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# TESTING STRATEGIES FOR COUPLE ENGAGEMENT IN PMTCT AND FAMILY HEALTH IN KENYA

**INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS**:


| Name | Organization | Role on Project |
|---|---|---|
| Janet Turan | University of Alabama at Birmingham (UAB) | Principal Investigator |
| Zachary Kwena | Kenya Medical Research Institute (KEMRI) | Site Principal Investigator |
| Elizabeth Bukusi | Kenya Medical Research Institute (KEMRI) | Co-Investigator |
| Lynae Darbes | University of Michigan (UM) | Principal Investigator |
| Abigail Hatcher | University of North Carolina, Chapel Hill | Co-Investigator |
| Harsha Thirumurthy | University of Pennsylvania | Co-Investigator |
| Thomas M. Braun | University of Michigan | Co-Investigator |
| Maria Pisu | University of Alabama at Birmingham (UAB) | Co-Investigator |
| Van T. Nghiem | University of Alabama at Birmingham (UAB) | Co-Investigator |

## ABSTRACT/ SUMMARY

Despite the potential for antiretroviral therapy (ART) to improve maternal health and reduce mother-to-child transmission of HIV to as low as 1%, HIV-related maternal deaths and HIV infection among infants remain unacceptably high across sub-Saharan Africa. This is particularly true in Kenya, where antenatal care attendance is high but crucial drop-offs occur in uptake of, and adherence to, key maternal and child health and prevention of mother-to-child transmission (PMTCT) services. Many pregnant women avoid couple HIV testing or do not adhere to PMTCT services because they fear negative consequences of HIV for their relationship with their male partner. Men can play a crucial decision-making and supportive role for family health, but male partners of pregnant women in Kenya are poorly engaged in PMTCT and only 4.5% have recently tested for HIV themselves. Many pregnant women prefer to engage in couple HIV testing and counseling (CHTC) to facilitate disclosure of HIV sero-status (positive or negative) to their partners—often shortly after participating in individual HIV testing. This preference highlights the potential for couples-focused approaches, and the need to develop new strategies to engage male partners in HIV-related programs and services. Thus, we propose to conduct a three-arm couple-randomized controlled trial among 800 pregnant women attending antenatal clinics (533 HIV-positive and 267 HIV-negative at baseline) and their primary male partners. We will randomize couples to home-based visits, multiple HIV self-test kits, or the standard care of male partner invitation letters and follow them up for 18 months postpartum to (a) determine the impact of a couples-focused home-based intervention on our primary outcome of couple HIV testing for pregnant women and their male partners (assessed through proportion reporting couples testing, yield of new HIV+ diagnoses of male partners, and identification of new sero-discordant couples) as compared to HIV self-test kits for couples and standard care; (b) examine the impact of the intervention on HIV prevention behaviors (PrEP and condom use),facility delivery, and postnatal healthcare utilization for all participants; as well as secondary health outcomes of maternal VL suppression, and HIV-free child survival up to 18 months for couples living with HIV*;* as compared to HIV self-test kits for couples and standard care and; (c) compare the cost-effectiveness of the home-based couples intervention to less resource-intensive strategies of standard care and HIV self-test kits for couples. Despite its promise, a home-based intervention may require more resources and it is important to assess whether it offers greater value for money than other strategies, which may cost less but be less impactful. This theory-based couples intervention has strong potential to increase couples HIV testing and use of essential health services by pregnant women and their male partners.

## LAY SUMMARY

HIV-related maternal deaths and HIV infection among infants remain unacceptably high across sub-Saharan Africa. This is despite the potential for antiretroviral therapy (ART) to improve maternal health and reduce mother-to-child transmission of HIV. This is particularly true in Kenya, where antenatal care attendance is high but crucial drop-offs occur in uptake of and adherence to key maternal and child health and prevention of mother-to-child transmission (PMTCT) services. Many pregnant women avoid couple HIV testing or do not adhere to PMTCT services because they fear negative consequences of HIV for their relationship with their male partner. Men can play a crucial decision-making and supportive role for family health, but male partners of pregnant women in Kenya are poorly engaged in PMTCT. Many pregnant women prefer to engage in couple HIV testing and counseling (CHTC) to facilitate disclosure of HIV sero-status (positive or negative) to their partners. This preference highlights the potential for couples-focused approaches, and the need to develop new strategies to engage male partners in HIV-related programs and services. Thus, we propose to conduct a three-arm couple-randomized controlled trial among 800 pregnant women attending antenatal clinics (533 HIV-positive and 267 HIV-negative at baseline) and their primary male partners to test whether seeking to test couples at home or provide them with self-tests can enhance male HIV testing and better health outcomes to mother and child and generally the health of the family. We will enroll couples into either home-based visits or multiple HIV self-test kits, or the standard care of male partner invitation letters to (a) determine the impact of a couples-focused home-based intervention on couple HIV testing for

pregnant women and their male partners; (b) examine the impact of the intervention on HIV prevention behaviors (PrEP and condom use), facility delivery, and postnatal healthcare utilization for all participants; as well as secondary health outcomes of maternal VL suppression, and HIV-free child survival up to 18 months for couples living with HIV*;* as compared to HIV self-test kits for couples and standard care and; (c) compare the cost-effectiveness of the home-based couples intervention to less resource-intensive strategies of standard care and HIV self-test kits for couples.

## INTRODUCTION/BACKGROUND:

**New strategies are needed to promote linkage to and retention in PMTCT and HIV treatment for pregnant and postpartum women.** Despite the demonstrated success of ART for the treatment of maternal HIV disease and PMTCT,[1-3] HIV prevalence among mothers and infants in Kenya remains persistently high.[4] While rates of antenatal HIV testing have been increasing over time—90% of women attending antenatal care were tested in 2014[5] compared to 83% in 2010[6]—only approximately half of women testing HIV-positive (54%) received the full course of antiretrovirals and only a portion of these women completed the series of steps required for efficacious PMTCT, known as the "PMTCT cascade".[7, 8] The PMTCT cascade begins with the testing of pregnant women for HIV during antenatal care (ANC), incorporates ART throughout the pregnancy and in the postpartum period, and involves treating both the mother and the infant.[7] Among those who initially access PMTCT, rates of subsequent drop-out are high; a recent systematic review and meta-analysis found that loss to follow-up in PMTCT programs in sub-Saharan Africa was around 49%.[9]

**Fears and experiences of HIV-related stigma, discrimination, and violence are key barriers to completion of the PMTCT cascade in sub-Saharan Africa.** It has been noted that fixing the PMTCT coverage problem could prevent as many infant HIV deaths as would developing more effective drug regimens.[8, 10] However, multiple social factors that contribute to dropout rates for the PMTCT cascade must be addressed in order to increase cascade retention rates.[10-12] Fears of stigma, discrimination, and violence are common themes in narratives of pregnant women affected by HIV.[10-12] 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.[11, 13-18] Theoretical frameworks indicate that different dimensions of stigma—anticipated stigma, perceived community stigma, enacted stigma (discrimination), and internalized stigma—adversely affect quality of life, healthcare access, and health outcomes for persons living with HIV,[19] and research suggests that stigma from close persons may have a significant impact.[20-23]Our research in Kenya has found that fears and experiences of stigma from a male partner decrease antenatal HIV testing, limit linkage to HIV care, and reduce the uptake of skilled childbirth services.[24-27] Two systematic reviews also suggest that stigma, violence, and discrimination hinder PMTCT uptake despite more efficacious regimens and improved guidelines in sub-Saharan Africa.[28, 29]

**Lack of disclosure of HIV testing and test results to male partners is a significant barrier to health service utilization by pregnant and postpartum women.** In addition, non-disclosure of HIV status between partners—often resulting from fears of stigma, discrimination, and violence—has been found to limit PMTCT uptake in sub-Saharan Africa.[30, 31] Disclosure of HIV status has important benefits including gaining access to social support, lowering risk of HIV transmission to partners, obtaining appropriate medical treatment, decreasing stress, and creating closer relationships with others.[31-34] In a systematic review of sub-Saharan African studies, partner non-disclosure was associated with poor PMTCT uptake both quantitative (6 of 9) and qualitative (17 of 24) studies.[29] 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;[35-37] it increases the odds of non-optimal adherence to PMTCT interventions[38, 39] and increases the risk of vertical transmission of HIV.[40] Studies have revealed long delays between HIV-positive diagnosis and disclosure,[41], [42] and one study in Kenya found that 4 years after diagnosis, individuals were still secretive about their status and were only slowly beginning to make plans to disclose to their partners.[43]Kenya now emphasizes lifelong ART treatment for all HIV-positive women early in pregnancy,[44]rendering timely disclosure and linkage to HIV care even more urgent.

**Pregnant women testing HIV-negative and their male partners are a high-risk group for incident infection.** Women who initially test HIV-negative, but who have potential to seroconvert during pregnancy, and their male partners are a crucial group for interventions. Often pregnant women and partners feel "safe" after an HIV-negative test result at the ANC clinic.[45]Studies have found around 3% seroconversion rates during and after pregnancy among previously HIV-negative pregnant women in sub-Saharan African settings [46],[47] These women are at high risk of becoming HIV-infected during late pregnancy, receive no counseling on infant feeding, no PMTCT services, and have an increased risk of MTCT.[46, 48, 49] Since HIV transmission risk increases by more than 2-fold during pregnancy, it is likely that uninfected women and their male partners are at heightened risk of incident infection and contribute a significant number of vertically transmitted HIV cases.[46, 47, 50-52] Promoting couples testing among HIV-negative pregnant women is therefore essential to reducing HIV acquisition risk.

**Despite recognition that male partners play a major role in uptake of services by pregnant women, most PMTCT programs have not been successful in engaging men.** Male partners are clearly a key factor in retention of women and infants in the PMTCT cascade. When male partners are uninvolved in HIV testing and antenatal care, women are less likely to:1)accept ART,[53, 54]2) deliver in a health facility, and 3) adhere to care.[55] Thus, it is unsurprising that scholars globally have advocated for engaging men in PMTCT.[53-58] Yet, most antenatal HIV testing strategies have not been successful in reaching out to men,[58, 59] making it challenging for men to become involved or for HIV-negative pregnant women to learn their partner's status.[60] This is compounded by gender norms that limit men's ability to involve themselves in pregnancy and label ANC clinics and health facilities as "female spaces."[60-62] Our research[63] and that of others[64, 65] shows that men themselves desire more involvement in PMTCT and antenatal services, but are unlikely to use traditional clinic-based services. Innovative approaches that do not involve facilities are necessary to ensure that male partner involvement occurs in a safe and supportive way.[62, 65, 66]

**Couples HIV counseling and testing (CHTC), an evidence-based intervention, offers potential to engage men and women, but has been underutilized in the PMTCT context.** Based on evidence of the need to include both pregnant women and their male partners in PMTCT, programs across Africa have increasingly called for CHTC.[39, 54, 66] Yet, most CHTC programs are implemented in clinics, making it unlikely that pregnant women and male partners will utilize them given poor male attendance in many settings.[59, 62, 67, 68]In Kenya, while the majority of pregnant women receive HIV testing, only 4.5% of their male partners underwent HIV testing within the last 12 months.[5]Further, many women, including pregnant women, express interest in participating in couples testing following individual testing—regardless of sero-status. Although women receive individual testing in antenatal care, participating in CHTC with their partners offers a safe environment for sero-status disclosure, combined with tailored counseling and solution-building for the couple.[69]

**There is also a need to compare and contrast different approaches for increasing male engagement and couples testing, including innovative approaches such as HIV self-testing (HIVST)**.[70-72]With HIVST, individuals collect their own sample and perform a simple, rapid HIV antibody test in the absence of a provider. Existing research shows a high level of acceptability and demand for HIVST across a wide range of populations and settings, as well as good accuracy in the hands of lay users.[73-78] A major development in the rapidly growing field of HIVST occurred in December 2016, when the WHO called for the scale-up of HIVST.[79]With its increased convenience and privacy, HIVST can make it easier for pregnant women and their partners to test together. One strategy that has received attention recently is the provision of HIV self-test kits to pregnant women for use by both partners of the couple - a "secondary distribution" strategy that members of our team have developed and tested, with promising results. Early evidence from Malawi[80] and Kenya[76, 81, 82]suggests this approach is feasible, safe, and promising, but further research is needed to establish how health outcomes and behaviors compare to standard care and to home-based couples testing interventions.

**We propose to test the efficacy and cost-effectiveness of a home-based intervention to facilitate HIV couples testing and disclosure in order to increase use of PMTCT and family health services.** Our study will assess effects on our primary outcome of couples testing uptake, as well as on secondary outcomes of HIV prevention behaviors, PMTCT and maternal child health service utilization and HIV-related health outcomes of HIV-free child survival and VL suppression. This approach aligns with increased efforts to engage male partners as a means to promote PMTCT retention,[82, 83]but will be among the first studies to address fears of disclosure of HIV status and harness couples' relationships to improve maternal and child health outcomes.

**STUDY AIMS**

We will conduct a three-arm couple-randomized controlled trial among 800 pregnant women attending antenatal clinics (533 HIV-positive and 267 HIV-negative at baseline) and their primary male partners. We will randomize couples to home-based visits, multiple HIV self-test kits, or the standard care of male partner invitation letters. We will follow couples for 18 months postpartum to assess impact and cost-effectiveness of the intervention on health behaviors and health outcomes. We propose the following specific aims:

**Aim 1:** To determine the impact of a couples-focused home-based intervention on our primary outcome of couple HIV testing for pregnant women and their male partners (assessed through proportion reporting couples testing, yield of new HIV+ diagnoses of male partners, and identification of new sero-discordant couples)as compared to HIV self-test kits for couples and standard care.

**Aim 2:**To examine the impact of the intervention on HIV prevention behaviors (PrEP and condom use),facility delivery, and postnatal healthcare utilization for all participants; as well as secondary health outcomes of maternal VL suppression, and HIV-free child survival up to 18 months for couples living with HIV*;* as compared to HIV self-test kits for couples and standard care.

**Aim 3:**To compare the cost-effectiveness of the home-based couples intervention to less resource-intensive strategies of standard care and HIV self-test kits for couples. Despite its promise, a home-based intervention may require more resources and it is important to assess whether it offers greater value for money than other strategies, which may cost less but be less impactful.

**JUSTIFICATION & INNOVATION:**

Our study strategy builds upon our team's extensive formative and pilot research and innovates in multiple ways as detailed below: Firstly, it **focuses on couples**. Recent literature and WHO guidance have called for a renewed emphasis on couples to enhance PMTCT and HIV prevention efforts[84-90]and couple-focused interventions have been found to be beneficial in a range of HIV treatment and prevention programs.[91-93]Arecent meta-analysis by Crepaz and colleagues found that couples-based interventions were more effective than individual approaches for both HIV testing and nevirapine uptake.[94]However, there are few couple interventions for pregnant women and male partners in low resource settings.[95].[96]Our proposed study fills this gap by targeting expectant mothers and fathers as a couple. Distinct from existing programs like mothers2mothers[97] our intervention is conducted by a pair of lay health workers (one male and one female) who engage both partners of the couple, and promote positive relationship dynamics(e.g., communication) in the promotion of family health.

Secondly, it **makes use of a theoretical framework based on couple interdependence**. Extensive research has shown that couple relationship factors are associated with health behavior change and health outcomes.[98-101]Similar associations have been found in HIV research, where partner dynamics influence both prevention and treatment adherence.[102] Yet, couples-based theories are only just beginning to be applied to HIV-related health behavior in sub-Saharan Africa.[87].[103]Although one intervention study in Kenya found that home-based couple strategies may improve male uptake of HIV testing,[104]the proposed study would be among the first research to test an intervention based on an interdependence model of communal couple coping and behavior change[105]on PMTCT-related and maternal health outcomes.

Thirdly, it **attempts to reach beyond the clinic with home-based interventions and with HIV**

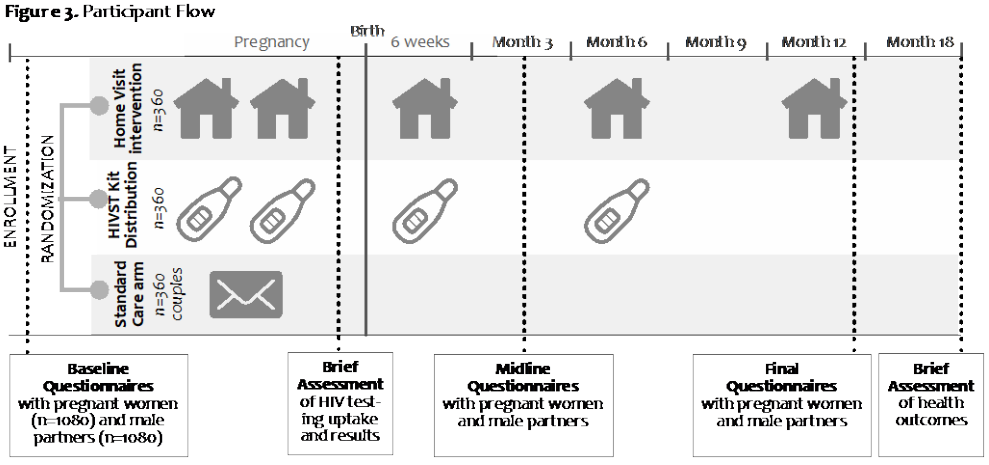
**self-testing**. Most current couples testing strategies require both partners to come to the clinic, thereby reaching only a minority of couples. Although home-based HIV counseling and testing has proven to be feasible in Kenya,[106-108]home-based strategies rarely target pregnant women and partners.[109][110]A recent study in Kenya achieved high acceptance rates for home-based HIV testing (82% of around 25,000 people), yet among couples who tested, less than half were tested together.[111]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, thereby increasing the likelihood of male involvement, and leveraging couple-level factors for positive health outcomes. We will compare our home-based intervention to one that relies on secondary distribution of HIV self-test (HIVST) kits by women to their partners, which will expand the evidence base on whether HIVST can play a useful role in PMTCT and HIV risk reduction. This will come at a time when many SSA countries are actively developing HIVST policies. Fourthly, it **integrates with MCH and family health**. Our intervention responds to the growing demand for PMTCT and HIV services to be integrated within existing Maternal and Child Health (MCH) services.[112, 113]Home visits are designed for all pregnant couples (regardless of woman's initial HIV test result at the ANC clinic) and include topics important for maternal, paternal, and child health during pregnancy and postpartum. This approach capitalizes on men's heightened concern for family health during pregnancy,[114] and is more likely to engage men than approaches that focus solely on HIV-related health.

## STUDY DESIGN/METHODOLOGY

### A. Study design

To accomplish the study aims, we will conduct a three-arm couple-randomized trial of the home-based couples intervention in 24 communities in southwestern Kenya. We will recruit pregnant women (and subsequently their male partners) from ANC clinics, collect baseline questionnaire data, and randomize those who are willing to either the home-based couple intervention (estimated n=267 couples), the HIV self-test kits intervention (n=267 couples) or the standard care arm (estimated n=267 couples). Each arm will include 178 HIV-positive women at baseline and 89 HIV-negative women at baseline. We will assess initial couples testing uptake and results with a brief phone-based assessment prior to birth and conduct follow-up assessments with both women and men at 3 and 12 months after expected infant delivery date of the infant. Midline and final questionnaires will assess primary and secondary outcomes along with potential mediators. Brief phone assessments at 6 and 18 months will ascertain the HIV status of infants and reconfirm any couples testing behaviors (Fig 3). A subset of young women at or below age 24 years (n=30) and a subset of women who have experienced intimate partner violence (n=30) will be selected to participate in in-depth qualitative interviews following birth of their infants in order to gain in-depth understanding of how these factors (young age, IPV) affect women's postnatal healthcare utilization and secondary health outcomes. These in-depth interviews will also allow for a deeper understanding of the experiences of young women and women impacted by IPV in their healthcare utilization after delivery and how the intervention may have impacted Aim 2 outcomes.

**Figure 3.** Participant Flow



## B. The setting

The area formerly known as Nyanza Province in Kenya has the highest HIV prevalence in the country, with approximately 14% of adults 15-49 years of age testing HIV-positive.[115] Maternal mortality in the region is 669 per 100,000 live births,[116] or more than four times the national target.[117]This region represents 54% of the country's new infant HIV infections and 45% of its need for PMTCT services.[118]The R34 research took place in Migori County, which borders Tanzania and Lake Victoria, where our team has worked for over a decade. We will now expand to include other high volume clinic sites in this region. This setting is 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%),[119] there are significant dropouts of women and infants along the PMTCT cascade.[120]The clinics in this setting provide integrated ANC/MCH and HIV services and are implementing the Option B+ strategy, in which all pregnant and breastfeeding women are immediately initiated on life-long ART, regardless of CD4 count or HIV disease stage.[121]

## C. Conceptual framework

We adapted the Interdependence Model of Health Behavior Change to understand mechanisms through which this intervention may impact health outcomes(Fig 1).[105]

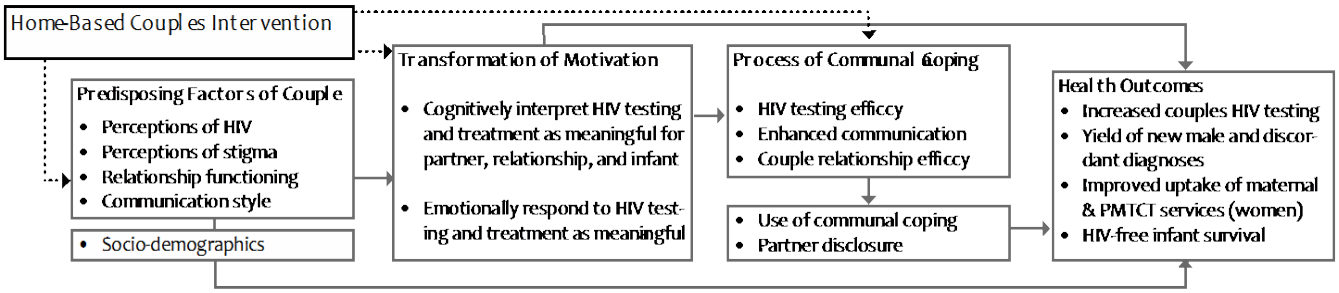



**Figure 1.** Conceptual framework for home-based couples intervention based on Interdependence Model

This model extends beyond an individually-based understanding of health behavior change (e.g., health beliefs, self-efficacy) by positing that both partners influence one another's health decisions and behaviors.[122] It hypothesizes that by shifting motivations and relationship dynamics, interventions can make lasting impacts on how couples initiate and maintain healthy behaviors:

- Predisposing characteristics of couples include both intrinsic qualities (e.g., socio-demographics 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 have adapted 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).[123]
- Transformation of motivation helps couples move from a self-centered understanding of a health issue to a relationship-centered perspective.[105] This process occurs when health issues are interpreted as having significance for the relationship or family, rather than simply for oneself.[124]We hypothesize that couple home visits by lay health workers, which aim to positively impact relationship dynamics (e.g., intimacy, satisfaction) and improved communication will facilitate a "transformation of motivation" which will make couples more likely to accept and undergo couples testing.
- The Interdependence Model suggests that communal coping can help couples make health-related decisions jointly and mutually support one another's goals around MCH, PMTCT uptake, linkage to HIV care and treatment. Communal coping 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, and working together to try new behaviors. Our pilot research suggests that the home-based couples visits aid the couple in developing efficacy to engage in key health services for maximum impact for all—including the infant.[125]

**D. The intervention:** In the Jamii Bora R34 pilot intervention, lay health workers delivered three home-based couples visits (two home visits during pregnancy; one postpartum) following enrollment of women at an ANC clinic. We will increase the number of home visits to five: 2 during pregnancy, 1 at six weeks after the birth, and two booster sessions, one at six months after the birth and one at 12 months after the birth. During the COVID-19 pandemic, the study will adopt teleconferencing to have as an option for delivering couple sessions for participants not comfortable with face-face contact, until the COVID-19 situation is under control. At each home visit, the health workers will meet with the woman and her partner together. The two booster visits will focus on repeat HIV testing, infant health messages, family planning, male health, IPV prevention, mental health, and HIV prevention. Key elements of the intervention sessions are presented in Table 1 and include:

a. **Maternal, child, and family health information**. Drawing on our team's prior experience in engaging couples in pregnancy and postpartum services,[126, 127] this component focuses on general family health promotion during the peri-natal period. This is also an opportunity for couples to ask questions about pregnancy, labor, and delivery. Lay health workers help couples develop strategies for service utilization. Specific content focuses on IPV prevention and mental health issues (e.g., depression).

**Table 1. Intervention Content at each Couple Home Visit**

| Visit # | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 |
|---|---|---|---|---|---|
| **Timing** | pregnancy | later pregnancy | 6 wks postpartum | 6 mos postpartum | 12 mos postpartum |
| **Main family health topics** | • ANC visits<br>• Nutrition<br>• Malaria<br>• Male partner support during pregnancy<br>• IPV<br>• Mental health | • Birth plan for HF delivery<br>• Danger signs<br>• Infant feeding<br>• Male partner support for birth<br>• What to expect | • Infant health visits and immunizations<br>• Family planning<br>• Male partner support after the birth<br>• Postpartum checkups | • Infant health<br>• Infant feeding<br>• Family planning<br>• Male health<br>• IPV<br>• Mental health | • Infant feeding<br>• Infant visits and immunizations<br>• Family planning |
| **HIV-related content** | • Couple HIV testing<br>• PMTCT**<br>• PrEP*<br>• Linkage to care** | • Repeat testing<br>• PMTCT**<br>• PrEP*<br>• Linkage to care** | • Infant HIV testing**<br>• PMTCT**<br>• PrEP*<br>• Linkage to care** | • Repeat testing<br>• PMTCT**<br>• PrEP*<br>• Linkage to care** | • Infant HIV testing**<br>• PMTCT**<br>• PrEP<br>• Linkage to care** |
| **Couple relationship** | Intro to couple relationship skills | Use of "I" language | Listening skills | Negotiation skills | Revisiting and practicing skills |
| **Services and Linkages offered** | • Introduction of CHTC<br>• Linkage to HIV care / PrEP | • Offer of CHTC***<br>• Linkage to HIV care/PrEP | • Offer of CHTC***<br>• Linkage to HIV care/PrEP | • Offer of CHTC***<br>• Linkage to HIV care/PrEP | • Offer of CHTC***<br>• Linkage to HIV care/PrEP |

* For discordant couples, ** For couples living with HIV, *** For those who have not done CHTC yet, or who need to repeat testing.

b. **Couple relationship skill-building.** Each visit includes couple relationship/communication content, including exercises on use of "I language", listening skills (initiator and receiver), and negotiation skills [128].

**c. Offers of Couple HIV Testing and Counseling (CHTC) services.** CHTC has been shown to increase male involvement and linkage to care in many sub-Saharan African settings.[84, 85, 129-132]The Centers for Disease Control CHTC Training Curriculum includes modules for mutual disclosure, tailored prevention, and treatment strategies for discordant and concordant couples.[133]Disclosure assistance allows a couple to discuss HIV test results and strategies in a safe and supportive setting,[134] and sessions include techniques to encourage communication between partners.[135]In our intervention, pregnant couples are encouraged to test together, even if one or both have tested individually previously, given that women often engage in CHTC to facilitate partner disclosure. Couples have the opportunity to engage in CHTC at any of the couple home visits, as we found in the pilot that some couples required time to be ready to accept CHTC and couples may need to test more than once during the longer study period.

d. **Linkage to clinic-based services**. Lay health workers actively link couples to family health and HIV prevention and treatment services (including PrEP for discordant couples) at nearby clinics.

Our team's prior research suggests that 87% of pregnant women in this region live with their male partner,[136]making home visits an optimal approach to reach couples. Recognizing that some pregnant women may live in extended family households where privacy is difficult to maintain,[137] in each community we will identify a location for couple sessions that participants may choose if privacy cannot be assured in the home. Use of lay health workers contributes to sustainability, given the lack of professional counselors in this setting.

In each of the home visits, participants shall be offered handouts containing key health messages relevant to the stage of pregnancy and encourages to read (see attached).

**E. Comparison Groups**

**HIV self-test kits to pregnant women for use together with their male partner:** In order to compare our intervention with a promising, but less resource-intensive, approach for encouraging couple and male partner testing, women in one study group will receive HIVST kits for themselves and their male partner. Trained study staff will provide4oral-fluid-basedrapid HIV test kits (OraQuickRapid HIV-1/2 Antibody Test, OraSure Technologies – approved for use in Kenya) during pregnancy and up to 4additional kits after the birth. Each test will be accompanied with an instruction sheet that describes step-by-step self-testing procedures in multiple languages. Study staff will also provide participants with a brief demonstration of how to use the tests. Participants will be encouraged to offer a test kit to their male partner or to use both test kits to undertake couples testing if they feel comfortable doing so. They will also be counseled on how to talk to their partners and the possibility of adverse partner reactions. Following Kenya's HIV testing services guidelines, participants will be instructed to seek clinic-based confirmatory testing if a reactive self-test result is obtained, and an invitation for confirmatory testing at a clinic will be included with each test. The procedures used in the HIVST group are adapted from our experience developing and testing this intervention in Kenya and have been found to be feasible and safe.[76, 77]

**Standard care:** All women in standard care are encouraged to come to the clinic with their male partner and are encouraged to undergo CHTC. Clinic staff give women who attend alone a referral letter to invite the male partner to ANC at the next visit. When couples come together to ANC, they are given priority in the line to receive services. Despite these measures, our site assessments for the current study indicate that less than 25% of pregnant women currently participate in couples testing during ANC visits.

**Rationale for the comparison groups:** The HIVST and Standard Care arms are lower-cost by design, since they do not include extensive health-related counseling and home visits. It is important to compare our home-based couples intervention with these approaches for both efficacy and cost-effectiveness, since male invitation letters are the current standard and HIVST has shown promise in boosting male partner and couples testing. This is crucial as policymakers may have a natural reluctance to adopt more expensive interventions without strong evidence that they are more effective that cheaper alternatives.

**F. Study procedures and methods**

**Start-up activities:** Using protocols and training materials developed during the R34 Study and pilot studies of HIVST kits for pregnant women in Kisumu, we will train lay health workers in informed consent processes, privacy and confidentiality, community sensitization strategies, maternal, paternal, and child health messages, CHTC protocols for couples with different sero-status combinations, information and counseling for HIV self-test kit distribution, and protocols for IPV and mental health risk assessment and support. All health workers at study health facilities will receive training on risk assessments, counseling, and referrals from protocols developed during our prior studies (See Human Subjects for details).

**Study population:** The target populations are pregnant women identified in the ANC facilities and their male partners. Marriage rates are high in Kenya, with over 85% of pregnant women identifying as currently married in our prior studies in this region.[138]The majority (87%) of women presenting for first ANC visits in Kenya are in the 2$^{nd}$ and 3$^{rd}$ trimesters of pregnancy,[139]but given importance of early initiation of ART for maternal health and PMTCT,[140] 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.

**Sample size:** Based on site assessments conducted in the summer of 2017, we had earlier conservatively estimated that each clinic will have an average of 5 eligible HIV-positive pregnant women per month (we will enroll both newly diagnosed women and known positives), for a total of 96

women from each of the 8 clinics in 24 months (n=960). By then, we were confident that we will identify the required number of HIV-negative women (n=480) in the same time period (total HIV-positive and HIV-negative N=1,440). However, we have observed fewer than 5 eligible HIV positive pregnant women in the 18 clinics we are currently operating in thus requiring us to increase the number of clinics to 24. The additional six clinics are necessary because of the lower than anticipated participant enrolment numbers due to COVID 19 pandemic and healthcare worker's strike that affected the numbers of pregnant women visiting health facilities and consequently our study accruals in the year 2020 and 2021. Using a stratified randomized design, we will recruit HIV-negative women in balanced numbers to HIV-positive women (1:2) each month, to ensure that these two groups are balanced over time. Given our experience in the R34 pilot study (which had more stringent eligibility criteria), we conservatively estimate a 75% participation rate for male partners in the study (target sample N=800 couples). If we subsequently experience as much as 17% loss-to-follow-up of couples (based on the 14% we experienced in the R34 pilot), we will still have approximately 664 couples (221 couples in each randomized group) for analysis. With a loss-to-follow-up rate as high as 20% (leaving 640 couples), we will still have strong power to detect differences in our primary couples testing outcome (Table 2).

Two groups of n=30 women each will be purposively selected from enrolled participants and invited to participate in in-depth qualitative interviews. The samples will include women who are HIV-positive or -negative and who participated in the different arms of the trial. One group will include women ≤24 years of age, and the other group will comprise women of any age who have reported IPV at any time during the trial.

**Recruitment and enrollment:** Pregnant women presenting at ANC clinics 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 study participation and for contacting her male partner. Those interested in participating but not comfortable with face- to- face contact due to COVID -19 pandemic will be asked to participate remotely via the phone after safety and privacy has been ascertained.

Postpartum women enrolled in the trial who are eligible to participate in the in-depth qualitative interviews will be contacted by a researcher and invited to participate in an interview (at least 12 months postpartum for the young women and ≤24 months postpartum for the women with IPV) at a private location at a date/place of her choosing, after going through the informed consent process described below. Interviews will be led by experienced qualitative interviewers in a local language (Luo, Kiswahili, or English) using IRB-approved interview guides developed by the research team. To contribute to the achievement of Aim 2, these interviews will explore topics that influence health behaviors and outcomes, such as reproductive health, relationships, HIV, and IPV.

**Obtaining informed consent:** A lay health worker will consent eligible women and their male partners separately. As was done in the R34 pilot study, with the woman's permission we will subsequently contact her primary male partner, arrange to meet with him in a community location, and conduct informed consent and the baseline questionnaire. For participants who wish to enroll in the study but prefer virtual/remote participation, we will conduct consenting process on the phone. The study staff shall read the consent word for word and verify the participant's understanding before obtaining verbal consent. Verbal consent shall be taken by asking the participant to repeat the participant declaration statement written in the tail end of the consent as the staff audio records. All participants choosing to be consented remotely will be informed of recording their declaration to participate and the consent form will be kept safely for signing by the participant when COVID-19 spread is brought under control. These initial sessions will also include screening for IPV based on our team's existing protocols, and all participants will receive information about available services.[141]Participants reporting severe IPV in

the past 6 months will not be included in the randomized part of the study, since participation in a couples intervention may not be appropriate for this group. All participants will be asked to provide informed consent for data abstraction from their medical records.

Women who are eligible and interested in participating in the in-depth qualitative interviews will undergo the informed consent process with study staff and sign a consent form specific to the interview.

**Randomization:** We will recruit pregnant women attending ANC clinics to participate in the study until we have achieved a sample size of 800 women (two-thirds HIV-positive at baseline) and 800 male partners. Women will complete baseline questionnaires at the ANC clinic and men will be asked to complete the questionnaire in a community location. After baseline interviews have been completed with both partners, we will randomize couples to one of the three approaches to increase couple engagement in HIV prevention and maternal and child health. Couples will receive a sealed envelope labeled with their newly assigned study ID numbers, which will contain their random assignment. If the participants are not comfortable with face-to-face contact during the COVID-19 pandemic, randomization can be carried during a joint phone call with the couple, in which case the couple will be informed of the envelope randomly picked by the study staff out of the container, and their randomly assigned study arm. Random assignments will be computer generated and will be stratified by clinic and couple HIV status. Blocked randomization with randomly permuted block sizes will be used to assure approximately equal numbers in each study arm and in each HIV status group in any given time period. Based on our prior experience in the R34 pilot study, at the end of this process we expect to have at least 267 couples (both male and female partners consented and enrolled) in each study arm (178 in which the woman is HIV-positive at baseline and 89 in which the woman is HIV-negative at baseline).

**Study arms:** After randomization, a lay health worker will obtain detailed locator information (including cell phone contacts). If they were randomized to the home visit intervention arm, the worker will consult with them about optimal times for a home visit. As described above, the intervention arm will consist of 5 home visits conducted together by one female and one male lay health worker. The HIV self-test kit arm will consist of distribution of pairs of self-test kits to women at up to 4 time points (twice during pregnancy and twice after the birth)The standard care arm will offer standard clinic-based services, including giving the pregnant woman a letter for her male partner inviting him to the clinic, and the option for women and partners to return to the clinic for male partner HIV testing or CHTC (although our past clinical experience in this setting and the results of the R34 study suggest uptake of these services is low).

**Data collection and measures:** Data will be collected from multiple sources (see below and Table 1):

- *Baseline questionnaires* with all study participants will be conducted with women and male partners through phone or in-person assessment depending on their preference during this challenging period of COVID-19. These questionnaires will assess baseline measures, including socio-demographic characteristics of both partners, couple relationship measures, and stigma. These measures, which were used successfully in the R34 pilot, will be interviewer-administered on tablets in the participant's preferred language (Swahili, Luo, or English), as per procedures piloted in the R34.
- *Brief phone-based assessment of HIV testing uptake and results will occur at 8 weeks after study enrollment (during pregnancy) and around 6 months after the birth:* All participants (women and men) will be contacted via mobile phone and asked to respond to a brief confidential survey on HIV testing (individual or couples) and results 8 weeks after study enrollment and around 6 months after the birth. This assessment will capture in more "real-time" any HIV testing behavior that occurs before the first follow-up questionnaire at 3 months after the birth, and between 3 and 12 months after the birth.
- *Follow-up questionnaires* with women and male partners will occur at 3 months after the birth (after 6-week home visit) and around 12 months after the birth (during the 4 weeks following the final 12-month home visit). Follow-up questionnaires will assess the same constructs as at baseline, as well as process and outcome measures, and be administered on tablets in the participant's preferred language during research visits or through phone by gender-matched independent interviewers.

- *Brief phone 18-month assessments* will capture infant HIV status, couples testing behavior, and viral loads.
- *Medical records*: Medical records will be abstracted to obtain objective (non self-report) data on healthcare utilization and health outcomes for all participants in the study.
- A *couple visit form* will be filled by lay health workers at each couple visit. The form will include information on topics covered, CHCT uptake and result, assessments of negative life events, including IPV (conducted with women and men individually),[142] other services provided, and process measures. This form, along with records of observations of visits by supervisors, will be used to assess intervention fidelity.
- *Qualitative interviews*: Utilizing one-to-one interviews, we will qualitatively explore experiences and perceptions of the home-based couples intervention, as well as other influences on health behaviors and outcomes of younger women and of women experiencing IPV.

**TABLE 1. Factors to be Assessed in Data Collection**

| | Factors | Study measurements | Group and timing |
|---|---|---|---|
| **PREDISPOSING FACTORS** | Socio-demographics | Age, education, literacy, ethnicity, religion, occupation | All participants at baseline and follow-ups |
| | Relationship characteristics | Marital status, type of union (monogamous/polygamous), relationship duration | |
| | Household conditions | House type, ownership of household goods, persons living in household, food insecurity, alcohol use (ref AUDIT-C) | |
| | Pregnancy & fertility | Parity, gravidity, number of living children | |
| **TRANS-FORMATION OF COUPLE MOTIVATION AND COUPLE COPING** | Couple relationship dynamics | Relationship Satisfaction[143], Dyadic Trust[144], Couple communication[145], Interpersonal closeness[146], Sexual Relationship Power Scale[147], Commitment[148] | All participants at baseline and follow-ups |
| | Disclosure | Reports of disclosure to others from both partners[149] | |
| | HIV-related couple | Male partner support for MCH specific, social support[150], Couple communal coping[151], Network of Relationships Social Provision Scale (ref) | |
| **OTHER POTENTIAL MODERATORS AND MEDIATORS** | Pregnancy intendedness | One item measure of the intendedness of the current pregnancy[152] | All participants at baseline and follow-ups |
| | Perceptions of stigma | Anticipated stigma and perceived community HIV-related stigma scales[153, 154] | |
| | Stigma experience | Anticipated, enacted, and internalized HIV-related stigma[155] | HIV-positive participant |
| | IPV | Dyadic version of WHO intimate partner violence measure[156] | All participants at baseline and follow-ups |
| | HIV treatment beliefs | Adaptation of the Beliefs about Medications Questionnaire[157] | |
| | Depression | PHQ-8[158] | |
| | Anxiety | GAD-7[159] | |
| **COUPLE HIV TESTING (PRIMARY OUTCOME)** | Couple HIV testing | Couples HIV testing uptake during observation period (Y/N)* | All participants at follow-ups |
| | HIV re-testing | Re-testing for HIV during pregnancy and postpartum * | |
| | New male HIV+ tests | Number of new HIV+ test results of male partners* | |
| | Discordant couples | Number of new serodiscordant couples identified | |
| **HEALTH CARE UTILIZATION** | PMTCT practices | Mother's use of ARVs for PMTCT *, Prophylactic ARVs for the infant *, infant feeding practices | HIV-positive women at follow-ups |
| | Use of MCH services | Number of ANC visits*, Childbirth with a skilled attendant (Y/N), Postnatal check-ups* | All participants at follow-ups |
| | PREP uptake | Initiation of PrEP | Discordant partners at follow-ups |
| | Woman's HIV care linkage and engagement | Time to linkage in HIV care,*Enrollment in HIV care (Y/N),*Self-reported ART adherence, [160] Number of HIV visits* | HIV-positive women at baseline and follow-ups |
| | Man's HIV care linkage | Time to linkage in HIV care,* Enrollment in HIV care (Y/N),* Self-reported ART adherence, [160] Number of HIV visits* | HIV-positive men at baseline and follow-ups |
| | Infant HIV testing | Date and result of infant HIV test * | Parents of HIV-exposed infants at follow-ups |
| **PROCESS MEASURES** | Intervention content | Topics covered, services delivered, referrals made during couple visits | All intervention participants at follow- |

| | | | |
|---|---|---|---|
| | Participation | Number of couple home visits completed, number of HIV self-tests received/used | ups |
| | Social consequences | Positive and Negative Life Events measures[142] | |
| | Acceptability | Satisfaction with intervention components, intervention content, and mode of delivery, attitudes toward PrEP and HIV self-testing | |
| **SECONDARY HEALTH OUTCOMES** | Viral suppression | Viral Load < 200 copies (undetectable)* | All HIV-positive participants at baseline and follow-ups |
| | HIV-free child survival | Child alive and HIV-free at 18 months after the birth* | |

* Measures to be confirmed through medical records

**Inclusion/exclusion criteria**

Our inclusion criteria are: (a) women at 36 weeks of pregnancy or less (b) 15 years of age or older (c) has been offered HIV testing at ANC, (d) is currently in a stable relationship with a male partner and living with that male partner, (e) has not yet participated in couple HIV testing during this pregnancy, and (f) not in an HIV-positive concordant relationship Male partners are the person identified by the pregnant woman as her primary male partner and should also be 15 years of age or older.

## STATISTICAL/ANALYSIS PLAN

**Sample size and power calculations**

The couple testing uptake outcome (primary outcome) will be assessed including both HIV-positive and HIV-negative women/couples. All three arms will be compared with each other (3 comparisons), so our Type I error rate is 0.05/3 = 0.017 (two-sided). With three repeated measurements (baseline, 3 months, and 12 months) and compound symmetry covariance structure, correlation between the observations on the same subject was assumed to be 0.50. With N=300 couples in each arm, our study will have >80% power to detect statistically significant differences in couple testing uptake of 30-40% either intervention arm and 23% in the control arm (Table 2). We conservatively used rates that are lower than proportions observed in the R34 study and studies of HIVST kits with pregnant women. The secondary outcomes are HIV-free child survival at 18 months and maternal viral load suppression at 18 months. HIV-free child survival up to 18 months will be assessed only in HIV-positive women with live births, with approximately N=200 in each arm. Based on prior estimates from sub-Saharan Africa,[161, 162] we expect proportions≥90% of HIV-free survivors in each arm. As there would be 2 comparisons (each intervention arm versus the control arm), we set our Type I error rate to 0.05/2 =0.025 (two-sided) when calculating power. If Arm 3 has a survival rate of 91%, the study will have power > 80% when Arms 1 and 2 have survival rates of 98% or higher. The other secondary outcome of maternal viral load suppression at 18 months will be assessed only in HIV-positive women with around N=200 in each arm. From Table 2, if Arm 3 has a maternal viral load suppression rate of 85%, the study will have power > 80% when Arms 1 and 2 have maternal viral load suppression rates of 95% or higher. We used PASS software for these calculations (NCSS, version 11).

**Table 2. Statistical Power for Comparison of Outcomes Among Study Arms**

| | | | | |
|---|---|---|---|---|
| **Couple Testing Uptake** (assuming 23% uptake in the standard care arm (Arm 3) | | | | |
| Proportion (%) of CHTC uptake in Arm 1 or 2 | 31 | 33 | 35 | 37 |
| Corresponding Odds ratio (ref=Arm3) | 1.50 | 1.65 | 1.80 | 1.97 |
| Power (%) to detect a sig. difference among Arms at 0.017 level, auto-correlation (rho)=0.50 | 63 | 84 | 95 | 99 |
| Power (%) to detect a sig, difference among Arms at 0.017 level, auto-correlation (rho)=0.10 | 87 | 97 | 100 | 100 |
| **HIV-free Child Survival at 18 months** (assuming 91% survival in Arm 3) | | | | |
| Proportion (%)HIV-free survival in Arm 1 or 2 | 93 | 95 | 97 | 99 |
| Corresponding Odds ratio (ref=Arm3) | 1.31 | 1.88 | 3.20 | 9.79 |
| Power (%) to detect a sig, difference among Arms at 0.025 level | 7 | 1.A.1.a. | 62 | 93 |
| **Maternal VL suppression at 18 mos**(assuming VL suppression of 85% in Arm 3) | | | | |
| Proportion (%) of VL suppression in Arm 1 or 2 | 90 | 92 | 94 | 96 |
| Corresponding Odds ratio (ref=Arm3) | 1.59 | 2.03 | 2.77 | 4.24 |
| Power (%) to detect a sig, difference among Arms at 0.025 level | 24 | 49 | 77 | 94 |

**Data analysis**

**Primary analyses to address Aim 1**: We will use all longitudinal measures of couple testing in a marginal model to compare rates among the three study arms. We will use a marginal modeling approach because our primary interest is to estimate the population-average effect of intervention participation on each outcome rather than the effect for a hypothetical average subject or couple.

Moreover, within-subject and within-couple correlations among outcomes are nuisance parameters, not quantities of interest to be modeled explicitly. Our models will include a dummy variable indicating study group (Arm 1 vs Arm 3; Arm 2 vs Arm 3), as well our stratifying variables and other additional covariates such as couple relationship length, if necessary. Little adjustment for confounding should be necessary due to our randomization. We will employ robust standard errors to obtain correct inferences because inference will be valid if the chosen correlation structure is slightly misspecified.[163] Statistical significance will be for $p<0.017$ for the three pairwise comparisons of the three arms to account for multiple comparisons. Between-arm differences for the other outcomes in Aim 1 (mean numbers of new HIV+ diagnoses of male partners and new sero-discordant couples) will be modelled with GEE.

**Primary analyses to address Aim 2**:Each of the outcomes examined in Aim 2, including rates of HIV prevention behaviors (PrEP and/or condom use), facility delivery, postnatal healthcare utilization, maternal VL suppression, and HIV-free infant survival up to 18 months, is binary (yes/no). Between-arm comparisons for the probabilities of these outcomes are facilitated with the same GEE models described for Aim 1.

**Supplementary mediation analyses for Aims 1 and 2:**Our assessment for potential mediation and moderation will follow the approach described by Valeri and Vanderweele.[164] We will refer to the treatment effect estimates from these models as Estimates A. We will then fit a second model, which takes our original GEE model and incorporates possible mediating variables, such as couple relationship dynamics and social consequences. We will refer to the parameter estimates for these three covariates as Estimates B. We will then determine the direct and indirect effects of the treatment on each of the outcomes in Aims 1 and 2, with corresponding standard error estimates determined using bootstrap methods as described by Whittle, etal.[165] These models can also be adjusted for any potential confounders that are discovered, although we expect the randomization to account for a majority of any potential confounding.

**TABLE 3. AIM 2 QUALITATIVE INTERVIEW TOPICS**

| Theme | Topics |
|---|---|
| **Contraceptive Use** | (1) Knowledge and use of contraceptives before current pregnancy and postpartum |
| **Male partner support** | (2) Support and dependability of male partner for maternal and child health |
| **Health Care Utilization** | (3) Barriers to utilization of health care services for pregnant women and partners |
| **Interventions** | (4) perceptions of the home visits for couples and the HIVST kit interventions |
| **IPV** | (5) Perceptions of change in violence and the role of pregnancy and HIV in IPV |
| **HIV Care and Treatment** | (6) Perceptions of change in HIV care and treatment over pregnancy and postpartum |

**Supplementary dyadic analyses for Aims 1 and 2**: Analyses with intact dyads enable investigation of couple-based research questions of how relationship dynamics affect behavior change in partnerships. For example, we might investigate whether one's own relationship satisfaction or one's partner's relationship satisfaction is more associated with couple testing uptake. To that end, we will extend the analyses described above to include actor and partner effects for covariates and mediators. *Actor effects* describe the influence that one's standing on independent or mediating variables of interest (e.g., communication, intimacy) has on one's own dependent variables (e.g., virologic control) whereas *partner effects* describe the influence that one's standing on independent variables has on the dependent variables of one's partner (e.g., partner's virologic control). This technique illuminates the effects that partners in intimate relationships can have on both their and their partner's behavior. In order to fit an actor-partner interdependence model (APIM)[166] to our data, we will change our GEE model to a random-effects model so that we can include a random effect for each couple, that will allow us to divide the variation in outcomes into within- and between-couple effects. Auto-regressive errors will be assumed for the longitudinal measures.

Qualitative data will be analyzed to elucidate themes and lessons to further inform our quantitative analysis (Table 3). Interviews will be audio-recorded and transcribed, translated (if necessary), and then coded and analyzed using a thematic analysis approach.

**Accounting for potential missing data.** We will also investigate and address incomplete data issues in our sample. Missing data within and between each wave of measurement should be minimal due to our careful interviewer training and cohort retention. However, intermittent missing responses are inevitable and some participants will be lost to follow-up. Our GEE models for Aims 1 and 2 make the assumption that missing data occur completely at random (MCAR). We will use univariate analyses such as chi-square and t-tests to assess whether individuals with complete data for any given analysis are different from those with incomplete data. These analyses will be extended to explore differential attrition by intervention group membership using logistic regression or analysis of variance (ANOVA) models. If our assumption of MCAR appears questionable, we will model the missingness pattern with logistic regression to estimate the probability of each subject's data is missing, conditional on their observed data. We can use these weights in an inverse-probability weighted GEE model and compare the results to those produced from models using only the observed data.

**Sex as a biological variable.** This study includes both men and women all analyses described above will be run separately by sex assigned at birth, with the exception of the dyadic analyses, which build in participant sex intrinsically, since we will use APIMs for distinguishable dyads distinguished by gender.

**Cost-Effectiveness Analysis for Aim 3:** We will assess the cost-effectiveness of the home-based couples intervention compared to two less resource-intensive strategies of HIVST kits and standard care. We hypothesize that this community-based intervention will prove to be a cost-effective strategy compared to the alternative strategies. However, cost-effectiveness might be sensitive to the intensity of services provided, levels of compensation, extent of training, levels of adherence to ART treatment, and other attributes. We will develop a decision analysis model using Tree Age Pro 2017 software (Williamstown, MA, USA). We will use data on costs, changes in HIV status, and mortality to provide inputs into a modified Markov model allowing for both transitions between health states and the occurrence of transient adverse health outcomes. Markov models are among the most frequently used modeling techniques in clinical decision analysis and health-economic evaluation, and are particularly helpful when a decision analysis involves the analysis of risk over long periods of time.[167, 168] The modification we propose will be a state transition model. State transition models combine Markov health state transitions with the probability that individual will experience transient events that lead to either a different health state (e.g. HIV transmission) or that can carry significant costs or mortality risk, such as hospitalization for an opportunistic infection. State-transition models have been utilized in many different populations and diseases, including diabetes, cardiovascular disease, HIV and malaria.[169-171]

The final integrated decision model will consist of two parts. In the first part, a couple consisting of a pregnant woman in antenatal care and her male partner, will be assigned to an arm of the decision model (couple home visits, HIV self-test kits, standard of care). The probabilities of health state transitions (e.g. changes in HIV status, viral load suppression, death) and adverse events will differ based on the assigned arm of the decision model. Each woman and male partner enters the model as HIV-negative or HIV-positive. Once a participant enters a new health state (HIV transmission), they remain in that health state until suffering a next event (HIV transmission of a partner or death). In the second part of the model, infant's transition states are considered (HIV-positive, HIV-negative, died). These two parts will then be integrated into one overall model.

**Cost-effectiveness analytical plan:** In our analysis, we will follow The WHO Guide to Cost-Effectiveness Analysis for the conduct of CEA that is most applicable to developing countries.[172] To determine the cost-effectiveness of the intervention, we will calculate ***incremental cost-effectiveness ratios (ICERs)*** for the intervention versus each comparator (standard of care; distribution of HIV self-test kits). The numerator of the ratio is the difference in costs expressed in US (purchasing parity adjusted) Dollars; the denominator is the difference in effectiveness.[172, 173] A 10-year time horizon

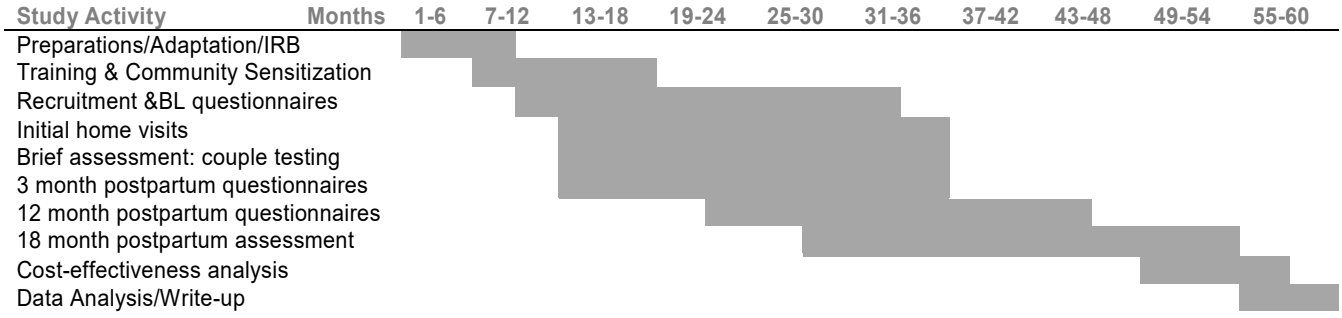
will be used because an extrapolation beyond this would be associated with substantial increases in uncertainty as to future developments in HIV prevention and treatment, as well as the lasting effectiveness of the intervention. ICERs will be compared to the gross domestic product (GDP) as per WHO recommendations to derive the following three categories of cost-effectiveness: highly cost-effective (less than GDP per capita), cost-effective (between one and three times GDP per capita), and not cost-effective (more than three times GDP per capita).

Following WHO Guide[172, 174], ***the effectiveness*** of the intervention will be assessed using the Disability Adjusted Life Year (DALY) as the unit of effectiveness. One DALY represents a year of healthy life lost due to death or disability.[175] We will calculate the DALY as the sum of the years of life lost (YLL) and the years lost due to disability (YLD) that would be saved for each HIV infection averted by study arm based on estimates and disability weights from the Global Burden of Disease (GBD).[176]

We will calculate the direct ***costs*** of each strategy utilizing established guidelines for costing HIV interventions[177, 178] from a program perspective using micro-cost techniques. Cost estimation will involve a uniform cost data collection protocol at each study site. We will conduct observations and interviews with purposively selected sample of health care providers, study and assistant study coordinators, finance and administration officers, to identify program activities on which resources were spent. Expenditures will be classified in one of four categories; (i) personnel (including fringe benefits); (ii) recurring supplies and services; (iii) durable equipment; and (iv) facility space. The costs of the program will be identified through interviews with administrative, finance and human resources officers, supplemented by direct observation in a limited number of formal “time and motion” studies. Costs for equipment and facility space (likely a small portion of total costs) will be amortized on a straight-line basis over their expected useful life assuming no salvage value. Other costs considered include laboratory, medication, and healthcare costs. We will account for costs related to increased use of PrEP, HIV or pregnancy-related services. Research costs (e.g. costs related to consenting and research-participation), any medical costs incurred offsite, or higher-level program costs incurred by the county/national government or donors will be excluded from the programmatic costs. Costs and DALYs will be discounted at a 3% rate.[172]

A key element of cost-effectiveness analysis involves properly accounting for the uncertainty associated with the ICER. Such ratios are estimates based on a sample of individuals. They are subject to sampling error, and performing the same trial over and over would lead to different estimates of the ratio. A variety of ***sensitivity analyses*** will be used to assess the performance of our state transition models.[172] One-way sensitivity analyses will be used to determine which model parameters are most important in determining whether the intervention can be considered cost-effective. Some anticipated parameters include certain clinical practice situations such as decreased testing, initiation, adherence and retention into care, and varying costs of inputs, particularly for the antiretrovirals. Markov Chain Monte Carlo probabilistic sensitivity analyses simulations will then be used to test the robustness of the model findings to uncertainty in the parameter inputs.

## TIME FRAME



Aim 1 of this study is to determine the impact of a couples-focused home-based intervention on our primary outcome of couple HIV testing for pregnant women and their male partners as compared to HIV self-test kits for couples and standard care. There is a need to understand how COVID-19 has influenced the Jamii Bora study, participating health facilities, and the study participants. There is also a lack of data on how the new coronavirus has affected research teams and studies, both in their perceptions of the pandemic and its potential effects on participants' health and accessing resources. We propose a standard of care health facility assessment, to assess the impact of the COVID-19 outbreak on standard care related to the HIV testing and counseling services for pregnant women and male partners, and compare this to service provision in the pre-COVID-19 period. Data will be collected for the period January to when the COVID-19 curve in Kenya starts to flatten. These data will be collected from registers and electronic medical records from the eighteen health facility sites in Kisumu and Migori counties. Additionally, we will survey our study staff and staff from other HIV prevention and treatment studies in the region to further understand the effects of COVID-19 on participants as well as staff to help the studies construct a positive response to the epidemic.

## COVID-19 RESTRICTIONS

To protect study participants, their families and research staff from the risk and spread of COVID-19, the study will adhere to all Ministry of Health directives and well as SERU guidelines aimed at mitigating the spread of COVID-19. We will inform research participants of requirements to undergo COVID-19 screening and reporting of screening results to the local public health authorities whenever the results may point at a possible infection with the disease, for their benefit. We will also provide participants and staff with 3 ply face masks, avail hand washing stations at the study sites, and provide sanitizers. We will pre-screen participants before physical contact, check temperature and observe social distancing requirement of 1.5 meters during face-to -face interaction with participants. Pens used for consenting will be disinfected before and after individual use. We will inform the participants of the measures that we will be taking during any form of face-to-face contact and unconditionally will respect their preferences in terms of in-person versus remote study visits. We will also have daily mandatory screening for staff who are making contact with participants and only those without any COVID-19 symptoms will be allowed to make contact with participants. The staff will also disinfect furniture and sanitize their hands after every contact with a participant.

## ETHICAL CONSIDERATIONS

This protocol will be reviewed by the Institutional Review Boards (IRB) of the University of Alabama at Birmingham and the University of Michigan, Ann Arbor. In Kenya, the protocols will be reviewed by KEMRI Scientific and Ethics Review Unit (SERU) (FWA# 00002066). We will ensure that all procedures conform to US, Kenyan, and international ethical standards regarding research involving human subjects.

The proposed research will be conducted in collaboration with investigators of the Kenya Medical Research Institute (KEMRI), county Ministry of Health (MoH) teams and clinics (see letters of support),and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) partners in counties in the former Nyanza Province in southwestern Kenya. Our team already has long-standing positive relationships with the local MoH teams and the study communities. Our intervention strategy takes advantage of the extensive existing infrastructure of these partners and is a direct response to needs identified by MoH and local clients and staff in the Nyanza Region. We have developed our research strategy after extensive consultations with MoH county teams and other local partners. Prior to our pilot study for this intervention, we conducted a series of meetings with the leadership and program staff to obtain their input and guidance as to the best methods for delivering a couples intervention for pregnant women and their male partners, and how such an intervention could best be incorporated into existing support of these health facilities. Before beginning the proposed study, we will also consult with local health workers, community leaders, and representatives of community groups (including HIV clinic

patient groups) in all study communities. We have purposely selected communities with active Community Units for participation in this study in order to assure close consultation with the local communities. The proposed research builds on our findings and our experience protecting human subjects in our other studies conducted in rural Nyanza and other relevant settings, including the "A Home-Based Couples Intervention to Enhance PMTCT and Family Health in Kenya" study, in which we developed and piloted the intervention to be tested in the currently proposed R01 study (R34MH102103, PI: Turan), the Maternity in Migori and AIDS Stigma (MAMAS) Study (NIMH 5K01MH81777, PI: Turan) and the Gender-Based Violence (GBV) Study (UCSF Center for AIDS Research, PI: Turan), Couples in Context: An RCT of a couples-based HIV prevention intervention (NIMH R01 MH086346, PI: Darbes), A randomized trial to prevent HIV among gay couples (NIMH R01 MH110280, M-PI: Darbes), Self-testing study (Bill and Melinda Gates Foundation grant number OPP1069673, PI: Thirumurthy) as well as during the ongoing "Maximizing adherence /retention for women /infants in the context of Option B+, Kenya" (MOTIVATE) Study (R01HD080477, PI: Turan/Abuogi). There will be a series of individual assessment interviews and intervention sessions as detailed in the narrative of the proposal. Below, we detail our plans for the inclusion and protection of human subjects.

**Potential Risks to the Subjects:**

*Human Subjects Involved:* A total of 1600 individuals (800 couples) will be recruited to participate in this research study (800 female and 800 male partners). Pregnant female participants will be recruited from antenatal care (ANC) clinics. We will ask all women attending ANC clinics to participate in the study until we have achieved a sample size of 800 women (two-thirds HIV-positive at baseline) and 800 male partners who agree to participate in the study. After baseline questionnaires are completed, we will randomize couples to one of three approaches for helping to increase couple engagement in maternal and child health. Participants will receive a sealed envelope labeled with their newly assigned study ID numbers, which will contain their random assignment. Random assignments will be computer generated and will be stratified by clinic and the woman's HIV status to assure approximately equal numbers of couples in each study arm and in each HIV status group in any given time period. We expect to enroll around 267 couples in each study arm (178 in which the woman is HIV-positive at baseline and 89 in which the woman is HIV-negative at baseline).

This study will thus involve recruitment of HIV-positive and HIV-negative or unknown HIV status pregnant women at ANC clinics and their male partners, baseline questionnaires, randomization of couples to one of the two interventions (home-based couples intervention or HIV self-testing for couples) or standard care arms of the study, and participation in home or clinic visits or HIV self-testing according to study arm. Follow-up questionnaires will be conducted with women and male partners at 3 months and 12 months after the expected due date (EDD) of the infant. In addition, brief mobile phone assessments of uptake of HIV testing and results will be conducted during late pregnancy and at 6 months after the birth, and a brief phone assessment of maternal and infant health outcomes will be conducted at 18 months after the birth.

For AIM 2 qualitative interviews with two groups of n=30 women each, a subset of young women and a subset of women with IPV will participate in a brief one-on-one interview during the postpartum period.

*Criteria for inclusion or exclusion:* The initial target populations are pregnant women identified in the ANC clinics in the Nyanza Region of Kenya and their male partners. The vast majority (87%) of women presenting for first ANC visits in Kenya are in the 2$^{nd}$ and 3$^{rd}$ trimesters of pregnancy, but given the importance of early initiation of ART for maternal health and PMTCT, 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) 15 years of age or older (b) has been offered HIV testing at ANC, (c) is currently in a stable relationship with a male partner and living with that male partner, (d) has not yet participated in couple HIV testing during this pregnancy, and (e) not in an HIV-positive concordant relationship. Male partners are the person identified by the pregnant woman

as her primary male partner and should also be 15 years of age or older. More details regarding inclusion of persons younger than 18 years is included in the Inclusion of Children attachment.

For the qualitative interviews with young women, the inclusion criteria are: (a) 15-24 years of age (b) at least 12 months postpartum (c) willingness/ability to give informed consent. For the qualitative interviews with women who have experienced IPV, the inclusion criteria are: (a) experience of IPV during the recent pregnancy and/or postpartum (b) ≤24 months postpartum (c) willingness/ability to give informed consent.

*Collaborating sites where human subjects' research will be performed and role of sites in performing proposed research:* The University of Alabama at Birmingham (UAB)will serve as the lead institution and overall Coordinating Center for this project and is the home institution of one of the M-Principal Investigators (Turan). UAB, along with the University of Michigan (home institution of M-PI Darbes) will oversee the overall study design, development of the intervention protocol, development of assessment materials, reports, data management and analysis, and relationship with the funding agencies. KEMRI will be the implementation site of the project in Kenya. Other institutions (University of Pennsylvania, University of Witwatersrand) are home institutions of Co-Investigators. All investigators will participate in the study design, protocol development, instrument design, quality assurance, data analysis, and production of manuscripts and presentation of findings from the study.

**Sources of materials**

*Research material:* Research data will be collected from the participants via individual questionnaires for research purposes only, administered in private settings. Questionnaires will be administered by a trained interviewer, and will pertain to demographic characteristics, ANC, HIV prevention and treatment behavior, and relationship dynamics. Questionnaire data will be collected via a tablet computer technology, which was used in our prior work in this site. The UAB server to which the data is uploaded is secure, and neither identifying information nor actual survey data are stored on the tablets themselves—it is uploaded at the end of each day, following completion of the questionnaires. All individuals will be given a confidential study identification number and all data will be labeled only with this identification number. There will only be one master list linking participants' names and study identification numbers. We will keep this list separate from all other materials in a locked file in a locked office at the KEMRI study site. We will keep a back-up file of this list on a password protected computer file, and select KEMRI study staff (site PI, Study Coordinators, and Interviewers) will have access. Access will be necessary by KEMRI staff for tracking purposes. Digital audio files from the couples' counseling sessions (again for QA purposes only) will be kept in a password protected, encrypted computer file. Some participants will undergo testing for HIV, either as individuals or in a couples-based session (CHTC). The testing will either be done at their home by counselors, or self-administered using HIV self-test (HIVST) kits. All counselors that conduct HIV testing will be certified test counselors, who are separate from interviewers, who have received specific training in couples-based HIV counseling and testing, in addition to individual-level testing.

*Potential Risks:*

The potential risks to participants are detailed as follows:

- Some participants may be uncomfortable answering questions about their relationships, their health, and/or their medical conditions, including pertaining to HIV: all information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected participation of the respondent, such that the respondent is aware of the nature of the questions to be included in the surveys. Respondents will complete their questionnaires separately from their partner, such that individuals will not be aware of their partner's responses. Informed consent documents will inform research participants of this, and the need to keep answers to questions confidential. Participants will have the option to refuse to answer or skip any questions on the questionnaires that they are uncomfortable answering.
- Some participants may be uncomfortable talking with their partner or a counselor about their medical conditions or history, pregnancy, or may feel uneasy about having HIV testing done. Each of the study counselors will be trained, and have experience, in the provision of individual

HIV testing and counseling (HTC) and couples HIV Testing and Counseling (CHTC), and thus will have experience in answering research participants concerns about HIV testing, comprehending the HIV testing process, and concerns around discussing HIV with a partner or counselor. At each study site we will follow existing protocols for HIV testing, which include establishing the client's willingness, readiness and comprehension of the HIV testing process.

- For participants who provide their name and address or other personally identifying information to study personnel, there is a risk that these data could be unintentionally disclosed to someone not authorized to access the data, compromising the confidentiality of the participant. In particular, women and men might face serious social risks (disruption of family, discrimination, and/or physical harm) if their HIV status were to be disclosed without their consent. These risks could be posed if questionnaires are not conducted with the utmost attention to confidentiality, or if home or clinic visits, or HIVST kit distribution are conducted in a way that results in inadvertent disclosure of HIV status to community members. To reduce this risk, all staff will be carefully trained in confidentiality and contact information for the study participants will be kept in a password protected location, with access restricted to authorized study staff.
- Participants who learn that they are HIV-positive may be distressed to learn of their health condition. This poses the greatest emotional and physical risk to participants in the research study. The informed consent documents will outline the HIV testing process, stating that results will be delivered the same day, and will explain in full what a positive, negative or indeterminate HIV test result mean. The counselor will assess the individual's readiness to receive both the HIV test and the result, following standard HIV testing guidelines. The study counselors (Study Arm 1),as well as clinic-based healthcare providers (standard care, Study Arm 3),are experienced in the delivery of HIV test results, and will follow standard clinic guidelines for results delivery. Individuals (or couples) receiving positive HIV test results will be provided with counseling, confirmatory testing, linkage to health workers at the nearest government health facility, and referrals to HIV care. All those receiving a positive result will be given referrals to the free HIV services at the nearest health facility and linked directly to a clinic outreach worker who can assist them in finding appropriate care. In our R34 pilot study, all participants testing HIV-positive in the context of the home-based couples intervention were successfully linked to HIV care. Those who receive HIV-positive results from an HIVST kit (Study Arm 2) will have received detailed information when receiving the kits about how and where to obtain counseling and confirmatory testing, as well as specific referrals for free HIV care and treatment services at the nearest government health facility.
- It is also possible that having a discussion about relationship dynamics, pregnancy, and/or HIV with a participant's partner might lead to subsequent conflict, or even violence, within their relationship. To ameliorate this risk, we propose to screen out those with a history of recent (in the past 6 months) severe intimate partner violence (IPV) in the relationship. It is possible that new, incident, episodes of IPV may occur in the course of the study. This will be recorded through questionnaires on the surveys at each study visit. Counselors will be trained to assess the severity of the violence, in order to determine the level of response necessary. Detailed protocols from our prior studies, including the R34 pilot of this home-based couples intervention in Kenya, have been developed in order to appropriately provide assessment, services, and referrals as needed. Individuals reporting IPV will be provided with referrals to locally appropriate services, per the standard protocols for the handling of IPV at each of the study sites. Individuals reporting IPV will be offered the opportunity to also meet individually with the study counselor, and will be provided with referrals to local services.
- Similarly, individuals may test positive for HIV at a follow-up visit, and this may be the result of a previously undisclosed outside sexual partner. For couples in the baseline visit, if one tests positive for HIV and one tests negative, the standard protocol for a CHTC session is to describe to the couple how this may have occurred – through a contact prior to the relationship, or through contact outside of the relationship – to remind the couple that we cannot identify from where the infection came, and to focus the counseling session on future risk reduction efforts and communal coping. Counselors are trained on blame diffusion techniques. For follow-up sessions, the protocol may vary slightly. Incident positives identified during follow-up may still have been infected from either their main partner or an outside partner. In the case of an

incident positive, the counselor will describe the possible routes of infection to the couple (from the main or an outside partner) and will focus on developing a risk reduction plan for the couple that is future focused. In the CHTC training, which all counselors have received, emphasis is placed on key skills of blame reduction, tension and anger diffusion, and on keeping the session focused on future prevention efforts.

- There is also a risk that one member of the couple may feel coerced into participating in the activities. In our previous RCT of CHTC in South Africa we included a question on whether the subject felt coerced into the enrollment and screening documents: approximately 10% reported feeling coerced. Given this, we will adopt a similar process and will include a question on coercion in the enrollment documents: any couples in which one member reports feeling coerced will be offered individual VCT, per standard clinic guidelines, and will not be randomized.
- Although not a risk caused by the trial, a potential ethical issue that arises is the counselor or study staff learning that one member of a couple is having risky sex outside the relationship, and not disclosing this risk to their main partner. The issue of disclosure of sex risk outside the relationship is difficult. If we inform participants in the consent process that information about sex outside the relationship would be disclosed to an unknowing partner, then we will likely reduce truthful reporting and bias against consent by the participants who are in most need of intervention. However, we also appreciate an ethical imperative to protect our study participants. We suggest the following compromise, which is now used in the provision on CHTC in clinical settings. First, all couples will have a session with a counselor, which will provide a supportive and protective environment in which to disclose such risk from sex outside the relationship. Second, all couples will be counseled in their initial session about the benefits of using condoms, and condoms are provided at the study health facilities at no cost to the participants. Third, if we identify a situation in which outside sex partners are reported, but not disclosed in the couple's discussion with the counselor, and either partner reports unprotected sex in the primary relationship, we will make a referral to the health workers present at each study site, which will be provided at no cost to the participants.
- Physical risks of the actual HIV testing are minimal. The test only requires the participant provide a blood via a finger prick.
- *Risks related to couple home visits that include offer of CHTC:* Due to the potential risks of HIV status disclosure 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 as a result of HIV status disclosure. Our own formative research[69], preliminary results of our couple home-visiting R34 pilot study, and other research in similar settings[110] suggests that home-based couple visits can be conducted in a safe and acceptable manner in rural East Africa.
- *Risks related to HIVST distribution to pregnant woman for use together with their male partner:* There are potential risks of adverse social consequences related to women offering HIVST kits to their male partners. Drs. Thirumurthy (Co-Investigator) and Agot (Consultant) conducted a cohort study of distribution of HIV self-test kits to HIV-negative women at ANC and postpartum clinics in Kisumu, (Bill and Melinda Gates Foundation grant number OPP1069673, PI: Thirumurthy). Pregnant/postpartum women were instructed on use of oral fluid based rapid HIV tests and received three self-tests. Structured interviews were conducted with participants at enrolment and over 3 months to determine how self-tests were used. Most participants with primary sexual partners distributed self-tests to partners: 53 (91%) of 58participants in antenatal care and 91 (86%) of 106 in post-partum care. Among self-tests distributed to and used by primary sexual partners of participants, women reported that couples testing occurred in 27 (51%) of 53 in antenatal care and 62 (68%) of 91 from post-partum care. In this study, two postpartum participants reported intimate partner violence as a result of self-test distribution. No other adverse events were reported. In a subsequent randomized controlled trial of HIV self-test

kit distribution with antenatal and postpartum women in Kisumu, the researchers found that this strategy was successful in promoting both partner testing and couple testing. Among570 participants analyzed, partner HIV testing was more likely in the HIVST group (90.8%,258/284) than the comparison group (51.7%, 148/286; difference = 39.1%, 95% CI 32.4%to 45.8%, p <0.001). Couples testing was also more likely in the HIVST group than the comparison group (75.4% versus 33.2%, difference = 42.1%, 95% CI 34.7% to 49.6%, p <0.001). No participants reported intimate partner violence due to HIV testing in this study.

- Risk related to the new Corona Virus Disease (COVID-19): COVID-19 is primarily transmitted from person to person, among those who are in close contact through respiratory droplets. Transmission can occur by direct contact with infected persons, or by contact with contaminated objects and surfaces. There are potential risks of exposure and contracting the disease to participants during movement from their home to the facility or any other location they choose to meet with study staff for participation in the study. They may interact with other people whose COVID-19 status is unknown and potentially may be exposed or contract the disease in the process. Additionally, there is risk of disclosure of participants' information to the Ministry of Health designated officials in the event that the study learns that a participant is potentially infected with COVID-19 for purposes of treatment. Participants will be informed during consenting of potential disclosure to health officials if they have COVID-19.The study will provide 3ply face masks, handwashing facilities, and sanitizers to participants and will observe Ministry of Health directives during all interactions with participants, in order to mitigate the potential for infection as much as possible.

**Adequacy of Protection against Risks:**

Any risks to subjects that stem from participation in assessments or intervention activities will be minimized by: 1) training of staff in the ethical conduct of research 2) training of staff in issues specifically pertaining to couples in this setting (e.g., potential for coercion for women participating, potential for partner violence) 3) close monitoring of any adverse events with appropriate IRB reporting and 4) referral to professionals or community agencies with mental health training or other appropriate services, when necessary. For those participants who engage in HIV testing during a couple home visit (Study Arm 1) or at the clinic (standard care, Study Arm 3)a separate consent procedure will be conducted for HIV testing, and all procedures will be conducted by trained HIV testing counselors.

In the case of any adverse event, including episodes of partner violence, we will have an established protocol describing our response to these events. These procedures will include having back-up systems in place for staff and possible referrals in the event of after-hours or weekend events. Our back up system will include the use of cell phones or pagers and designated staff that can directly assess the severity of the situation and determine a plan of response (e.g., immediate medical or psychological attention, referral to community-based services). All procedures will be documented in the study protocols and manuals, and discussed in staff trainings. These procedures are based on our previous experience with couples-based interventions, including with couples in the proposed setting. In our prior work in the pilot R34 trial in Kenya, adverse events included adverse maternal and pregnancy outcomes not related to participation in the study (1 miscarriage, 5 stillbirths, 3 infant deaths, and 2 maternal deaths) and two cases of relationship dissolution that were also not attributed to study participation and in South Africa, our only adverse events had to do with couples breaking up and attributing the break-up to participation in the intervention (N=1).

**Recruitment and Informed Consent**

Pregnant female participants will be recruited from ANC clinics, using methodologies from our previous studies with pregnant women. Potential participants will be asked if they would like to hear about the study, and the nature of the study will be explained to them using standardized recruitment scripts. Study descriptions will indicate that there is a possibility of different experiences due to the presence of three study groups. Male partners will be contacted, informed about the study, and consented subsequently, with the express permission of the pregnant woman. If the female partner is eligible for the study and willing to connect the study team with her male partner for potential inclusion in the study

as well, research staff will obtain contact information for the woman and the male partner. Those interested but not comfortable with face- to- face contact due to COVID -19 pandemic will be asked to participate remotely through phone after safety and privacy has been ascertained.

We will include screening for intimate partner violence in our eligibility questionnaires, in which each partner will be interviewed separately. We will ask participants questions based on our prior studies with couples used in this location. The questions will screen for physical violence (e.g., "My partner pushed, grabbed, or slapped me" "My partner hit me with his fist or something else that could hurt") and sexual violence ("My partner physically forced me to have sex when I did not want to."). Potentially controlling behaviors by a partner will be assessed during the intervention and assessments, but will not be used as screening questions. If participants report severe physical or sexual violence in the past 6 months, they will be informed at the end of the screening/eligibility interview that they are not eligible to participate, (e.g., "This intervention is not helpful for everybody, and we believe it may not be helpful for you and your partner at this time."). All couples who are deemed ineligible, regardless of reason of ineligibility will be provided with a list of couples-oriented services in the community—including those agencies which provide services pertaining to intimate violence and HIV.

*Process of obtaining informed consent:* Following initial contact, and screening for eligibility, informed consent will be obtained. If both members of the couple are eligible and willing to participate, each member of the couple will be consented individually. The study's consent form will be read and explained to them by an interviewer, and if they agree, they will be asked to sign the consent form.For participants who wish to enroll in the study but prefer virtual/remote participation, we will conduct consenting process on the phone. The study staff shall read the consent word for word and verify the participant's understanding before obtaining verbal consent. Verbal consent shall be taken by asking the participant to repeat the participant declaration statement written in the tail end of the consent as the staff audio records. All participants choosing to be consented remotely will be informed of recording their declaration to participate and the consent form will be kept safely for signing by the participant when COVID-19 spread is brought under controlVersions of the consent form will be available in English, Luo, and Swahili. A detailed description of the study procedures will be included. The consent form will include the information that they have the right to refuse or withdraw from participation at any time. The consent form will provide detailed descriptions of the expectations of being a participant in any of the study groups, along with the accompanying potential risks and benefits of each. Information will be presented on randomization, following procedures used to describe randomization in prior studies in the community. An information sheet will be provided with the goals of the research, the study procedures, and the names and contact info for the principal investigators will also be provided, and a contact number for the chair of the Ethics Committee of the Kenyan IRB. We will ask for signatures, but should participants be more comfortable, they can mark the form with an "x". We will confirm that participants understand the material covered in the consent form by asking questions prior to their signature, e.g. "could you tell me what will happen if you participate in the study?". If interviewers assess that the participant's level of understanding is insufficient and cannot be addressed by additional clarification the participant will be excluded from the study and provided with appropriate referrals. We have had experience obtaining consent from couples in prior studies in this context, and similar consent procedures will be followed. All consent forms will be approved by the IRBs of both UAB and U-Michigan and KEMRI in Kenya.
For receiving CHTC similar procedures will be followed, with a separate consent process and consent form. Consent will also be obtained for audio files to be digitally recorded of the home-based intervention couples' counseling sessions, but this material will only be used for quality control procedures.

For the in-depth qualitative interviews, similar procedures will be followed, with a separate consent process and consent form. Consent will also be obtained for digital audio recording of the interviews so that verbatim transcriptions may be made.

**Protections against Risk:**

In general, any potential risks from participation will be minimized by ensuring that study staff is well trained in ethical research standards and by developing detailed protocols to limit the likelihood of any risk. However, we have identified the following potential risks associated with participation in this study: 1) discomfort/distress 2) loss of confidentiality, and 3) conflict, or tension between partners 4) risks associated with HIVST distribution, and 5) risks associated with home visits. In addition, there are risks associated with individual testing for HIV and CHTC.

**Participant distress/discomfort:** Our research team has a significant amount of experience conducting behavioral surveys and interviews within the field of HIV prevention, PMTCT, and with couples, including in the proposed setting. It has been our experience that it is rare for a participant to find the interview upsetting. We have infrequently encountered episodes of mild embarrassment or awkwardness, which quickly dissipate. Interviewers and study staff will be trained to minimize distress/discomfort to participants, to recognize any signs of symptoms of distress, and to make appropriate referrals to appropriate community-based services, if necessary. Experienced mental health counselors will be on the study staff, and can be consulted or referred to should a participant exhibit severe symptom of mental distress. Should a participant experience distress after-hours or on weekends a back-up system will be in place in the event a mental health or medical professional is needed for assessment or immediate referral. All couples' counseling sessions will be conducted by lay counselors, but who have received significant training pertaining to couples, so any distress during an intervention session will be able to be processed and dealt with appropriately. All staff will be trained in the proper referral procedures, and will be provided with ongoing supervision of such issues by the Study Coordinator, who will be an experienced couples counselor. Through our prior work in the community, we have compiled a list of community-based resources for couples, including mental health counseling, general health services, mental health counseling, intimate partner violence, substance use, and other issues. These lists will continue to be updated, and a copy will systematically be provided to every couple during baseline questionnaires, and then during follow-up assessments. Providing them to all couples will reduce the likelihood that any one couple would be identified as needing a particular service, and implying that they have a particular need for a type of service. In addition, it could ameliorate tension between partners, as one partner could become distressed if a partner were given referrals following disclosure of information in an interview.

**Loss of confidentiality:** To protect participants' confidentiality the following steps will be taken: 1) all staff will receive training at the initiation of the study (all staff receive GCP training at the KEMRI study site), and ongoing supervision to ensure their understanding of any and all confidentiality-protecting procedures; 2) participants' names will not be associated with any research instruments; 3) only research identification numbers will be used on data; 4) any tracing or other contact information obtained in locator form (see Appendix R), including signed consent forms will be stored separately from survey data; 5) all records will be stored in locked file cabinets in study offices at KEMRI study office; 6) the files linking research identification numbers and names will be stored in a separate locked file cabinet, and a computer file only accessible by the Study Coordinator, MPIs and Co-Is; 7) all computers on which any data are stored will be password protected.

As this is a study involving couples, additional measures are needed to protect each participant's confidentiality from their partner. From our prior work, we have developed procedures to minimize risk. For the ongoing assessment questionnaires, all participants will be interviewed by a gender-matched interviewer who will conduct the assessment in a private room, or privately. Couples will typically be interviewed in their homes, but will be consented and interviewed separately. Prior to their separation, study staff will inform them that they may contact the staff member who interviewed them, but they will not be permitted to have contact with the interviewer who administered the survey to their partner. This procedure will enhance the participants' confidence that the information they disclose will be kept confidential and not disclosed to their partner.

Each interviewer will only interact with one participant of the couple, and the interviewers will be instructed not to compare answers between them regarding a couple's answers. Thus, it will not be possible for interviewers to become aware that one member of a couple is unaware of potential HIV risk posed to them by the other member of the couple. However, it is possible when analyzing the data that the investigators will be able to identify a condition of unrecognized HIV risk, such as non-disclosure of

HIV status. Should the situation arise where we identify that one partner has not disclosed their HIV-positive status to their partner, we will have protocols in place to first work with the participant to facilitate disclosure to their partner. We will have several resources (e.g., our own couples counselors and couples testing counselors) and referral pathways in place for this situation. Should, after counseling a participant still refuse to disclose their status, we would, in consult with the local IRB and our DSMB about next steps.

The consent form will include specific language regarding the confidentiality of the partner's study data: "Please be aware that you will not be told any information that your partner says in his or her interview. This includes any information your partner might say about his or her sexual health, including HIV status, even if we think you do not know this information. Likewise, no information you say in your interview will be told to your partner, even if we think your partner might not know this information." Interviewers will be trained to ensure that participants understand this condition during the informed consent process, including information about the confidentiality of their own and their partner's data. As mentioned above, systematically providing this information will eliminate partner's surmising that it is being provided due to information disclosed during the interview.

**Possibility of intra-couple tension, conflict, or violence**: It will be clear in the consent form that each partner completes that, while study staff members will not reveal their information to their partner, it is possible that their partners might ask them about their responses to certain questions or issues they discussed. Interviewers will be trained to discuss with participants ways of coping with this situation if the participant they are consenting expresses concern or distress about this matter either during consent, the administration of the survey, or after it is completed. Interviewers and other intervention staff will also be trained in the identification of, and proper response to, issues of coercion or abuse, and will be familiar with how to facilitate referrals for intimate partner violence assistance (either for the violent partner or the victimized partner). For example, staff will assess the degree of threat, whether the participant's life is currently at risk, or whether the crisis is not of an imminent nature. Depending on the degree of threat, the participant could be referred immediately to a crisis center in the nearest town, or, in lesser threat situation could be provided with referrals for community-based services. As stated in the inclusion criteria, couples will be excluded if they report a history of severe intimate partner violence in the past three months. The 2014 Kenya Demographic and Health Survey found a lifetime prevalence for spousal violence (physical, sexual, or emotional) of 47% of women of reproductive age, and 33% for the past year.[179] We do not wish to exclude a lifetime experience of domestic violence from our sample, as that would potentially exclude those women most at risk for HIV. By screening out recent episodes (past three months) of intimate partner violence, we aim to have a sample that balances potential benefit with relatively low risk from a couples-based intervention. In our prior studies, we have had very few instances where couples presenting for our couples-focused studies reported any history of domestic violence with their current/study partner. In our prior RCT with couples in South Africa, less than 5 couples were excluded for reporting severe violence. In the R34 pilot study in Kenya, 10 women were excluded from the randomized part of the study at baseline using the same criteria (and their partners were not subsequently contacted for study participation).

Studies of voluntary counseling and testing (VCT) in sub-Saharan Africa have not found significant differences in adverse events when comparing women who participated with their partner compared to women who participated alone. A study in Zambia found that 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.[180] 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 than HIV-positive women in the individual counseling and testing arm.[84]Never-the-less, due to the potential risks of HIV status disclosure it is clear that home-based strategies need to be carefully designed.

Although we have not had problems in the past in our studies with couples in Nyanza, Kenya with participants reporting being there under coercion, staff members will be trained to be sensitive to the possibility that one member of the couple was pressured or coerced by the other partner to participate

in the study. Questions may be posed such as “Did you come here freely?” or “Will something bad happen to you if you say no?”Should the staff member have this suspicion, s/he will be trained to immediately terminate the survey or session and provide the participant with appropriate referrals and the study incentive. Any data collected will be destroyed. The staff member will also be trained to offer the participant the opportunity to remain in the interview room for the appropriate amount of time that it would have taken to complete the survey or interview so that the study partner would not be alerted to the fact that the interview was terminated. If necessary, back-up staff members who are clinicians can be contacted to assess the appropriate immediate steps, should intervention be needed.

Should evidence of coercion arise in a couples’ counseling session, the counselor will provide the appropriate clinical intervention regarding participation of the couple and provide community referrals. Should a participant specifically request an intimate partner violence referral, the staff member will immediately terminate the interview, provide the participant with the study incentive, offer to let the participant remain in the interview room for the approximate time of completion, and assist the participant in contacting an appropriate service agency. In addition, our resource list given to all participants will include intimate partner violence programs, clinicians, and support groups specializing in relationship abuse and violence.

*Risks associated with HIVST kit distribution:* Our study will use procedures developed and utilized by co-investigators Thirumurthy and Agot to minimize probability of violence associated with participants’ offering HIV testing to male partners and to minimize probability of adverse reactions to test results and ensuring receipt of appropriate services. To minimize the likelihood of violence against study participants, participants will be encouraged to distribute a test kit to their male partner or to use both test kits to undertake couples testing if they feel comfortable doing so; they will also be counseled on how to talk to their partners about HIV testing, the possibility of adverse reactions associated with suggesting HIV testing, learning their partner’s HIV status, and disclosing their own HIV status. Study staff will be trained to talk to female participants at the time of enrollment about the importance of *using their discretion* and *assessing the risk of IPV* when deciding whether to introduce self-tests to their male partners. It will be emphasized to study participants that they are not obligated to distribute self-tests to their male partners. Participants will be counseled to never offer a self-test to someone who they will believe will become violent due to the introduction. Following Kenya’s 2015 HIV testing services guidelines, participants will be informed about the need to seek clinic-based confirmatory testing if a reactive self-test result is obtained, and an invitation for confirmatory testing at a clinic will be included with each test. Information will also be provided on clinics in the area where free HIV care and treatment is available. Additionally, we will inform study participants on where they can seek help if experience mental distress, experience violence, or need other counseling or advice. The proposed study will utilize the training materials for study staff that were implemented during Drs. Thirumurthy and Agot’s studies on HIV self-testing with pregnant/postpartum women in this part of Kenya. Additionally, in our home-based couple visit pilot study, we set up intensive procedures and referral systems for participants experiencing IPV and mental distress.

*Risks related to couple home visits:* Home visits for those randomized to the home-based couples intervention arm of the study will be conducted in a manner such that we uphold the highest standards of confidentiality and prevent unwanted disclosure of HIV status in the community and the family. Prior to starting this phase of the study, community announcements will be made through the community partners, stating that the health facility will be starting home visits for pregnant women and male partners to support maternal and child health. Lay health workers conducting home visits will use unmarked vehicles and will not wear any garments that identify them as working on HIV/AIDS. When visiting the household, the lay health workers will request to speak to the couple alone in a private room in the household, or at a nearby location in the community, and will not begin the study explanations and informed consent process for the man until they have obtained this privacy. In each community, we will identify a location for couple sessions that participants may choose if privacy cannot be maintained in the home (such as the home of the local community health worker). The lay health worker will offer HIV counseling and testing to the couple together, as if the woman had not already tested for HIV at the ANC clinic. Our experiences with couple/family HIV counseling and testing in Uganda and South Africa

reveal that most "index clients" (persons who initially tested HIV-positive in the clinic) prefer this approach.

*Risks associated with testing for HIV:* Engaging in voluntary counseling and testing for HIV, CHTC, will have a separate informed consent process, which will detail the potential risks, procedures involved, and any benefits. The risks associated with testing could include pain or complications from the finger prick in order to obtain serum for the rapid test. Testing will be conducted by trained HIV counselors, who are trained in phlebotomy and GCP in order to minimize the likelihood of any complications. There is a risk that participants could learn that they or their partner are HIV-positive. The testing counselors will be trained in all aspects of aiding participants through the testing process to alleviate as much distress as possible and to help them come to terms with this information. Additional referrals for couples' counseling, services for HIV care and treatment, and other relevant services will also be provided as part of the intervention.

**Potential benefits of the proposed research to the subjects and others:**
There are no direct benefits to the study participants. However, they may learn information regarding HIV treatment and prevention, pregnancy, and infant health, and may learn skills for communicating better with their partner, and potentially reduce their risk for HIV. The larger public health community could benefit if the intervention demonstrates efficacy, as improving rates of treatment and reducing levels of HIV viral load in individuals can potentially lower the burden of HIV in the community. There could be benefits to the mother and child with regard to increased likelihood of health care facility delivery, preventive healthcare utilization, and/or ART treatment for the pregnant women. While there are some risks to participating in the study, based on prior experience, we feel that the likelihood of participants experiencing negative events due to participation is low. It is our aim that participation in the intervention could serve to improve treatment and prevention for HIV, including the reduction of viral load levels, and possibly learn skills to improve relationships with one's partner. The risk to individual participants is small, and the potential to provide information that could benefit the target population outweighs the risk.
**Reimbursement of participants:** Each participant will be reimbursed for each assessment visit (questionnaires), but not for brief phone assessments and intervention activities. Each participant will receive approximately 500Kenyan Shillings (roughly 5 US dollars) per assessment. This reimbursement is in accordance with other studies being conducted through KEMRI, and will be approved by the local Kenyan IRB. Reimbursements will be paid in cash following the completion of each visit. Participants in the home visit study arm will also receive a small gift (such as a bar of soap or a bag of sugar) of approximately 200 KSh value ($2.66 US) at each home visit, which is a cultural expectation for persons visiting the home of pregnant/postpartum couples.

Participants in the in-depth qualitative interviews will be reimbursed 500 Kenyan Shillings (KSh) for their transportation expenses related to participation in the interview, which is equivalent to around $5 US dollars, which is approximately the cost of round-trip minibus fare from a long-range location.

## EXPECTED APPLICATION OF RESULTS

This study could improve our ability to improve HIV prevention behaviors, identification of pregnant women and male partners infected with HIV, treatment engagement, and reduce viral load for pregnant women and their male partners, thereby reducing the likelihood of vertical and horizontal HIV transmission, among couples in western Kenya, a population at high risk for HIV. Most HIV infections in sub-Saharan Africa are occurring within primary partnerships.[2] Intervening with couples also increases the participation of men in HIV prevention activities, which have previously focused on women, and could contribute to a shift in community norms regarding gender and couple relations. The ability to reduce the likelihood of transmission with partnerships, as well as mother-to-child transmission of HIV, has the potential for high public health impact. Thus, through this study, we will gain evidence of the comparative effectiveness of these three different approaches to engaging couples on health behaviors and outcomes. Following completion of the study, we will be able to present to the

Kenyan MOH and partners, for potential expansion of effective strategies to more sites across the country. If found to be effective, these strategies can also be adapted to other similar settings in sub-Saharan Africa, with important potential benefits for maternal, paternal, and infant health.

## LIMITATIONS

In the case that we are not able to recruit enough couples in a timely manner, due to decreasing HIV prevalence in the study counties or other factors, we have the ability to add additional study sites due to our strong relationships with Ministry of Health County teams (see Letters of Support). Contamination across study arms due to availability of HIV self-test kits in the study communities may also be a challenge. However HIV self-test kits are not widely available or accessible, and we will assess use of HIV self-test kits in all three arms and account for this in analyses. There are potential risks of couple conflict related to HIV testing and disclosure. We have demonstrated that we can mitigate these risks through careful training of lay counselors in the home visit arm, special counseling for women in the HIV self-test kit arm, and a free number to text study staff (see Human Subjects section). Neither the R34 pilot in Kenya (PI: Turan), nor the couple R01 in South Africa (PI: Darbes) found any increased couple conflict or violence related to the couple interventions.

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**ENROLLMENT INFORMED CONSENT TO BE A RESEARCH PARTICIPANT**
**(Pregnant women)**

**Testing Strategies for Couple Engagement in PMTCT and Family Health in Kenya**

Conducted by the Kenya Medical Research Institute, the University of Alabama at Birmingham (USA), the University of Michigan (USA), University of Pennsylvania (USA), and University of the Witwatersrand (South Africa).


| Name | Institution | Contact |
|---|---|---|
| Janet M. Turan | University of Alabama at Birmingham (UAB) | 000-1-205-934-6780 |
| Zachary Kwena | Kenya Medical Research Institute (KEMRI) | 0733 333 005 |
| Elizabeth Bukusi | Kenya Medical Research Institute (KEMRI) | 0733 617 503 |
| Lynae Darbes | University of Michigan (UM) | 000-1-734-763-7265 |
| Thomas Braun | University of Michigan (UM) | 000-1-734-936-9844 |
| Abigail Hatcher | University of the Witwatersrand, South Africa | 000-27-84-406-7773 |
| Harsha Thirumurthy | University of Pennsylvania (UPenn) | 001-1-215-898-7136 |
| Maria Pisu | University of Alabama at Birmingham (UAB) | 000-1205-972-7366 |

**24-hour Emergency contact number** 0718441874


I would like to tell you about a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI), the University of Alabama at Birmingham (UAB), the University of Michigan (UM), and the University of Pennsylvania (UPenn) in the United States, and the University of the Witwatersrand in South Africa. The study is funded by the United States National Institutes of Health. The purpose of this consent form is to give you the information you will need to help you decide whether to be in this study or not. You may ask questions about the purpose of the research, what happens if you participate in the research, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

When we have answered all your questions, you can decide if you want to be in the study or not. This process is called „informed consent." We will give you a copy of this form to take home if you wish to. If you do not wish to take a copy, we will keep your copy in a locked cabinet in the research office.

**Why is this study being done?**

We are learning how to promote family health. We are trying three ways. The first way is healthcare workers teach women and their husbands about family health topics during a home visit. Two health workers talk about HIV testing during pregnancy. The second way is women and their husbands get HIV self-test kits. They can choose to use the self-test kits to test on their own. The last way is normal health care at the clinic around the time of pregnancy.

**Why are you being asked to take part?**

You are being asked to take part in this study because you said that you would like to learn about participating in a study together with your husband. I am speaking with you because you come to antenatal care at one of the clinics where the study is being conducted. We are inviting women who are pregnant and are interested. You and your husband may benefit from

participating in this study if you decide to take part.

**How many people will take part in the study?**
A total of around 1080 pregnant women like you will be asked to take part in the study. If your husband and you both agree, you will be assigned to one of three groups. We will draw from an envelope (like a lottery) and you will be able to: 1) get home visits with your husband from two health workers, 2) get multiple oral fluid-based HIV self-testing kits for you and your husband to use if you choose, or 3) go to normal ANC services at the clinic by yourself or with your husband. Anyone in group 1 2 or 3 can get normal services at the clinic. The group you will be in with your husband will be decided randomly, like a lottery.

**What will happen if I take part in this study?**
If you agree to take part in the study, the following things will happen:

- Once you agree to participate in the study, we will ask you to sign this form to show that you understand and agree to participate.
- We will ask you questions in a survey that takes about an hour.
- We will contact your husband by phone to find a time to give him information about the study, sign a form, and answer questions that take about an hour.
- We will ask you and your husband to come together to the clinic or for us to visit your house or other convenient location, so that you can find out which group you are in.
- If you are in the home visit group, we will ask locator information (including cell phone contacts) for you and your husband and ask about good times visit you at home. You will receive up to 5 home visits from a pair of counselors during pregnancy and after the birth.
- If you are in the HIV self-testing group, when you come to the ANC clinic we will give you self-test kits and show you how to use the tests if you want to use them. With self-testing, individuals collect their own sample and perform an HIV test in the absence of a care provider by swabbing inside of their mouths. You will be given two self-test kits to take home to distribute to your husband or use yourself. The staff will explain how these tests are to be used so that you can use the tests correctly later or that you can explain how to use the tests when giving them to other people. Even though the self-tests are highly accurate, it is important to have HIV-positive test results confirmed at a clinic where HIV testing services are available. Each self-test kit will include a referral voucher for clinic-based confirmatory testing in case an HIV-positive result is obtained. Each self-test kit will include instructions on how to perform the test and a phone number to call in case you or another user has questions. You will receive additional self-test kits during the study.
- Participants in all three groups can continue to come to clinic like normal.
  We will ask both you and your husband to answer questions at a few more clinic or home visits: before baby's birth, when the baby is 3 months old, 12 months old, and 18 months old. Also, we will ask both you and your husband a few questions by phone during late pregnancy, when the baby is 6 months old, and when the baby is 18 months old.

**How long will I be in the study?**
If you agree to participate, you will remain in the study until your baby is 18 months old, which will be about two years from now, depending on your stage of pregnancy today.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**

- Study researchers will ask sensitive questions about sexual behavior and HIV testing and will be trained not to share the information with anyone.
- Some of the questions may make you feel uncomfortable or upset, so if you do not wish to answer a question you can skip. You can ask to take a break or stop the interview at any time.
- Some people may experience bleeding from the gums when using the oral swab used in the HIV self-test kit; this risk is similar to that when brushing your teeth. You or your husband may also test HIV-positive during the study. Knowing your status or the status of your husband may make you feel worried. If you test HIV-positive using an HIV self-test, we encourage you to seek confirmation of the result at a health facility. If clinic-based HIV tests indicate you or one of your sexual partners is HIV-positive, you or he will receive counseling at the facility on how to cope with an HIV-positive result and also be linked to appropriate care.
- Sometimes, discussions with your husband about HIV or sensitive topics can cause arguments or disagreements. We will never share information you tell us with your husband. We are here to offer referrals if you or your husband responds badly or is upset by the study.

**Are there benefits to taking part in this part of the study?**

You and your husband may benefit from home or clinic visits, or HIV self-testing during this study. You may learn about being a parent to your new baby. Your answers to study questions will help us learn more about better ways to help pregnant women and men with family health. If you decide to go through Couples HIV Counseling and Testing (CHCT) together with your husband it may improve your relationship or your health.

**What other choices do I have if I do not take part in this part of the study?**

You can choose to take part in any part of the study or to skip any part of the study. You can choose to stop the study at any time. If you decide not to take part in this study, you will still receive clinic services like normal.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. Our team is trained to only talk about the study with other study researchers. However, we cannot guarantee total privacy. Your personal information may be given out to university review boards or others who are responsible for the laws and ethics of good research. This may include people at the United States National Institute of Health (NIH) and the Office for Human Research Protections. The information you provide will be entered into a tablet computer but WITHOUT your name or other identifying information on you. Your name and locator information will be kept in a locked cabinet. The answers you share will be looked at by the team conducting this study and will be analyzed and published for scientific purposes without naming you or any other participant.

**What are the costs of taking part in this part of the study?**

There will be no costs to you as a result of taking part in this study.

**Will I be paid for taking part in this part of the study?**

You will be reimbursed in the amount of 500 KSh for your time or travel expenses each time

you answer questions for this study in person at the clinic or your home lasting about one hour (once during pregnancy, and two times after baby's birth). Similar to yourself, your husband will also be reimbursed in the amount of 500 KSh after answering questions in person in this manner. If you are in the home visit group of the study, your family will also receive a small gift for each couple home visit that you complete. When answering baseline questions for this study at the clinic, you will be offered a packet of milk during the interview of which you are free to decline or accept. We have observed in the past that after a long days antenatal clinic process, pregnant women are tired and hungry hence they find it difficult to concentrate during the baseline interviews. You will not receive reimbursement for brief questions that we will ask you and your husband by phone during late pregnancy, when the baby is 6 months old, and when the baby is 18 months old.

**What are my rights if I take part in this study?**
Taking part in this study is your choice. You may choose to take part or not to take part in this study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will still get the same medical treatment and can access all health services offered at your clinic.

**Who can answer my questions about the study?**
If you have any questions or concerns about participating, please call our study staff at 0718441874. You may also contact any of the investigators listed above. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Secretary of the *Ethical Review Committee*, Kenya Medical Research Institute at Tel. 020-2722541. You may also contact the UAB Office of the IRB (OIRB) in the United States at by email at IRB@uab.edu or by mail at 701 20th Street South, Birmingham, Alabama, 35294-0104, USA; or the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board by email at irbhsbs@umich.edu or by mail at 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, Michigan, 48109-2800, USA. You may contact these offices in the event the research staff cannot be reached or you wish to communicate with someone else. These committees are concerned with the protection of volunteers in research projects.

**CONSENT**
You will be given a copy of this consent form to keep. If you do not wish to take a copy, we will keep your copy in a locked cabinet in the research office.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this part of the study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled. You are not waiving any of your legal rights by signing this informed consent document.

**Participant's Statement**
This study described above has been explained to me. I volunteer to take part in this part of the research. I have had a chance to ask questions. If I have future questions about the research, I can ask one of the investigators listed above. If I have questions about my rights as a research participant, I can contact those listed above.

If you wish to participate in this study, you should sign below.

Do you provide consent to participate in this study?

☐Yes ☐ No

DATE CONSENT OBTAINED _____

GIVEN BY:_____ _____
NAME OF PARTICIPANT SIGNATURE OF PARTICIPANT

BY: _____ _____
NAME OF PERSON OBTAINING CONSENT SIGNATURE OF PERSON OBTAINING CONSENT

WITNESS SIGNATURE (IF NEEDED):

_____ _____
NAME OF WITNESS SIGNATURE OF WITNESS

***If illiterate***

I have witnessed the accurate reading of the consent form to the participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely**.**

Name of witness_____ AND Thumbprint of participant

Signature of witness _____

**Date _____ Day/month/year**

BY:

_____ _____
NAME OF STAFF MEMBER SIGNATURE OF STAFF MEMBER

**ENROLLMENT INFORMED CONSENT TO BE A RESEARCH PARTICIPANT**
**(Male partners)**

**Testing Strategies for Couple Engagement in PMTCT and Family Health in Kenya**

Conducted by the Kenya Medical Research Institute, the University of Alabama at Birmingham (USA), the University of Michigan (USA), University of Pennsylvania (USA), and University of the Witwatersrand (South Africa).

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**HIV TEST INFORMED CONSENT FORM**

**Testing Strategies for Couple Engagement in PMTCT and Family Health in Kenya**

Conducted by the Kenya Medical Research Institute, the University of Alabama at Birmingham (USA), the University of Michigan (USA), University of Pennsylvania (USA), and University of the Witwatersrand (South Africa).


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| Zachary Kwena | Kenya Medical Research Institute (KEMRI) | 0733 333 005 |
| Elizabeth Bukusi | Kenya Medical Research Institute (KEMRI) | 0733 617 503 |
| Lynae Darbes | University of Michigan (UM) | 000-1-734-763-7265 |
| Thomas Braun | University of Michigan (UM) | 000-1-734-936-9844 |
| Abigail Hatcher | University of the Witwatersrand, South Africa | 000-27-84-406-7773 |
| Meredith Kilgore | University of Alabama at Birmingham (UAB) | 000-1-205-975-8840 |
| Harsha Thirumurthy | University of Pennsylvania (UPenn) | 001-1-215-898-7136 |


**24-hour Emergency contact number**: 718441874

***Introduction***

A virus called HIV (Human Immunodeficiency Virus) causes the disease AIDS (Acquired Immunodeficiency Syndrome). Anyone with HIV can spread it to others. It is spread through unsafe sex, sharing needles, or donating blood or other tissues. Infected mothers can spread HIV to their babies. The test for HIV detects the body's reaction to the virus (antibody). It does not detect the virus itself. The decision to be tested for antibody to the virus that causes AIDS is voluntary; you are not required to have the test. This test is being done for a research study.

You should know the advantages and disadvantages of testing before you decide to take the test. Please read this consent form with care so that you can make an informed choice about having the blood test.

***What the test means***

If you test POSITIVE, you have the HIV virus. That means you can pass it to others. The test cannot tell how long a person has been infected. It does not mean that you have AIDS, which is the most advanced stage of HIV infection.

If the test is NEGATIVE you probably do not have the HIV virus. It may mean that you have the virus, but your body has not yet made antibody to fight the virus. It could take up to six months after infection for the test to turn positive. False results are rare. Unclear results are also rare. When a test result does not seem to make sense, we do the test again. We might do another kind of blood test to find out if you are infected or not.

***Procedures***

This is what will happen if you decide to have the test. First, you will meet with a counselor. The counselor will give you more information about the risks and benefits of the test. They will explain the meaning of test results. They will teach you how to reduce the

chance of spreading HIV. They will explain the dangers of HIV infection. A finger prick blood will be obtained for the antibody test. We will test your blood for HIV at the study clinic and later in the laboratory in case of invalid results. For participants with invalid HIV results at study clinic, we will make every effort to locate you and give you the definite results. When you learn the test results, you will also be counseled to increase your understanding of HIV transmission and how to reduce your risks of getting or transmitting sexually transmitted diseases by being faithful to one uninfected partner, abstaining from sex if you are diagnosed with a sexually transmitted disease while on treatment, and using a condom consistently and correctly each time you have sex. You will also be counseled about how to notify your sexual partners if your test result is positive

***Benefits of being tested***

The benefits of being tested are very personal. If you are worried about AIDS, you might feel better if you have a negative test. Sometimes knowing that the test is positive can relieve stress. You may want to know your test result before you have sex with a partner. In some cases, test results may help diagnose a medical problem or help you make decisions about your future or on health care. Those who test positive for HIV will be referred to HIV care clinics for further management. There may be other benefits of testing that we don't know about now.

***Risks of being tested***

Learning test results may cause you and your partner severe stress, anxiety and depression. This may result into blaming each other and even cause separation or divorce. Other people learning about your HIV status may lead to discrimination in travel, work and insurance. You might be tempted to have unsafe sex if the result is negative. This would increase your risk of getting AIDS. If the results of the test get into the wrong hands, prejudice, discrimination, risk to employment, travel restrictions, and other adverse effects could result. There may be other risks and stresses of being tested that we don't know about now.

You may get a bruise where the needle enters the vein and there is a small risk of infection. You may feel some pain as the needle enters your vein.

***Information about confidentiality***

Your HIV antibody test results will be held in the strictest confidence, and no identifying information of any kind will be released to any other person or agency without your specific permission in writing. We will not publish or discuss in public anything that could identify you.

Do you have any questions? Do you agree to participate?

| _____ | _____ | _____ |
|---|---|---|
| Name of researcher | Signature | Date |

***Participant's Statement***

I have read this form/this for has been read and explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have future questions about the research, I can ask one of the investigators listed above. If I have questions about my rights as a research subject, I can contact: The Secretary, KEMRI Ethics Review Committee, P.O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0722-205901, 0733-400003; Email address: ERCadmin@kemri.org.

| Printed name of participant | Signature/thump print | Date | Time |
|---|---|---|---|

| Printed name of witness | Signature of witness | Date | Time |
|---|---|---|---|

Copies to: Investigator's files, study participant

may benefit from participating in this study if you decide to take part.

**How many people will take part in the study?**
A total of around 1080 couples (pregnant women and their husbands) like you will be asked to take part in the study. If your wife and you both agree, you will be assigned to one of three groups. We will draw from an envelope (like a lottery) and you will be able to: 1) get home visits with your wife from two health workers, 2) get multiple oral fluid-based HIV self-testing kits for you and your wife to use if you choose, or 3) your wife will go to normal ANC services at the clinic by herself or with you. Anyone in group 1 2 or 3 can get normal services at the clinic. The group you will be in with your wife will be decided randomly, like a lottery.

**What will happen if I take part in this study?**
If you agree to take part in the study, the following things will happen:

- Once you agree to participate in the study, we will ask you to sign this form to show that you understand and agree to participate.
- We will ask you questions in a survey that takes about an hour.
- We will ask you and your wife to come together to the clinic or for us to visit your house or other convenient location, so that you can find out which group you are in.
- If you are in the home visit group, we will ask locator information (including cell phone contacts) for you and your female partner and ask about good times visit you at home. You will receive up to 5 home visits from a pair of counselors during pregnancy and after the birth.
- If you are in the HIV self-testing group, when your wife comes to the ANC clinic we will give her self-test kits and show her how to use the tests if she wants to use them. With self-testing, individuals collect their own sample and perform an HIV test in the absence of a care provider by swabbing inside of their mouths. She will be given two self-test kits to take home to distribute to you or use herself. The staff will explain how these tests are to be used so that she can use the tests correctly later or so that she can explain how to use the tests when giving them to other people. Even though the self-tests are highly accurate, it is important to have HIV-positive test results confirmed at a clinic where HIV testing services are available. Each self-test kit will include a referral voucher for clinic-based confirmatory testing in case an HIV-positive result is obtained. Each self-test kit will include instructions on how to perform the test and a phone number to call in case you or another user has questions. Your wife will receive additional self-test kits from the ANC clinic during the study.
- Participants in all three groups can continue to come to clinic like normal.
  We will ask both you and your wife to answer questions at a few more clinic or home visits: before baby's birth, when the baby is 3 months old, 12 months old, and 18 months old. Also, we will ask both you and your wife a few questions by phone during late pregnancy, when the baby is 6 months old, and when the baby is 18 months old.

**How long will I be in the study?**
If you agree to participate, you will remain in the study until your baby is 18 months old, which will be about two years from now, depending on your wife's stage of pregnancy today.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**

- Study researchers will ask sensitive questions about sexual behavior and HIV testing and will be trained not to share the information with anyone.
- Some of the questions may make you feel uncomfortable or upset, so if you do not wish to answer a question you can skip. You can ask to take a break or stop the interview at any time.
- Some people may experience bleeding from the gums when using the oral swab used in the HIV self-test kit; this risk is similar to that when brushing your teeth. You or wife may also test HIV-positive during the study. Knowing your status or the status of your wife may make you feel worried. If you test HIV-positive using an HIV self-test, we encourage you to seek confirmation of the result at a health facility. If clinic-based HIV tests indicate you or one of your sexual partners is HIV-positive, you or he will receive counseling at the facility on how to cope with an HIV-positive result and also be linked to appropriate care.
- Sometimes, discussions with your wife about HIV or sensitive topics can cause arguments or disagreements. We will never share information you tell us with your partner. We are here to offer referrals if you or your wife responds badly or is upset by the study.

**Are there benefits to taking part in this part of the study?**

You and your wife may benefit from home or clinic visits, or HIV self-testing during this study. You may learn about being a parent to your new baby. Your answers to study questions will help us learn more about better ways to help pregnant women and men with family health. If you decide to go through Couples HIV Counseling and Testing (CHCT) together with your wife it may improve your relationship or your health.

**What other choices do I have if I do not take part in this part of the study?**

You can choose to take part in any part of the study or to skip any part of the study. You can choose to stop the study at any time. If you decide not to take part in this study, you will still receive clinic services like normal.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. Our team is trained to only talk about the study with other study researchers. However, we cannot guarantee total privacy. Your personal information may be given out to university review boards or others who are responsible for the laws and ethics of good research. This may include people at the United States National Institute of Health (NIH) and the Office for Human Research Protections. The information you provide will be entered into a tablet computer but WITHOUT your name or other identifying information on you. Your name and locator information will be kept in a locked cabinet. The answers you share will be looked at by the team conducting this study and will be analyzed and published for scientific purposes without naming you or any other participant.

**What are the costs of taking part in this part of the study?**

There will be no costs to you as a result of taking part in this study.

**Will I be paid for taking part in this part of the study?**

You will be reimbursed in the amount of 500 KSh for your time or travel expenses each time you answer questions for this study in person at the clinic or your home lasting about one hour (once during pregnancy, and twice after baby's birth). Similar to yourself, your wife will also be reimbursed in the amount of 500 KSh after answering questions in person in this manner. If you are in the home visit group of the study, your family will also receive a small gift for each

couple home visit that you complete. You will not receive reimbursement for brief questions that we will ask you and your husband by phone during late pregnancy, when the baby is 6 months old, and when the baby is 18 months old.

**What are my rights if I take part in this study?**
Taking part in this study is your choice. You may choose to take part or not to take part in this study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will still get the same medical treatment and can access all health services offered at your clinic.

**Who can answer my questions about the study?**
If you have any questions or concerns about participating, please call our study staff at 0718441874. You may also contact any of the investigators listed above. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Secretary of the *Ethical Review Committee*, Kenya Medical Research Institute at Tel. 020-2722541. You may also contact the UAB Office of the IRB (OIRB) in the United States at by email at IRB@uab.edu or by mail at 701 20th Street South, Birmingham, Alabama, 35294-0104, USA; or the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board by email at irbhsbs@umich.edu or by mail at 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, Michigan, 48109-2800, USA. You may contact these offices in the event the research staff cannot be reached or you wish to communicate with someone else. These committees are concerned with the protection of volunteers in research projects.

**CONSENT**
You will be given a copy of this consent form to keep. If you do not wish to take a copy, we will keep your copy in a locked cabinet in the research office.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this part of the study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled. You are not waiving any of your legal rights by signing this informed consent document.

**Participant's Statement**
This study described above has been explained to me. I volunteer to take part in this part of the research. I have had a chance to ask questions. If I have future questions about the research, I can ask one of the investigators listed above. If I have questions about my rights as a research participant, I can contact those listed above.

If you wish to participate in this study, you should sign below.

Do you provide consent to participate in this study?

☐Yes ☐ No

DATE CONSENT OBTAINED _____

GIVEN BY:_____ _____
NAME OF PARTICIPANT SIGNATURE OF PARTICIPANT

BY: _____ _____

NAME OF PERSON OBTAINING CONSENT SIGNATURE OF PERSON OBTAINING CONSENT

WITNESS SIGNATURE (IF NEEDED):

_____ _____

NAME OF WITNESS SIGNATURE OF WITNESS

***If illiterate***

I have witnessed the accurate reading of the consent form to the participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely**.**

Name of witness_____ AND Thumbprint of participant

Signature of witness _____

**Date _____ Day/month/year**

BY:

_____ _____

NAME OF STAFF MEMBER SIGNATURE OF STAFF MEMBER