatal HIV counseling for HIV primary prevention: an acceptability study. *BMC Public Health*. 2010;10:197. PMC2873579.
97. Villar-Loubet OM, Bruscantini L, Shikwane ME, Weiss S, Peltzer K, Jones DL. HIV disclosure, sexual negotiation and male involvement in prevention-of-mother-to-child-transmission in South Africa. *Cult Health Sex*. Sep 13 2012.
98. Orne-Gliemann J, Balestre E, Darak S, et al. Couple communication about the prevention of sexual risks: the role of a prenatal HIV counselling intervention - Prenatest ANRS 12127 trial. *XIX International AIDS Conference*. Washington, DC July 22-27, 2012.
99. Brusamento S, Ghanotakis E, Tudor Car L, Majeed A, Car J. Male involvement for increasing the effectiveness of prevention of mother-to-child HIV transmission (PMTCT) programmes. *Cochrane Database of Systematic Reviews*. 2012(11):CD009468.
100. Baek C, Mathambo V, Mkhize S, Friedman I, Apicella L, N R. *Key Findings from an Evaluation of the mothers2mothers Program in KwaZulu-Natal, South Africa. Horizons Final Report*. Washington DC: The Population Council;2007.
101. Rotheram-Borus MJ, le Roux IM, Tomlinson M, et al. Philani Plus (+): a Mentor Mother community health worker home visiting program to improve maternal and infants' outcomes. *Prevention science : the official journal of the Society for Prevention Research*. Dec 2011;12(4):372-388.
102. Lewis MA, Rook KS. Social control in personal relationships: impact on health behaviors and psychological distress. *Health Psychol*. Jan 1999;18(1):63-71.
103. Umberson D. Gender, marital status and the social control of health behavior. *Soc. Sci. Med*. Apr 1992;34(8):907-917.
104. Sexton M, Bross D, Hebel JR, et al. Risk-factor changes in wives with husbands at high risk of coronary heart disease (CHD): the spin-off effect. *J. Behav. Med*. Jun 1987;10(3):251-261.
105. Lewis MA, Kalinowski CT, Sterba KR, Barrett TM, DeVellis RF. Interpersonal processes and vasculitis management. *Arthritis Care Res*. 2006;55(4):670-675.
106. Rohrbaugh MJ, Shoham V, Coyne JC, Cranford JA, Sonnega JS, Nicklas JM. Beyond the "self" in self-efficacy: Spouse confidence predicts patient survival following heart failure. *J Fam Psychol*. Mar 2004;18(1):184-193.

107. van Doorn C. Spouse-rated limitations and spouse-rated life expectancy as mortality predictors. *J. Gerontol. B. Psychol. Sci. Soc. Sci.* May 1998;53(3):S137-143.
108. Ware NC, Wyatt MA, Haberer JE, et al. What's love got to do with it? Explaining adherence to oral antiretroviral pre-exposure prophylaxis for HIV-serodiscordant couples. *J. Acquir. Immune Defic. Syndr.* Apr 15 2012;59(5):463-468.
109. Negin J, Wariero J, Mutuo P, Jan S, Pronyk P. Feasibility, acceptability and cost of home-based HIV testing in rural Kenya. *Trop. Med. Int. Health.* Aug 2009;14(8):849-855.
110. Liverpool VCT. Community Based HIV Testing and Counseling (CBHTC). <http://www.liverpoolvct.org/index.php?PID=83&showsubmenu=83>. Accessed April 1, 2010.
111. National AIDS and STI Control Programme (NASCOP). *Kenya AIDS Indicator Survey 2007: Final Report*. Nairobi, Kenya: NASCOP;2009.
112. Dalal W, Feikin DR, Amolloh M, et al. Home-based HIV testing and counseling in rural and urban Kenyan communities. *J. Acquir. Immune Defic. Syndr.* Feb 1 2013;62(2):e47-54.
113. Njau B, Watt MH, Ostermann J, Manongi R, Sikkema KJ. Perceived acceptability of home-based couples voluntary HIV counseling and testing in Northern Tanzania. *AIDS Care.* 2012;24(4):413-419.
114. Tudor Car L, van-Velthoven MH, Brusamento S, et al. Integrating prevention of mother-to-child HIV transmission (PMTCT) programmes with other health services for preventing HIV infection and improving HIV outcomes in developing countries. *Cochrane Database Syst Rev.* 2011;CD008741.
115. Davis J, Luchers S, Holmes W. *Men and maternal and newborn health*: Centre for International Health, Burnet Institute, Australia;2013.
116. Kelley HH, Thibaut JW. *Interpersonal relations: A theory of interdependence*: Wiley New York; 1978.
117. Muga GO, Onyango-Ouma W. Changing household composition and food security among the elderly caretakers in rural western Kenya. *Journal of cross-cultural gerontology.* 2009;24(3):259-272.
118. Rusbult CE, Van Lange PA. Interdependence, interaction, and relationships. *Annu Rev Psychol.* 2003;54:351-375.
119. Lyons RF, Mickelson KD, Sullivan MJL, Coyne JC. Coping as a communal process. *Journal of Social and Personal Relationships.* 1998;15(5):579-605.
120. Turan JM, Onono M, Cohen CR, Bukusi EA. Stigma and lack of disclosure as barriers to use of maternity and HIV services by HIV-positive pregnant women in rural Kenya. *APHA 140th Annual Meeting, October 27-31, 2012*. San Francisco, CA, USA.
121. Hatcher AM, Romito P, Odero M, Bukusi EA, Onono M, Turan JM. Social context and drivers of intimate partner violence in rural Kenya: implications for the health of pregnant women. *Cult Health Sex.* Apr 2013;15(4):404-419. PMC PMC Journal - In Process.
122. Odero M, Hatcher AH, Bryant C, Onono M, Turan JM. Responses and resources for gender-based violence during pregnancy: A qualitative study in rural Nyanza, Kenya. *Journal of Interpersonal Violence.* In Press.
123. Turan JM, Hatcher AM, Odero M, et al. A Community-Supported Clinic-Based Program for Prevention of Violence against Pregnant Women in Rural Kenya. *AIDS Res Treat.* 2013;2013:736926. PMC3657417.
124. Cohen CR, Montandon M, Carrico AW, et al. Association of attitudes and beliefs towards antiretroviral therapy with HIV-seroprevalence in the general population of Kisumu, Kenya. *PLoS One.* 2009;4(3):e4573.
125. Kwena Z, Sharma A, Wamae N, Muga C, Bukusi E. Provider characteristics among staff providing care to sexually transmitted infection self-medicating patients in retail pharmacies in Kibera slum, Nairobi, Kenya. *Sex. Transm. Dis.* May 2008;35(5):480-483.
126. Ng'ayo MO, Bukusi E, Rowhani-Rahbar A, et al. Epidemiology of human papillomavirus infection among fishermen along Lake Victoria Shore in the Kisumu District, Kenya. *Sex. Transm. Infect.* Feb 2008;84(1):62-66.
127. Kwena ZA, Camlin CS, Shisanya CA, Mwanzo I, Bukusi EA. Short-term mobility and the risk of HIV infection among married couples in the fishing communities along Lake Victoria, Kenya. *PLoS One.* 2013;8(1):e54523. PMC3545885.
128. Leddy A, Johnson M, Dladla S, Darbes L. South African couples' preferences for the delivery of a couples-based voluntary counseling and testing intervention. *19th International AIDS Conference*. Washington, DC, 2012.

129. Darbes LA, Chakravarty D, Leddy A, Dladla S, de Bruyn G. Sexual communication self-efficacy (SCSE) is a significant predictor of couples engaging in couples-based voluntary counseling and testing (CBVCT) for HIV in Soweto, South Africa. *19th International AIDS Conference*. Washington, D.C.2012.
130. Darbes LA, Lewis MA. HIV-specific social support predicts less sexual risk behavior in gay male couples. *Health Psychol*. Nov 2005;24(6):617-622.
131. Lewis MA, Gladstone E, Schmal S, Darbes LA. Health-related social control and relationship interdependence among gay couples. *Health Educ. Res*. Aug 2006;21(4):488-500.
132. Darbes LA, Chakravarty D, Beougher SC, Neilands TB, Hoff CC. Partner-provided social support influences choice of risk reduction strategies in gay male couples. *AIDS Behav*. Jan 2012;16(1):159-167. PMC3254781.
133. Johnson MO, Dilworth SE, Taylor JM, Darbes LA, Comfort ML, Neilands TB. Primary relationships, HIV treatment adherence, and virologic control. *AIDS Behav*. Aug 2012;16(6):1511-1521. PMC3607313.
134. Turan JM, Steinfeld RL, Onono M, et al. The study of HIV and antenatal care integration in pregnancy in Kenya: design, methods, and baseline results of a cluster-randomized controlled trial. *PLoS One*. 2012;7(9):e44181. PMC3435393.
135. Sahip Y, Turan JM. Education for expectant fathers in workplaces in Turkey. *J. Biosoc. Sci*. Nov 2007;39(6):843-860. PMC Not applicable to Public Access Policy.
136. Turan J, Nalbant H, Bulut A, Mosley W, Gökçay G. Promoting Postpartum Health in Istanbul: Does Including Fathers Make a Difference? *Responding to Cairo: Case Studies of Changing Practice in Reproductive Health and Family Planning*. New York, NY: The Population Council; 2002.
137. Turan JM, Nalbant H, Bulut A, Sahip Y. Including expectant fathers in antenatal education programmes in Istanbul, Turkey. *Reprod Health Matters*. Nov 2001;9(18):114-125. PMC Not applicable to Public Access Policy.
138. Turan JM, Tesfagiorgis M, Polan ML. Evaluation of a community intervention for promotion of safe motherhood in Eritrea. *J Midwifery Womens Health*. Jan 2011;56(1):8-17. PMC3498940.
139. NACC, NASCOP. *Kenya AIDS Epidemic update 2011*. Nairobi, Kenya: NACC and NASCOP;2012.
140. Desai M, Phillips-Howard PA, Odhiambo FO, et al. An Analysis of Pregnancy-Related Mortality in the KEMRI/CDC Health and Demographic Surveillance System in Western Kenya. *PLoS One*. 2013;8(7):e68733.
141. FACES. FACES- Family AIDS Care and Educational Service 2012; <http://www.faces-kenya.org>.
142. Turan JM, Bukusi EA, Onono M, et al. Effects of Antenatal Care-HIV Service Integration on the Prevention of Mother-to-Child Transmission Cascade: Results from a cluster-randomized controlled trial in Kenya. *Integration for Impact: Reproductive Health & HIV Services in sub-Saharan Africa*. Nairobi, Kenya, September 12-14, 2012.
143. Lewis Kulzer J, Penner JA, Marima R, et al. Family model of HIV care and treatment: a retrospective study in Kenya. *J Int AIDS Soc*. 2012;15(1):8. PMC3298805.
144. Mujugira A, Baeten JM, Donnell D, et al. Characteristics of HIV-1 serodiscordant couples enrolled in a clinical trial of antiretroviral pre-exposure prophylaxis for HIV-1 prevention. *PLoS One*. 2011;6(10):e25828.
145. Reece M, Hollub A, Nangami M, Lane K. Assessing male spousal engagement with prevention of mother-to-child transmission (pMTCT) programs in western Kenya. *AIDS Care*. Jun 2010;22(6):743-750.
146. TRAC Plus. *HAS UNIT 2008 ANNUAL REPORT*. Kigali, Rwanda: Center for Treatment and Research on AIDS, Malaria, Tuberculosis and Other Epidemics;2009.
147. Centers for Disease Control and Prevention. *Couples HIV Counseling and Testing Intervention and Curriculum*. Atlanta, GA: Centers for Disease Control and Prevention, National Center for STD HIV Viral Hepatitis and TB Prevention, Global AIDS Program;2007.
148. National AIDS and STI Control Programme, Ministry of Public Health and Sanitation. *Guidelines for HIV Testing and Counselling in Kenya*. Nairobi, Kenya: NASCOP;2008.
149. The Voluntary HIV-1 Counseling and Testing Efficacy Study Group, Kamenga C, Sweat M, et al. The voluntary HIV-1 counseling and testing efficacy study: design and methods. *Aids and Behavior*. 2000;4(1):5-14.
150. Ministry of Health Uganda. *Positive Prevention Counseling: A Training Course for HIV/AIDS Counselors*. Kampala, Uganda: Ministry of Health, Uganda, Strengthening HIV Counsellor Training Project (SCOT), USAID, EngenderHealth/ACQUIRE Project, PEPFAR, CDC 2007.

151. Turan JM, Say L. Community-based antenatal education in Istanbul, Turkey: effects on health behaviours. *Health Policy Plan*. Dec 2003;18(4):391-398. PMC Not applicable to Public Access Policy.
152. Cuca YP, Onono M, Bukusi E, Turan JM. Factors associated with pregnant women's anticipations and experiences of HIV-related stigma in rural Kenya. *AIDS Care*. 2012;24(9):1173-1180. PMC3492416.
153. Awiti Ujiji O, Ekström AM, Ilako F, Indalo D, Wamalwa D, Rubenson B. Reasoning and deciding PMTCT-adherence during pregnancy among women living with HIV in Kenya. *Culture, Health & Sexuality*. 2011/08/01 2011;13(7):829-840.
154. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ*. Jan 8 2000;320(7227):114-116. PMC1117368.
155. Turan JM, Bukusi EA, Cohen CR, Sande J, Miller S. Effects of HIV/AIDS on maternity care providers in Kenya. *J. Obstet. Gynecol. Neonatal Nurs*. Sep-Oct 2008;37(5):588-595. PMC2556865.
156. le Roux IM, Tomlinson M, Harwood JM, et al. Outcomes of home visits for pregnant mothers and their infants: a cluster randomized controlled trial. *AIDS*. Jun 1 2013;27(9):1461-1471.
157. Tsai AC, Bangsberg DR, Katz IT, et al. Internalized stigma, social distance, and disclosure of HIV seropositivity in rural Uganda. *Ann. Behav. Med*. 2013:1-10.
158. Pulerwitz J, Amaro H, De Jong W, Gortmaker SL, Rudd R. Relationship power, condom use and HIV risk among women in the USA. *AIDS Care*. Dec 2002;14(6):789-800.
159. Weiser SD, Heisler M, Leiter K, et al. Routine HIV testing in Botswana: a population-based study on attitudes, practices, and human rights concerns. *PLoS Med*. Jul 2006;3(7):e261.
160. Holzemer WL, Uys LR, Chirwa ML, et al. Validation of the HIV/AIDS Stigma Instrument - PLWA (HASI-P). *AIDS Care*. Sep 2007;19(8):1002-1012.
161. Grinstead OA, Gregorich SE, Choi KH, Coates T. Positive and negative life events after counselling and testing: the Voluntary HIV-1 Counselling and Testing Efficacy Study. *AIDS*. May 25 2001;15(8):1045-1052.
162. Judd CM, Kenny DA, McClelland GH. Estimating and testing mediation and moderation in within-subject designs. *Psychol Methods*. Jun 2001;6(2):115-134.
163. Kenny DA, Ledermann T. Detecting, measuring, and testing dyadic patterns in the actor-partner interdependence model. *Journal of Family Psychology*. 2010;24(3):359.
164. Brown LB, Miller WC, Kamanga G, et al. HIV partner notification is effective and feasible in sub-Saharan Africa: opportunities for HIV treatment and prevention. *J. Acquir. Immune Defic. Syndr*. Apr 15 2011;56(5):437-442. PMC3207356.
165. Kairania R, Gray RH, Kiwanuka N, et al. Disclosure of HIV results among discordant couples in Rakai, Uganda: a facilitated couple counselling approach. *AIDS Care*. Sep 2010;22(9):1041-1051. PMC2936701.