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Effectiveness of home-based HIV testing and education among partners of
pregnant women in Kenya: a mixed methods approach

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Abstract

Effectiveness of home-based HIV testing and education among partners
of pregnant women in Kenya: a mixed methods approach

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Male partner involvement has been recognized as an important component of prevention-of-mother-to-child transmission of HIV (PMTCT); however, male antenatal attendance has been difficult to achieve. Home-based testing among pregnant couples may be an effective strategy to test men.

Women attending their first antenatal visit at Kisumu District Hospital in Kenya were screened for eligibility and randomized to home-based education and HIV testing (HOPE) or to written invitations for male partners to attend clinic (INVITE). Of 1101 women screened, 620 were eligible and 601 were randomized either to HOPE (n=306) or INVITE (n=295). At 6 months postpartum, male partners were more than twice as likely (RR=2.10; 95% CI: 1.81-2.42) to have been HIV tested in the HOPE arm (n=233, 87%) compared to the INVITE arm (n=108, 39%).

Couples in the HOPE arm (n=192, 77%) were three times more likely (RR=3.17; 95% CI: 2.53-3.98) to have been tested as a couple than the INVITE arm (n=62, 24%) and women in the HOPE arm (n=217, 88%) were also twice as likely (RR=2.27; 95% CI: 1.93-2.67) to know their partner's HIV status as the INVITE arm (n=98, 39%). More serodiscordant couples (RR=3.38; 95% CI: 1.70-6.71) were identified in the HOPE arm (n=33, 13%) than in the INVITE arm (n=10, 4%).

In qualitative interviews with participants, it was found that home-based couple HIV testing and counseling facilitated partner testing and disclosure, was preferable due to privacy and quality time, and helped participants overcome their fear of testing. Couples also appreciated the efficiency and appropriateness of partner involvement and joint education, and spoke of intervention influence on partner support in pregnancy and postpartum as well as improved relationship due to disclosure. Couples overwhelmingly had positive feedback for the intervention, although had preferences in terms of health advisors, especially having non-local advisors.

Home-based HIV testing among pregnant couples resulted in higher uptake of male testing and couple testing as well as rates of disclosure and identification of serodiscordant couples. This intervention not only has implications for PMTCT, but also for testing men as part of overall HIV testing strategies to reach the UNAIDS 90-90-90 targets by 2020.

TABLE OF CONTENTS

List of Figures	iii
List of Tables	iv
Chapter 1. Overall Introduction	1
1.1 Dissertation overview	1
1.2 Male HIV testing and involvement during the antenatal period: A background	1
1.3 Impetus for the HOPE Study	7
1.4 Remaining chapters.....	8
1.5 References.....	8
Chapter 2. Effectiveness of Home-based HIV Testing and Education: Quantitative Results	13
2.1 Manuscript title	13
2.2 Authors.....	13
2.3 Abstract.....	13
2.4 Introduction.....	14
2.5 Methods.....	16
2.5.1 Female recruitment and enrollment	16
2.5.2 Male enrollment and follow-up	16
2.5.3 Home-based intervention	16
2.5.4 HIV testing.....	17
2.5.5 Data collection and statistical methods.....	17
2.6 Results.....	18
2.7 Discussion.....	24
2.8 Conclusion	27
2.9 References.....	27
Chapter 3. Perspectives of Home-based HIV Testing and Education: Qualitative Results.....	30
3.1 Title.....	30

3.2	Authors.....	30
3.3	Abstract.....	30
3.4	Introduction.....	31
3.5	Methods.....	32
3.5.1	Parent study.....	32
3.5.2	Subject selection	33
3.5.3	Instrument development.....	33
3.5.4	Data collection	33
3.5.5	Data analysis	34
3.6	Results.....	34
3.6.1	Participant characteristics	34
3.6.2	Overview of themes	37
3.6.3	Experiences of home-based couple HIV testing and counseling.....	37
3.6.4	Experiences of partner involvement	48
3.6.5	Intervention influence on health behaviors.....	50
3.6.6	Feedback and suggestions for improvement.....	52
3.7	Discussion.....	54
3.8	Conclusion	57
3.9	References.....	57
Chapter 4. Conclusion: Next Steps in HOPE.....		61
4.1	Using mixed methods to increase understanding.....	61
4.2	Refining the intervention with new evidence	63
4.3	Using implementation science to scale-up HOPE	66
4.4	References.....	69
Appendix A.....		70

LIST OF FIGURES

Figure 2.1 Enrollment and follow-up in the Home-based Partner Education and Testing (HOPE) Study	19
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LIST OF TABLES

Table 2.1 Characteristics of participants in the Home-based Partner Education and Testing (HOPE) Study	21
Table 2.2 Outcomes of the Home-based Partner Education and Testing (HOPE) Study.	24
Table 3.1 Characteristics of subjects who participated in in-depth interviews.....	36
Table 3.2 Facilitation of partner testing and disclosure in home-based testing and education	40
Table 3.3 Privacy and quality time in home-based testing and education.....	42
Table 3.4 Fear of HIV testing overcome with counseling	44
Table 3.5 Improved relationship due to disclosure.....	47
Table 3.6 Local community health worker (CHW) vs. non-local health advisors	53

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DEDICATION

I would like to dedicate this dissertation to all pregnant women, their partners and their babies,
including my husband Ross, myself and baby Sky.

Chapter 1. OVERALL INTRODUCTION

1.1 DISSERTATION OVERVIEW

This dissertation discusses the effectiveness and perceptions of home-based HIV testing and education of partners of pregnant women, as was studied in Kisumu, Kenya from 2013-2015 as part of a randomized clinical trial (The HOPE Study). This first chapter provides the impetus for the trial, including an overall introduction to the topic of male involvement and HIV testing in the antenatal period and how home-based testing may overcome identified barriers as was identified prior to the study. The next two chapters focus on the results from the study and use both quantitative and qualitative approaches to better understand home-based partner HIV testing and education. The final chapter offers an overall conclusion in light of the mixed methods results and new evidence as well as provides ideas for next steps.

1.2 MALE HIV TESTING AND INVOLVEMENT DURING THE ANTENATAL PERIOD:

A BACKGROUND

Antenatal care programs around the world have focused their attention on the attendance of pregnant women to health clinics for care [1]. Naturally, prevention of mother-to-child transmission of HIV (PMTCT) programs have been integrated into antenatal clinics as a way to access pregnant women as the target population, test them for HIV and treat those who are HIV positive [2]. While this model leverages on already established antenatal clinics and female antenatal attendance, it has struggled to address male partners, whose inclusion has been recognized in recent years as an important component to PMTCT as HIV acquisition has been discovered to be high in pregnancy [3-6] and in the postpartum phase [7-9]. Furthermore, male involvement has not only been proven to be important in terms of prevention of HIV transmission between partners and thus from mother-to-child, but also in adherence to other PMTCT interventions and for maternal and infant outcomes [10-15].

Many programs have attempted to integrate male partners in antenatal care and PMTCT, mostly with the use of invitations encouraging men to return to the clinic, and have had limited success [16-18]. At the same time, the issue of male involvement in PMTCT programs has been

the topic of many qualitative studies [19-24]. Alternative approaches to involving men in antenatal care and PMTCT are of much current interest, including home-based HIV testing and education, which shifts the focus away from bringing men to the antenatal clinic and, instead, takes the intervention to them. There are many advantages to this method, spanning individual, public health and program perspectives. Overall, home-based testing addresses many of the concerns men have about attending antenatal clinics, including clinics not being male friendly and lost time/income to attend, and may be a promising method to reach partners in order to improve maternal and child health as well as the partner's own health.

Home-based testing and education of partners of pregnant women was proposed and developed as an intervention in light of the literature that men seldom attend antenatal appointments in many countries, even after trying to encourage their attendance. From May 2002 to April 2009, only 469 male partners (1.1%) of the 54,429 new antenatal PMTCT attendees accessed antenatal services in a regional referral hospital in Uganda [25]. In the same hospital from October 2009 to February 2010, when invitation letters were given to women to take to their male partners, 86 out of 530 (16.2%) women returned with their male partner within 4 weeks and 82 agreed to HIV testing (95%) [17]. However, male partners of women who received an information leaflet rather than a direct invitation (the control group) had similar return and uptake rates [17]. While this is an improvement when compared to the previous study of antenatal records, male attendance was still low and not better than the control arm. In Kenya, a similar study in 2001-2002 encouraged 2,104 women to return with their male partners, of which 1,993 reported informing their partner of the availability of HIV testing and 313 (16%) returned with their male partner [16]. More men were reached in another Kenyan study completed in 2013 in the clinic invitation arm (55 out of 150, 36%), which is an improvement over previous studies, but the majority of male partners (64%) still did not attend the antenatal clinic by clinic invitation [26].

Many qualitative studies have been conducted to ask men and sometimes women about the barriers of male antenatal clinic attendance. Common themes have included antenatal care being a female activity, male reluctance to undergo HIV testing, and clinics not being male friendly. In a particularly relevant qualitative study, conducted in rural western Kenya in 2011, eight focus groups of men were held to understand their perceptions of antenatal care [19]. While men had positive views of antenatal care, they themselves rarely attended the clinic with their wives. Three main barriers were identified: 1) women turned to other women rather than their husbands for

pregnancy support (i.e. mother-in-laws, co-wives, or friends); 2) the male's role was to financially support the women in pregnancy; 3) healthcare workers have a negative attitude toward male participation in the clinic. Likewise, in a systematic review of literature on this topic, 38% of studies (n=24) cited the perception of antenatal care being a woman's activity and that it was shameful and/or culturally inappropriate to be involved [27]. In several additional studies, attending the antenatal clinic was seen as a female responsibility since women are the ones who are pregnant and are capable of handling issues pertaining to motherhood [22, 24, 28]. The male role of providing support in other ways, such as working and providing an income [19, 22], as well as viewing antenatal clinics as not being a place for men [22, 24], was stated by a man in a Tanzanian qualitative study in 2007 and echoed by others in the focus group:

“Due to difficulties of life, it is better to go and seek money for the family, instead of attending clinics which were designed for women only” [24].

Another man in a different focus group in the same study shared his thoughts this way:

“A lot of men when told about the (PMTCT) service, they don't give attention to it, as they see it is to do with women and children. After all, the women are thought to be capable to handle the situation. Because of economic hardships and constraints caused by the time he will be there, he may lose time to work. Also, they don't know what they are being called for. Men are afraid of testing” [24].

This response demonstrates that men may have more than one reason to not attend the antenatal clinic, including the fear of HIV testing. However, in the same study cited above in rural western Kenya, some men voiced that it would be a benefit to them to attend the clinic to learn their female partner's HIV status and to encourage disclosure between couples, and only brought up that *other* men might find couple HIV testing as a barrier [19]. One quantitative study in 2006-2007 also found HIV testing as a positive motivator: a written invitation for voluntary counseling and testing (VCT) for partners of pregnant women in South Africa resulted in a 32% return and HIV testing rate (161 of 500) versus 11% who were invited for pregnancy information sessions (57/500) [18]. Yet, a systematic review of 24 studies found that 25% of them reported HIV testing as a barrier rather than a facilitator in involving men in care, as men were reluctant or fearful of learning their status [27]. In a study in South Africa completed in 2009, there were mixed results in which some men described it being important to know one's status and to get tested as part of PMTCT efforts, while other men were also fearful and worried about guilt with the possibility of

receiving a positive HIV test result [20]. Combined with the fear of HIV testing was the belief that it may be required: in Uganda, focus group discussions in 2009 revealed that men (and sometimes women) were reluctant to go to the antenatal clinic as they were worried about HIV testing being compulsory [29]. In some studies, men reported that it was enough to know their partner's status as this would be a proxy for their own [20-22]. This misperception, along with a low knowledge of PMTCT or that partner involvement was important, also serve as barriers for male attendance to antenatal clinics [24, 28].

Clinics have also been described as not being male friendly and/or having long wait times [19, 20]. Not being male friendly can mean many things, including not having enough physical space for the male partner in the waiting or exam rooms, not being treated as a welcomed client by clinic staff, or that fatherhood preparation is not discussed at all [20, 22, 24]. In one study, male participants discussed an idea of having a space for fathers at the antenatal clinic, staffed by male staff and nurses, who would address health topics other than HIV [20]. As one man put it, he thought it would be a good idea to have “a consulting room for advice about life or fatherhood, and maybe you talk about HIV as part of that” [20].

There are also female factors that are at play, in that women do not involve their male partners out of fear of domestic violence, accusations of infidelity, stigmatization, abandonment or divorce [10, 23, 24, 30-32]. Disclosure is many times a challenge for HIV positive women and rates of disclosure are thus quite low [31, 33-38]. With the variety of barriers to involve male partners in PMTCT, the solution to this issue should strive to address as many as possible.

Home-based testing alleviates many of the barriers of male partner involvement, with few disadvantages from the perspective of individuals, public health and health programs. On the individual level, home-based testing has the potential to overcome the issues of male participation in PMTCT, namely because the location is not associated with a service for pregnant women and the onus of inviting and initiating partner testing and disclosure is on the health provider, not the female or male clients. Furthermore, home-based testing for PMTCT has been found to acceptable and even favored by clients to clinic-based testing [26, 33]. The advantages for male partners is that they would not need to attend the antenatal clinic for testing, that they can schedule a time that is best for them and not wait in lines, and that they will be able to rely on the health provider to lead HIV status disclosure. For females, the advantages are similar, although women will still need to attend clinic at other times in pregnancy. Additionally, women will not be the ones who have to

bring the men back to the clinic, a task that may not be pleasant, especially if it is not culturally appropriate for women to lead or if women are fearful of asking their male partner to be HIV tested [10, 23, 24, 30-32].

The disadvantages for both partners is that they still may be worried about testing and the confidentiality of their results, particularly if their home does not offer adequate privacy. For females, there may still be a concern that intimate partner violence (IPV), or other events such as abandonment, may occur after the health provider has left the home, especially if she is HIV positive. The risk of intimate partner violence should also be weighed on a public health level, as the introduction of an overall beneficial intervention that is harmful to some is still of concern. This is an important outcome to follow in studies, even if overall IPV may be low, it has been found to be higher among women who test HIV positive [30]; however, recent studies have NOT found an increase in IPV risk associated with partner testing [26, 39].

The advantages of home-based testing on a public health level are numerous. First, young males are a difficult group to test as they seldom attend health clinics and when HIV positive men are linked to care, it is usually delayed [40, 41]. Men in Mozambique are 33% more likely to present late for ART initiation (defined as CD4 <100 or WHO stage IV) than females (female vs. male aOR=0.66, 95% CI: 0.62-0.69) while men under 45 years old in Cameroon were 50% more likely to initiate ART late (male vs. female aOR=1.5, 95% CI: 1.3-1.7) [40,41]. Home-based testing is an opportunity to test men and link them to care. Second, home-based testing in sub-Saharan Africa has a higher uptake than clinic-based testing (26, 42-47). In a recent study in western Kenya completed in 2013, home-based testing as part of antenatal care resulted in 85% of couples undergoing couple HIV counseling and testing versus only 36% in the clinic-invitation arm [26]. Bars and churches also resulted in higher male uptake of HIV testing than clinics in a study conducted in the Democratic Republic of Congo, although attendance at these venues was lower than studies which included home-based testing [48]. Third, the benefits of male involvement during PMTCT has a cascade effect for the mother and unborn child, including higher uptake of PMTCT interventions such as use of nevirapine, lower risk of vertical transmission and higher rate of HIV-free infant survival [10-15]. In a study in Nairobi, Kenya, between 2001-2002, women who returned with their partners were 3 times as likely to return for nevirapine for their infants ($p=0.02$) and administer nevirapine at delivery ($p=0.009$) [10]. In another cohort following pregnant and postpartum women in Kenya completed in 2005, the infants of partners who attended

antenatal care had an HIV acquisition or mortality that was nearly halved compared to infants of partners who did not attend (aHR=0.55, 95% CI: 0.35-0.88) [11]. Home-based testing can also leverage the opportunity to educate the couple on facility delivery, postpartum family planning, exclusive breastfeeding and other health topics. These benefits have a great public health impact, as all of these are directly related to the health of females, their male partners, and the unborn child.

However, a discussion of the benefits of home-testing is not complete without the programmatic perspective. Home-based testing requires staffing resources and the ability to travel to clients, some of whom live far from clinics. The rural to urban ratio, which gives us an idea of the distance some Kenyans may live from fully staffed hospitals and clinics, was more than 2-to-1; in 2009, 26.1 million Kenyans lived in rural areas while 12.5 million lived in urban areas [49]. Health providers working in home-based care programs, now that they have entered a new domain, may feel responsible for what occurs in the home or come across family or private situations that are challenging to navigate professionally. There may be an expectation that other services will become home-based, which may not be feasible. However, in the process of doing home-based testing, opportunities arise for conducting couple counseling around relevant health topics which could result in fewer negative outcomes, including a reduction in unwanted pregnancies, in mixed-fed infants, and HIV infections, all of which are costly to the health system [50, 51]. Indeed, community home-based testing has been found to be cost-effective in rural Kenya [52]. During this testing, the cost of was \$2.60 USD per community member (n=6750), \$5.88 per person tested, and \$84 for each positive case detected. In studies of home-based testing for male partners in PMTCT, cost-effectiveness as well as acceptability from all parties involved should be included. Importantly, cost-effectiveness for this research was conducted by a colleague and will be presented in the same journal supplement as the main quantitative results of the study.

In summary, home-based testing for male partners in PMTCT, which may include a package of services, health education and referrals, can address the barriers of male testing in antenatal clinics and maximize the advantages of client convenience, facilitation of HIV disclosure to partners, and higher uptake of HIV testing. Home-based testing, at an individual, public health, and programmatic level, shows promise in having more advantages than disadvantages, and the ongoing research of this approach will help policy makers provide recommendations for PMTCT programs.

1.3 IMPETUS FOR THE HOPE STUDY

The impetus of the Home-based Partner Education and Testing (HOPE) Study, a randomized clinical trial that conducted in Kisumu, Kenya from 2012 to 2013, was based on the aforementioned findings that male participation in prevention of mother-to-child-transmission (PMTCT) is associated with better outcomes for the mother and the child, however male involvement has been difficult to achieve in antenatal settings. The research literature suggests that antenatal clinics may pose too much of a barrier, while other non-clinic venues, including homes, may be better. Therefore, a randomized clinical trial was justified to investigate whether 1) home-based testing results in higher male uptake of testing; and 2) home-based education results in better maternal and child health outcomes (facility delivery, exclusive breastfeeding and postpartum contraception).

To begin answering the first question, a pilot study was undertaken by Dr. Alfred Osofi, a fellow student and colleague, in Ahero, Kenya [26], where women who presented to the antenatal clinic were randomized to take home an invitation for the male partner to return (control arm) or to home-based HIV testing (intervention arm). The partners of the women in the home HIV testing arm were 2.37 times (95% CI 1.90-2.96) more likely to be tested at 6 weeks following enrollment than in the control arm. This pilot study of 300 women and their partners also gave evidence there was no increased risk for intimate partner violence. In fact, women in the home testing arm self-reported an improvement in relationship. The pilot study also gave us a sense of the feasibility of running a home-based testing intervention from an antenatal clinic.

While we were quite confident that home-based testing leads to higher uptake of HIV testing as evidenced in the pilot project, the HOPE Study was designed with an additional component, home-based education, to examine whether other health behaviors can be influenced by a home-based visit and if the difference in uptake of testing would withstand a longer follow-up time. In addition, a cost-effectiveness component was added to test whether the intervention would lead to a cost savings and be financially feasible as a national program. This randomized clinical trial was designed to assess the efficacy of the intervention at several sites, but due to a budget reduction in the grant, the study was limited to a single site. A qualitative study was also added after the trial began in order to understand the intervention better and to identify potential areas for improvement that would be useful in a larger study or a scale-up of the program.

It is important to note that the University of Washington and Dr. Carey Farquhar, Principal Investigator, have close ties with Kenyan institutions, including the Kenyatta National Hospital and the University of Nairobi. These ties were critical in being able to conduct research and plan next steps for the HOPE intervention. Dr. John Kinuthia, as Co-PI on the study, and Dr. Alfred Osoi, who ran the pilot study and is a leader of the HOPE team, also provided expertise and links to the Ministry of Health. This strong leadership provided me the opportunity to be a part of study design, implementation and management as well as lead the analysis.

1.4 REMAINING CHAPTERS

The remaining chapters of this dissertation present the results and discuss next steps for the Home-based Partner Education and Testing (HOPE) Study. The second chapter presents the quantitative results of the study, including the effectiveness of the intervention to increase partner uptake of HIV testing, disclosure of HIV status, identification of serodiscordant couples as well as facility delivery, postpartum family planning and exclusive breastfeeding, which is in manuscript form for submission to a JAIDS supplement publication in January 2016. The third chapter presents the qualitative results of the study, including the perceptions of couples who received the intervention as well as feedback on potentially modifiable aspects of the intervention and discusses this in the context of quantitative results, in a draft manuscript form for submission to a qualitative journal. The final chapter closes with thoughts on mixed methods, refining the intervention and next steps for research and implementation of home-based partner education and testing.

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Chapter 2. EFFECTIVENESS OF HOME-BASED HIV TESTING AND EDUCATION: QUANTITATIVE RESULTS

2.1 MANUSCRIPT TITLE

Home-based HIV testing among pregnant couples increases partner testing and identification of serodiscordant partnerships

2.2 AUTHORS

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2.3 ABSTRACT

2.3.1 *Introduction*

Male partner involvement and HIV testing have been recognized as important components to prevention-of-mother-to-child transmission (PMTCT); however, male antenatal attendance has been difficult to achieve. Home-based HIV testing among pregnant couples may be an effective strategy to reach and test men.

2.3.2 *Methods*

Women attending their first antenatal visit at Kisumu District Hospital in Kenya who were married or cohabiting, did not have their partner with them at the clinic, ≥ 8 weeks gestation, had not experienced intimate partner violence in the past month and were living within study boundaries, were enrolled from September 2013 to June 2014. Women were randomized to home-based education and HIV testing (HOPE) or to written invitations for male partners to attend clinic (INVITE). Male partner HIV testing, couple testing, disclosure, serodiscordant status, facility delivery, exclusive breastfeeding and postpartum family planning were compared at 6 months postpartum.

2.3.3 *Results*

Of 1101 women screened, 620 were eligible and 601 were randomized either to HOPE (n=306) or INVITE (n=295). Women and men had a median age of 24.9 and 30.1, respectively. At 6 months postpartum, male partners were more than twice as likely (RR=2.10; 95% CI: 1.81-2.42) to have been HIV tested in the HOPE arm (n=233, 87%) compared to the INVITE arm (n=108, 39%). Couples in the HOPE arm (n=192, 77%) were three times more likely (RR=3.17; 95% CI: 2.53-3.98) to have been tested as a couple than the INVITE arm (n=62, 24%) and women in the HOPE arm (n=217, 88%) were also twice as likely (RR=2.27; 95% CI: 1.93-2.67) to know their partner's HIV status as the INVITE arm (n=98, 39%). More serodiscordant couples (RR=3.38; 95% CI: 1.70-6.71) were identified in the HOPE arm (n=33, 13%) than in the INVITE arm (n=10, 4%). No differences were found for facility delivery, exclusive breastfeeding or postpartum family planning.

2.3.4 *Conclusion*

Home-based HIV testing among pregnant couples resulted in higher uptake of male testing and couple testing as well as rates of disclosure and identification of serodiscordant couples. This intervention not only has implications for PMTCT, but also for testing men as part of overall HIV testing strategies to reach the UNAIDS 90-90-90 targets by 2020.

2.4 INTRODUCTION

In 2013, an estimated 11,000 children were infected with HIV in Kenya, as approximately 14% of HIV positive pregnant women transmitted the virus to their infant [1]. Great progress has been made in scaling up prevention of mother-to-child transmission (PMTCT) efforts in the last five years, but more needs to be done in order for Kenya to reach its goal of elimination.

While the cornerstone of PMTCT has been female testing and linkage to care, male testing in antenatal care has been recognized as an important component to PMTCT. Male testing during the antenatal period is particularly important for HIV negative women as HIV acquisition is high in pregnancy [2-5] and in the postpartum phase [6-8]. Furthermore, male involvement is associated with better adherence to PMTCT interventions and maternal and infant outcomes [9-14]. However, according to Kenya PMTCT programme data, while over 90% of

women attending antenatal testing were tested for HIV in Kenya in 2013, only 4.5% of male partners were tested for HIV in the preceding 12 months [1]. In 2014, the National AIDS Control Council of Kenya identified increased male involvement as a key strategy to eliminate mother-to-child-transmission (eMTCT) [1].

Partner invitations are the most widely used method among PMTCT programs to try to involve men but have demonstrated limited success until recently [15-18]. In two randomized clinical trials published in the last year, partner invitation plus tracing in Malawi as well as home-based testing in Kenya have demonstrated better effectiveness at reaching and testing male partners than invitation alone [19-20]. In the partner tracing study, 74% of men presented to the clinic in the partner tracing arm compared to 52% of men in the invitation only arm while in the home-based testing study, 89% of men were reached in the home visit arm compared to 37% reached in the invitation only arm. However, both studies had sample sizes of 200-300, had short follow-up time of 4-6 weeks, and did not assess costs of the intervention to our knowledge. Home-based testing and education in particular may overcome implementation barriers of finding ways to bring men to the clinic and instead brings the intervention to them.

As a larger pragmatic trial with a cost-effectiveness component, the Home-based Partner Education and Testing (HOPE) Study compared effectiveness of scheduled home visits with pregnant women and their partners against written invitations encouraging men to return to the clinic with a 6 month postpartum follow-up time. This study takes the necessary next step of testing a proposed intervention with the goal of influencing policy and practice if proven to increase partner testing in an acceptable and cost-effective manner.

This study was conducted in close collaboration with National AIDS STD Control Programme (NAS COP), Kenyatta National Hospital, and Kisumu District Hospital. We recognized challenges in working with the de-centralized government system as Kenya governs largely from the county-level. Nevertheless, our collaborations with NAS COP and the national and local hospital were successful in facilitating the study and our discussions regarding the results and next steps.

2.5 METHODS

2.5.1 *Female recruitment and enrollment*

Pregnant women attending their first antenatal visit at Kisumu District Hospital from September 2013 to June 2014 were recruited for participation in a randomized clinical trial. Women gave verbal consent to be screened and were asked about demographics, HIV testing history, and relationship status. Women who were ≥ 14 years of age, ≥ 8 weeks gestation (prior criteria ≥ 14 weeks gestation changed midway through enrollment late January 2014), married or cohabiting, did not have a male partner present at the present clinic visit, had a partner ≥ 18 years of age, planned to live ≤ 40 km from the clinic now until 9 months postpartum (prior criteria ≤ 20 km changed midway through enrollment), and had not experienced physical, verbal or sexual abuse in the past month, were eligible for participation in the study. Eligible women who gave written informed consent were randomly assigned to receive a home-based partner education and testing (HOPE) visit within a two weeks of enrollment or a written invitation encouraging the male partner to attend the clinic (INVITE) and delayed home-based partner education and testing at 6 months postpartum. Home location visits were completed for all participants for tracking and follow-up purposes.

2.5.2 *Male enrollment and follow-up*

Men in the home visit arm were consented and enrolled at the HOPE intervention visit within two weeks of female enrollment while men in the invitation arm were consented and enrolled at the 6 month postpartum follow-up visit at home. In the INVITE arm, couples received a delayed home-based partner education and testing intervention at 6 months postpartum. Women had visits at 6 weeks and 14 weeks postpartum at the clinic and both women and men were visited at 6 months postpartum at home. Follow-up of couples ended in June 2015.

2.5.3 *Home-based intervention*

A team of two health advisors, one male and one female, arranged a time to meet at the couple's home within 2 weeks of the woman's enrollment. In addition to HIV testing, couples received education regarding facility delivery, exclusive breastfeeding, postpartum family planning. This

brochure was developed using WHO and UNICEF resources [21-23] and translated into Dholuo and Kiswahili, the local languages, and provided to couples and also served as a guide for health advisors (see Appendix A). Serodiscordant and concordant positive couples received further education on HIV treatment, PMTCT and the importance of enrolling at a Comprehensive Care Clinic (CCC).

2.5.4 *HIV testing*

Women were initially tested at the clinic after enrollment into the study and were tested again with their partners at home (HOPE), or at the 6 month follow-up visit (INVITE), after receiving pre-test counseling and giving consent for testing. While couple testing was primarily offered, individual testing was offered to those who did not want to test as a couple although this was infrequent. Type of rapid tests and testing algorithms used were according to Kenya National AIDS/STI Control Programme (NASCOP) protocol at the time, which called for Colloidal Gold (KHB)[®] as the initial test, First Response[®] as the second test, and Unigold[®] as the tie-breaker.

2.5.5 *Data collection and statistical methods*

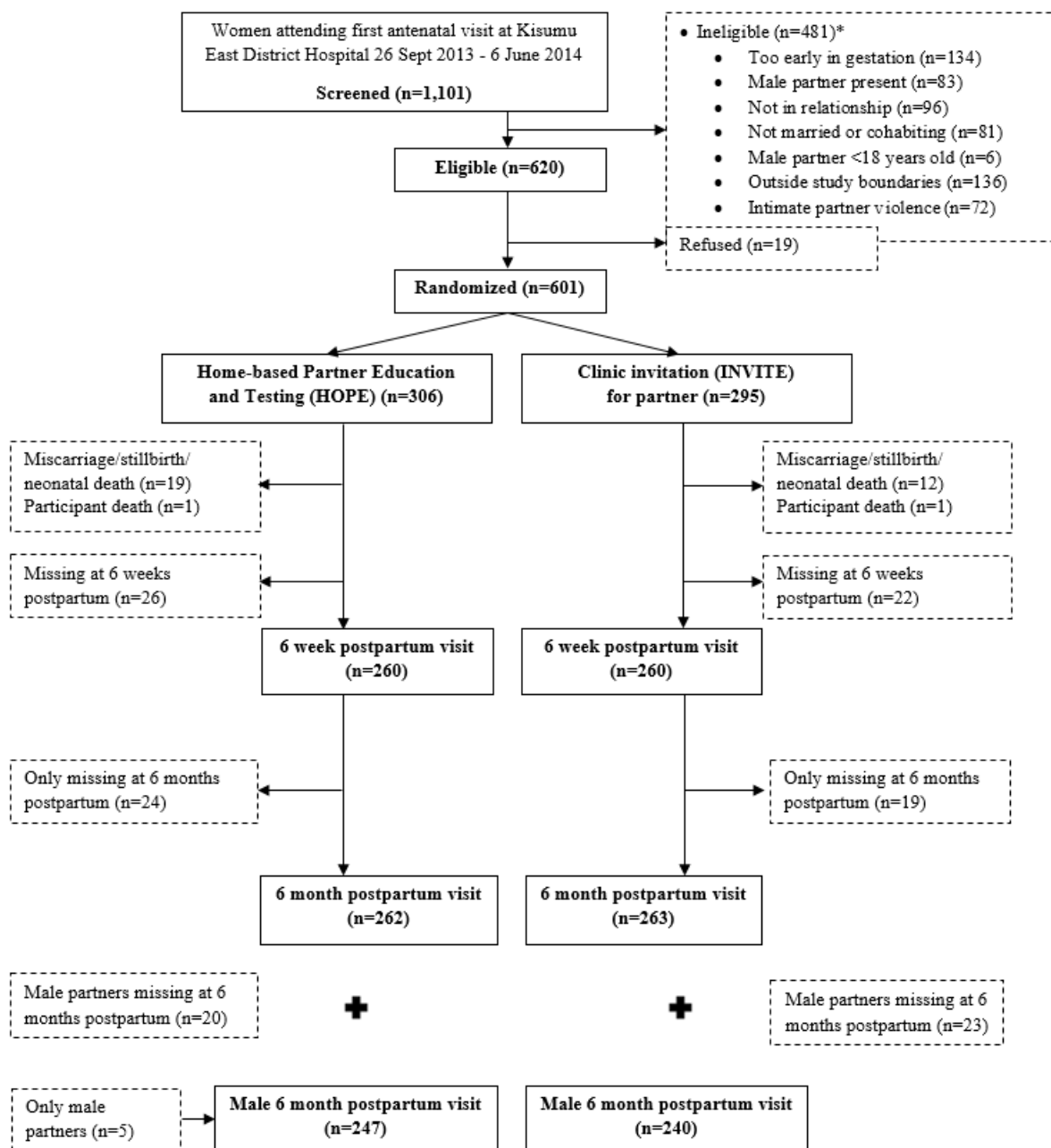
Data were collected with mobile smartphones and tablets using Open Data Kit (ODK), an open-source data collection platform developed by Google and University of Washington's Department of Computer Science and Engineering.

Stata version 12.0 (College Station, Texas, USA) was used to conduct statistical analyses. All analyses were conducted using the intent-to-treat principle. To determine adequacy of randomization, baseline parameters were compared: independent t-tests were calculated for comparisons of continuous variables and chi-squared tests were calculated for comparisons of categorical variables. Relative risks were calculated for each outcome of interest (male report of uptake of HIV testing; and female report of disclosure, couple testing, discordant couples identified, facility delivery, exclusive breastfeeding and postpartum family planning) using data from the 6 month postpartum follow-up visit. Relative risks were also calculated for exclusive breastfeeding and postpartum family planning from data from the 6 week follow-up visits.

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2.6 RESULTS

Between September 26, 2013 and June 6, 2014, 1101 pregnant women attending their first antenatal care visit were screened. Of the 620 (56.3%) eligible women, 601 (96.9%) were randomly assigned to received home-based partner education and testing (HOPE) (n=306) or a written invitation encouraging the male partner to attend the clinic (INVITE) (n=295). Reasons for ineligibility among the 481 ineligible women, with some being ineligible for more than one reason, included <14 weeks gestation (n=105, 21.8%), with a change in criteria midway through enrollment to <8 weeks gestation yielding fewer ineligible clients (n=29, 6.0%), male partner present (n=83, 17.3%), not in a relationship (n=96, 20.0%), in a relationship but not married or cohabiting (n=81, 16.8%), male partner <18 years old (n=6, 1.2%), being >20 km from clinic now until 9 months postpartum (n=53, 11.0%), with a change in criteria midway through enrollment to >40 km not improving eligibility (n=83, 17.3%), and experienced intimate partner violence (physical, sexual or verbal) in the past month (n=72, 15.0%). Nineteen eligible women were not enrolled as they did not want to participate in the study (n=19, 4.0%). Figure 2.1 illustrates the enrollment and follow-up of participants in the HOPE Study.



*Women could be ineligible for more than 1 reason

Figure 2.1 Enrollment and follow-up in the Home-based Partner Education and Testing (HOPE) Study

The HOPE and INVITE arms had similar baseline characteristics (see Table 2.1). Average age was 24.9 years (SD=4.9) for women and 31.0 years (SD=6.4) for men. Women were in their 21.1 week of pregnancy at enrollment on average (SD=6.2), and had an average of 2.3 prior pregnancies (SD=1.4). Due to eligibility criteria of being married or living together, all but 3 in the INVITE arm were married, with the majority of couples living together (n=554, 92.2%), and about ten percent being in polygamous marriages (n=54, 9.3%). Nearly half of women completed primary school only or less (n=260, 44.4%). Household income did differ by arm (p=0.005) as a greater proportion of women in HOPE had <10,000 Kenyan shillings/month of household income (n=174, 61.7%) than in INVITE (n=139, 50.0%), although having a separate income from their partner was similar in both arms (n=189, 49.4%). About twenty percent of women were HIV positive (n=117, 19.5%), with nearly half of them being diagnosed for the first time at enrollment (n=53, n=45.3%). About two-thirds of women reported that their partner had been tested for HIV before (n=373, 63.7%), with the majority reporting they knew their partner's status (n=345, 58.9%), but less than forty percent had been tested as a couple (n=221, 37.7%). For those who reported they knew their partner's status (n=345), 13.9% men (n=48) were reported being HIV positive.

Table 2.1 Characteristics of participants in the Home-based Partner Education and Testing (HOPE) Study

Baseline characteristic*	HOPE (n=306)^{‡¶}	INVITE (n=295)^{‡¶}
	mean (SD)	mean (SD)
Female age in years	24.7 (4.9)	25.0 (4.9)
Male partner age in years	30.6 (6.1)	31.3 (6.7)
Gestational age in weeks	21.0 (6.0)	21.1 (6.3)
Gravidity not including current pregnancy	2.4 (1.3)	2.3 (1.4)
Number of living children	1.4 (1.2)	1.2 (1.3)
Number of lifetime sexual partners	2.4 (1.3)	2.4 (1.2)
	n (%)	n (%)
Married	299 (100%)	284 (99.0%)
Living together	285 (95.3%)	269 (93.7%)
Polygamous	23 (7.7%)	31 (10.9%)
Completed education		
Primary school or less [‡]	137 (46.0%)	123 (42.9%)
Some secondary school	55 (18.5%)	47 (16.4%)
Secondary school completed	59 (19.8%)	69 (24.0%)
Above secondary	47 (15.8%)	48 (16.7%)
Has separate income	142 (47.5%)	147 (51.4%)
Household monthly income <10,000 Ksh*	174 (61.7%)	139 (50.0%)
Female HIV status		
Total % positive	62 (20.3%)	55 (18.6%)
Newly diagnosed	28 (9.2%)	25 (8.5%)
Male partner tested for HIV before	198 (66.2%)	175 (61.0%)
Female knows male status	179 (59.9%)	166 (57.8%)
If knows status, % HIV positive	27 (15.1%)	21 (12.7%)
Previous HIV couple testing	119 (39.8%)	102 (35.5%)

*No significant differences ($\alpha=0.05$) between arms for all categories except for household income ($p=0.005$)

[‡]7 missing in HOPE (home-based partner education and testing), 8 missing in INVITE (clinic invitation for partner), but none missing for female HIV status

[¶]1 in HOPE, 1 in INVITE preferred not to respond to gestational age; 1 in HOPE, 2 in INVITE were not sure for lifetime sexual partners; 2 in INVITE, 4 in HOPE preferred not to respond for lifetime sexual partners; 1 in HOPE preferred not to respond, 3 missing in INVITE for polygamous relationship

Available data for the 6 week and 6 month postpartum visits are explained in Figure 2.1. Women with miscarriage/stillbirth/neonatal death or had died before 6 weeks postpartum were excluded from follow-up (n=20 in HOPE, 6.6%; n=13 in INVITE, 4.4%). Therefore, the number of women expected for follow-up was 286 for HOPE and 282 for INVITE. Both arms had similar loss to follow-up and greater than 85% retention for females (n=248, 86.7% in HOPE; n=254, 89.8% in INVITE) and males (n=247, 86.4% in HOPE; n=240, 84.8% in INVITE) at 6 months postpartum.

At 6 months postpartum, male partners were more than twice as likely (RR=2.10; 95% CI: 1.81-2.42) to have been HIV tested in the HOPE arm (n=233, 87%) compared to the INVITE arm (n=108, 39%) per their own self-report. Females in the HOPE arm (n=217, 88%) were also twice as likely (RR=2.27; 95% CI: 1.93-2.67) to know their partner's HIV status as the INVITE arm (n=98, 39%). One reason for the increased likelihood of disclosure is that couples in the HOPE arm (n=192, 77%) were three times more likely (RR=3.17; 95% CI: 2.53-3.98) to have been tested as a couple than the INVITE arm (n=62, 24%). Increase in uptake of partner testing in the HOPE arm also identified more discordant couples (RR=3.38; 95% CI: 1.70-6.71) in the HOPE arm (n=33, 13%) than the INVITE arm (n=10, 4%). No women in the HOPE arm seroconverted during the study, but two in the INVITE arm did.

However, maternal child health outcomes of facility delivery, exclusive breastfeeding and postpartum family planning, did not differ by study arm as there were high rates of uptake in both HOPE and INVITE, with HOPE having slightly higher uptake. Nearly all women delivered in a health facility (n=504, 97%), with no significant difference between study arms (RR=1.02; 95% CI: 0.99-1.06). Most women were exclusively breastfeeding at 6 weeks postpartum (n=470, 90.4%), which did not differ by study arm (RR=1.05; 95% CI: 0.99-1.11). By 6 months postpartum, about a third of women were still exclusively breastfeeding, with a slightly higher uptake in HOPE (n=95, 36%) than in INVITE (n=81, 31%), but was also not statistically significant (RR=1.18; 0.92-1.50). Family planning uptake was high in both arms at 6 weeks postpartum, as more than half of all women were using a hormonal method, IUD or sterilization (n=301, 57.9%), which increased to three-quarters of women by 6 months postpartum (n=398, 75.8%), with also no significant differences between arms (RR=1.06; 95% CI: 0.92-1.23 | RR=1.02; 95% CI: 0.92-1.12, respectively).

Additionally, at 6 months postpartum, women were more than three times as likely to report an improved relationship with their partner (RR=3.62; 95% CI: 2.72-4.83) in the HOPE arm (n=157, 61%) compared to the INVITE arm (n=44, 17%). One woman in the HOPE arm at 6 months postpartum reported no longer being in the relationship, but she did not attribute it to study participation. Additionally, four women and one man in the HOPE arm declined to participate at the 6 months postpartum visit due to separation, although further information regarding their separation was not attainable. Twelve women in INVITE and 16 in HOPE reported being physically harmed by their partner, and one in each arm attributed this to the study. All women who experienced domestic violence were referred to local gender violence services. Table 2.2 presents the study outcomes.

Table 2.2 Outcomes of the Home-based Partner Education and Testing (HOPE) Study

6 Month Postpartum HIV Outcomes^a	HOPE	INVITE	RR	95% CI
Male HIV tested	233 (87%)	108 (39%)	2.10	1.81-2.42
Female knows male status	217 (88%)	98 (39%)	2.27	1.93-2.67
Tested as couple	192 (77%)	62 (24%)	3.17	2.53-3.98
Discordant couples identified	33 (13%)	10 (4%)	3.38	1.70-6.71
MCH Outcomes*	HOPE	INVITE	RR	95% CI
Facility delivery	255 (98%)	249 (96%)	1.02	0.99-1.06
Exclusive breastfeeding at 6 weeks postpartum	241 (92%)	229 (88%)	1.05	0.99-1.11
Exclusive breastfeeding at 6 months postpartum	95 (36%)	81 (31%)	1.18	0.92-1.50
Family planning hormonal, IUD or sterilization use at 6 weeks postpartum	160 (62%)	158 (61%)	1.01	0.88-1.16
Family planning hormonal, IUD or sterilization use at 6 months postpartum	214 (82%)	211 (80%)	1.02	0.92-1.12
6 Month Postpartum Relationship Outcome	HOPE	INVITE	RR	95% CI
Improved relationship	157 (61%)	44 (17%)	3.62	2.72-4.83

^aOf 568 women with live births and no neonatal deaths, 487 men (86%) had 6 month postpartum visits and 502 women (88%) had both a 6 week and 6 month postpartum visit which captures information for entire study period. Male report for Male HIV tested: n=247 for HOPE, n=240 for INVITE; Female report for other testing outcomes: n=248 for HOPE, n=254 for INVITE.

*Female report for facility delivery and 6 week postpartum outcomes: n=260 for HOPE, n=260 for INVITE; Female report for 6 month postpartum outcomes: n=262 for HOPE (n=261 for family planning outcome), n=263 for INVITE

^Female report for improved relationship: n=259 for HOPE, n=263 for INVITE

2.7 DISCUSSION

Home-based partner education and testing resulted in a more than 2-fold increase in male partner testing and HIV status disclosure and more than a 3-fold increase in couple testing and discordant couples identified among pregnant women when compared to partner invitation to attend antenatal care. The identification of discordant couples is highly relevant in the context of

PMTCT as couples can take steps in pregnancy to prevent vertical and thus potentially horizontal transmission. This randomized clinical trial had similar outcomes to a study conducted in nearby Ahero, Kenya, which also compared HIV testing uptake between partners receiving home-based testing and those receiving clinic invitation at six weeks post-enrollment [20]. The longer follow-up time in our study also suggests that the higher uptake of testing between home-based and clinic invitation arm persists through pregnancy and up to 6 months postpartum. Home-based scheduled testing also appears to be more promising than invitation plus tracing male partners to come to clinic for testing [19], home-based door-to-door testing [24], and more effective than written invitations alone without follow-up [15-18]. However, a one-size-fits-all approach may not be as efficient as leveraging multiple strategies, which may be reasonable given that invitations and partner tracing have recently demonstrated effectiveness in reaching men in two studies published in 2015 [18, 19]. These methods may be included as part of a comprehensive strategy of male partner involvement during the antenatal period, starting with invitations to attend clinic, then tracing and home-based visits for those who are not reached with the first methods. Also, the influence of financial incentives should not be overlooked in studies conducted such as this one, as even transport allowance and study compensation may have played a role in convincing male partners to join.

Home-based partner education and testing did not result in increases in facility delivery, exclusive breastfeeding or postpartum family planning, although rates of these outcomes were high in both arms. Therefore, the education provided in the intervention may have had the potential to be effective, but in the context of high background uptake, there was little room to improve. Reasons for high background uptake include a recent introduction of free maternity care including delivery in Kenya as well as the direct physical referral to family planning nurses from immunization clinic nurses at Kisumu District Hospital. The exception to high uptake was 6 month exclusive breastfeeding, where only a third of women in both arms achieved this, suggesting that a one-time couple education visit during pregnancy may not be enough to support women to breastfeed their infants exclusively for 6 months postpartum. Additionally, women in HOPE were more than 3 times as likely to report an improvement in relationship with their partner at 6 months postpartum than women in INVITE, suggesting that this intervention may have had impacts in partner communication and support.

Our study had several strengths. Besides being a randomized trial, our study also included both a cost-effectiveness component, also published in this supplement, and a qualitative evaluation of the intervention from the participants' perspectives (to be published). Our study followed both women and men until 6 months postpartum to gauge the long-term effect of the intervention, which gave men in the INVITE arm the opportunity to test throughout pregnancy and even after delivery into the postpartum phase. Men were also included as participants and were able to report their own testing. We were able to retain >85% of women and men in both arms 6 months postpartum. Our study was conducted in a high HIV prevalence setting with high antenatal attendance, and our results lends generalizability to similar settings.

The main weakness of our study was that of limited eligibility; almost half of women attending their first antenatal visit for their pregnancy were excluded from the study, mostly due to being early in gestation, and being outside of study boundaries either at the present time or were planning on leaving the area sometime before 9 months postpartum. Both of these exclusions were for study considerations; the former to reduce the number of early pregnancy losses in the study and the latter to reduce lost to follow-up. However, early in gestation and leaving the area may not need to be an exclusion criteria for programmatic considerations. About sixteen percent of women reported not being in a relationship, and would be excluded in a real-world setting as the intervention is not relevant unless these women identify a partner. Women not being married or living together were also excluded as it may be have been challenging to identify a potential home location to conduct the intervention, although perhaps there are solutions to these situations such as conducting the scheduled visit at a clinic location. Also, while participants were comparable between HOPE and INVITE, a statistically significant larger proportion of women in HOPE reported lower monthly income. However, we hypothesize that if this would have had an effect on the study, it would have attenuated our result since lower income is likely related to lower likelihood of testing.

In summary, our study found that scheduled home-based visits are an effective, acceptable and feasible strategy to conduct couple testing for pregnant women and their partners. Additionally, more discordant couples were identified with this method than with written invitation to attend clinic, which is important as the intervention has the potential to prevent further HIV transmission vertically and horizontally. However, the intervention was not able to impact facility delivery, exclusive breastfeeding or postpartum family planning, as most of these

had high background rates. Home-based couple education on these topics may be influential in areas of low uptake and less support while different interventions should be pursued for exclusive breastfeeding. Overall, the intervention was most effective at its central and direct objective of male partner testing and related HIV testing outcomes.

2.8 CONCLUSION

As a strategy that tests partners, home-based testing during pregnancy reaches beyond PMTCT and could be also considered as a type of partner services or family-based model. While women have been relatively easier to reach for HIV testing through antenatal care and other healthcare visits as well as community-based strategies such as door-to-door testing and mobile clinics, men as a population have been difficult to reach. Therefore, home-based testing during pregnancy should be added not only to the toolkit of PMTCT interventions but to overall HIV testing strategies, particularly now as the HIV community tackles the challenge of the UNAIDS 90-90-90 targets by 2020 [25].

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Chapter 3. PERSPECTIVES OF HOME-BASED HIV TESTING AND EDUCATION: QUALITATIVE RESULTS

3.1 TITLE

Evaluation of home-based HIV testing and health education among pregnant couples in Kenya: a qualitative study

3.2 AUTHORS

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3.3 ABSTRACT

3.3.1 *Introduction*

Testing men for HIV as part of antenatal care has been identified as an important but difficult component of prevention-of-mother-to-child transmission (PMTCT). Home-based partner testing has been explored as an alternative to clinic-based testing and invitation-based models of engaging male partners. The objective of this qualitative study is to better understand the quantitative results found in the Home-based Partner Education and Testing (HOPE) Study, a randomized clinical trial.

3.3.2 *Methods*

Couples who received the home-based couple HIV testing and education intervention as part of the HOPE Study who had not yet exited the main study were eligible to participate. Twenty-one couples were purposively selected based on HIV status and participated as individuals and couples in in-depth interviews. Two coders were involved in the analysis, including codebook creation, independent coding, reconciliation of codes, and identification of major themes.

3.3.3 *Results*

Home-based couple HIV testing and counseling facilitated partner testing and disclosure, was preferable due to privacy and quality time, and helped participants overcome their fear of testing.

Couples also appreciated the efficiency and appropriateness of partner involvement and joint education and reported increased partner support in pregnancy and postpartum as well as improved relationship due to disclosure. These qualitative results align well with and explain quantitative outcomes of high HIV testing uptake and rates of disclosure as well as report of improved relationship. Couples reported having learned or reinforced knowledge of facility delivery and family planning and cited that this knowledge affected their behaviors. However, in quantitative results, these behaviors were high in both those who received and did not receive the intervention most likely due to programmatic clinic changes occurring at the same time.

Exclusive breastfeeding was identified as a challenge in both qualitative and quantitative results. Couples overwhelmingly had positive feedback for the intervention, although when asked about the possibility of being visited by a local community health worker instead of a non-local health advisor, most were opposed.

3.3.4 *Conclusion*

Home-based couple HIV testing and education was identified by couples as having many benefits, which is also supported by quantitative results. Antenatal programs should consider engaging male partners with home-based testing and education in order to facilitate partner testing and disclosure, potentially averting MTCT, and to improve partner support during the time of pregnancy.

3.4 INTRODUCTION

Implementing HIV testing and maternal and child health education in resource-poor settings among pregnant couples remains a challenge as women often present alone at antenatal appointments. Pregnant women are at an increased risk of acquiring HIV and transmitting the infection to their infants, which makes HIV testing and prevention during the antenatal period critical [1-5].

Testing only women for HIV when they attend antenatal appointments addresses half of the equation for HIV transmission risk and leaves men out of the discussion on maternal health topics, as men seldom attend antenatal appointments with their partners, even when invited [6-8]. In a recent study in Kenya, only 37% of men who received written invitations from their partners to attend the antenatal clinic for counseling and testing came to the clinic. Invitations may have

improved upon standard of care [9], but more than half of men did not become involved in antenatal visits using this method, signifying that an alternative or complementary approach is needed [10]. Qualitative studies have reported numerous barriers to male attendance, including the perception of antenatal attendance as a female responsibility, the experience of not being welcome at the clinic and the belief that it is culturally inappropriate as a male to be involved in these clinic visits [11-18]. Finding ways to involve men is important because when male partners do attend antenatal clinics with their partners, higher rates of uptake of prevention of mother-to-child transmission (PMTCT) interventions are observed [19-23].

Home-based testing and education has been explored as an alternative to clinic-based testing and invitation-based models of engaging male partners [10, 24-28]. This qualitative study was nested within a larger randomized clinical trial of home-based partner education and testing (HOPE Study). Rather than explore barriers of male involvement to antenatal care as past qualitative studies have done, the objective of this qualitative study was to better understand why home-based testing and education was successful in the parent study so as to guide future studies and scale-up of home-based testing and education.

3.5 METHODS

3.5.1 *Parent study*

Between September 2013 and June 2014, women attending their first antenatal visit at Kisumu District Hospital were recruited for a randomized clinical trial of home-based partner education and HIV testing in Kisumu, Kenya. To be eligible, women had to be ≥ 14 years of age, ≥ 8 weeks gestation (prior criteria ≥ 14 weeks gestation changed midway through enrollment late January 2014), be in a relationship and either be married or cohabiting, not have a male partner present at the clinic visit, have a partner ≥ 18 years of age, planning to live ≤ 40 km from the clinic now until 9 months postpartum (prior criteria ≤ 20 km changed midway through enrollment), and had not experienced physical, verbal or sexual abuse in the past month. Of 601 eligible women, 306 women were randomized to receive home-based partner education and testing within two weeks of enrollment, which was delivered usually by a team of two health advisors, one male and one female, and included couple HIV counseling and testing as well as education on facility delivery, postpartum family planning and exclusive breastfeeding. An educational brochure was created

using WHO, CDC, UNICEF and USAID counseling and education tools [29-31], translated into Dholuo and Kiswahili, and provided to couples (see Appendix A). The brochure also served as a guide for health advisors. The other 295 women were randomized to receive a written invitation encouraging the male partner to attend the clinic (INVITE) and delayed home-based partner education and testing at 6 months postpartum. Women and their partners were retained in the study until 6 months postpartum for follow-up of outcomes.

3.5.2 *Subject selection*

Once approval for the qualitative component for the study was attained in 2015, couples who had received the intervention and had not yet exited the study were invited to participate in in-depth interviews. We purposively selected couples based on HIV status and oversampled couples in which one or both were HIV positive. This meant those who were concordant negative were randomly selected whereas all remaining couples in which one or both were HIV positive were invited to participate. Couples were interviewed as female and male individuals to gather individual perspectives and were also interviewed together to capture joint responses to health behavior and decision-making. Written, informed consent was obtained from all participants prior to being interviewed.

3.5.3 *Instrument development*

A semi-structured interview guide was developed to explore female and male perceptions and experiences of home-based HIV testing and education, comprehension of intervention messages, intervention influence on behaviors and outcomes, as well as to collect feedback and suggestions for improvement. Topics and questions were written in English, translated into Luo and back-translated to English to confirm accuracy of translation.

3.5.4 *Data collection*

An experienced qualitative interviewer from Maseno University in Kisumu, Kenya, administered the interviews using a semi-structured guide in participant's homes, at the study site at the clinic, or other locations where couples agreed to be interviewed based on preference. The interviews were taped on digital recorders, transcribed, and translated into English from Luo and Kiswahili by the same person who conducted the interviews.

3.5.5 *Data analysis*

English transcripts were imported into ATLAS.ti version 7.5.10 (Berlin, Germany) for analysis. Two coders, the qualitative investigator (primary coder) and an experienced qualitative coder (secondary coder), were directly involved in the data analysis. Four transcripts, one of each type of couple serostatus, were used by both coders to independently create a codebook; the coders met to reconcile these codebooks and create a unified codebook. The primary coder used these codes to code the initial four transcripts and the secondary coder reviewed these transcripts, using memos to comment where there was code disagreement. The coders met to discuss these memos and came to an agreement on the final coded transcripts. The primary coder proceeded to independently code 11 additional transcripts, and the secondary coder reviewed these transcripts using memos to comment on code disagreement. Likewise, the secondary coder independently coded 6 transcripts, and the primary coder reviewed and commented on them. The coders met to resolve the memos and agreed on the final coded transcripts. The transcripts were divided by couple serostatus and allocated so that the coders had independently coded a variety of transcripts.

The primary coder reviewed the coded quotations from the transcripts to identify themes and patterns in the data. The secondary coder reviewed these identified themes and patterns and provided feedback. Quotes were identified as being representative of those themes and patterns and are presented in the text and supporting tables.

3.6 RESULTS

3.6.1 *Participant characteristics*

Twenty-one couples were enrolled: 9 concordant HIV negative couples, 8 HIV discordant couples (5 in which the female was HIV positive, and 3 in which the male was HIV positive), 3 HIV concordant HIV positive couples, and 1 whose concordance status was unknown (female positive, male not tested). Of the 21 couples, 17 interviews were conducted in which both the female and male participated, 2 interviews in which only the female participated (one case of male refusal and one case of separation), and 2 interviews in which only the male participated (one case of female death and one case of separation). There were two interviews in which the entire interview was conducted with both the female and male present.

A summary of characteristics is presented in Table 3.1. The median age at the time of intervention for women was 24 years and 28 years for men. Median relationship duration was 3 years and couples had a median of 2 prior pregnancies. There were no polygamous relationships in the sample. The median education level for women was upper primary grades 4-8 and for men was secondary school completion.

Table 3.1 Characteristics of subjects who participated in in-depth interviews

Participant couple (P)	Gender	HIV status	Age	Relationship duration (years)	Prior pregnancies together	Education completed
1	Female	Positive	20	2	2	Some secondary
	Male	Negative	23			Upper primary 4-8
2	Female	Positive	32	15	5	Some secondary
	Male	Positive	38			Secondary completed
3	Female	Negative	20	<1	1	Secondary completed
	Male	Negative	24			Secondary completed
4	Female	Negative	19	3	2	Upper primary 4-8
	Male	Negative	23			Upper primary 4-8
5	Female	Positive	25	4	3	Upper primary 4-8
	Male	Positive	29			Some secondary
6	Female	Negative	31	6	3	Secondary completed
	Male	Negative	39			Secondary completed
7	Female	Negative	22	1	1	Upper primary 4-8
	Male	Negative	28			Secondary completed
8*	Female	Negative	29	13	4	Above secondary
	Male	Negative	38			Secondary completed
9	Female	Negative	19	3	1	Upper primary 4-8
	Male	Negative	23			Above secondary
10	Female	Negative	29	3	2	Upper primary 4-8
	Male	Negative	31			Secondary completed
11	Female	Negative	27	10	4	Upper primary 4-8
	Male	Negative	35			Above secondary
12*	Female	Positive	26	8	3	Upper primary 4-8
	Male	Negative	39			Secondary completed
13	Female	Negative	23	4	2	Upper primary 4-8
	Male	Negative	28			Upper primary 4-8
14	Female	Positive	18	2	1	Upper primary 4-8
	Male	Negative	24			Upper primary 4-8
15	Female	Positive	28	2	1	Secondary completed
	Male*	Negative	38			Upper primary 4-8
16	Female*	Positive	24	3	1	Secondary completed
	Male	Negative	30			Secondary completed
17	Female	Positive	27	13	4	Secondary completed
	Male	Positive	46			Some secondary
18	Female	Negative	36	3	1	Upper primary 4-8
	Male	Positive	26			Secondary completed
19	Female	Negative	24	6	3	Upper primary 4-8
	Male*	Positive	28			Lower primary 1-3
20	Female*	Positive	23	2	1	Upper primary 4-8
	Male	Unknown	25			Secondary completed
21	Female	Negative	21	6	3	Upper primary 4-8
	Male	Positive	28			Some secondary

*Male and female interviewed together per male request (P8, P12); Only the female participated (one case of male refusal in P19, one case of separation in P15); Only the male participated (one case of female death in P20, one case of separation in P16)

3.6.2 *Overview of themes*

In the analysis, four major themes emerged from experiences of home-based couple HIV testing and counseling: facilitation of partner testing and disclosure, home testing preference due to privacy and quality time, fear of testing overcome with counseling and improved relationship due to disclosure. Two additional themes were identified from experiences of partner involvement: efficiency and appropriateness of partner involvement and joint education and partner support in pregnancy and postpartum. In regards to intervention influence on health behaviors, including facility delivery, postpartum family planning and exclusive breastfeeding, two themes emerged of learning/reinforcement of health behaviors and knowledge affecting behaviors. Lastly, for opinions for the intervention, themes of health advisor preferences and positive reviews of the intervention surfaced.

3.6.3 *Experiences of home-based couple HIV testing and counseling*

3.6.3.1 *Facilitation of partner testing and disclosure*

A major advantage of home-based couple testing discussed by women and men was the facilitation of male partner testing. Men were often either reluctant, afraid or too busy to go to the clinic and were more willing to participate in a scheduled home visit due to convenience and being held more accountable with a scheduled appointment. One woman expressed (whose sentiment was echoed by many):

“It [the home visit] was good because I have pleaded with him to go for test and he refuses, so when you came here I was very happy because he had to.” (P6, concordant negative female, age 31)

Another woman explained that her partner does not want to attend clinic and it is easier to have him tested at home than to bring him to the hospital:

“It [the home visit] is good because it is being done with your partner because sometimes your partner doesn’t want to go to the hospital, so when they come home the test is done together and the result is out.” (P3, concordant negative female, age 20)

Some men explained that home testing may be the only way to reach men as men are afraid to go to the clinic without this facilitation:

“It [home testing] is a good method. That is the only way you could reach out to those who are afraid [...] she brings you along the way my wife did and you found me in the house because most men do not escort their wives to the clinic that is the only way you could reach the other villagers when their wives are expecting.” (P6, concordant negative male, age 39)

Furthermore, home-based couple testing facilitated disclosure. Respondents appreciated that couple testing was a less daunting disclosure method than disclosing without the help of a health advisor. One woman in a concordant positive partnership expressed this common theme this way:

“It is good because sometimes you can be tested alone and you will be afraid to tell him the results so if you are tested together and he sees his and you see yours it is going to be easy.” (P5, concordant positive female, age 25)

Others, including men, also pointed out the mutual disclosure benefit of home-based couple testing. A man in a discordant partnership stated:

“I think that was also good because there are some people who don’t disclose their status to their spouses so if you are tested together the woman knows and the husband also.” (P18, discordant positive male, age 26)

More women spoke about facilitated disclosure when asked about what it was like being visited at home or being testing together but many men and women expressed that the main benefit of home-based couple HIV testing was getting to know their partner’s status. Also, disclosure was oftentimes discussed in improving trust and confidence in a relationship (see 0 Some men expressed supporting their partners in previous pregnancies, but most mentioned they were encouraged by the intervention to support their partners. Support given was mainly in helping with providing a balanced diet in pregnancy and postpartum, taking the woman to the hospital for delivery, and helping around the house with chores. A man in a discordant partnership attributed his support to the visit:

“If this education did not take place, then it would not be well; it is because of this study that I now and have the confidence to give her support [...] for instance buying for her fruits, food that she wants, her coming to the hospital, you prepare early enough and ensure she does not miss transport, she comes in time and does not fail to attend, I also

don't refuse her [deny her permission] to come at the days of her appointment." (P1, discordant negative male, age 23)

Another man explained his support as though they were now a team:

"I felt to be a part of this it was like we were carrying the pregnancy, we used to go to the clinic together when something is wrong we try and solve it together. I was more concerned [than before] because in this community where I come from, we believe pregnancy is for a woman and when she gives birth, your responsibility is to go to the hospital for the discharge and bring her to the house and look for some chicken and shed its blood. But even when she was going to give birth I took her to the hospital, besides that after giving birth I was checking on her on a daily basis and we were together in this concerning the child and even before she gave birth." (P8, concordant negative male, age 38)

Most men reported giving this type of support and women spoke of getting this assistance and receiving empathy from the partner. A woman in a discordant partnership expressed:

"It was good according to the education we got together, there were some parts that he could know and help me [...] when I delivered, he now understood the difficulty I had." (P19, discordant negative female, age 24)). Table 3.2 presents additional supporting quotes for facilitated partner testing and disclosure.

Table 3.2 Facilitation of partner testing and disclosure in home-based testing and education

<p>“It [the visit] helped because of the test which was done may be he could not have a chance of going to the hospital for the test so coming here made us know our status and the teaching they gave us.” P3, concordant negative female, age 20</p>
<p>“It [home testing] is not bad because sometime somebody is afraid of going to the hospital so you can find them at home and help them early.” P17, concordant positive female, age 27</p>
<p>“There are some people who are afraid of going to the hospital, it is easier when you come to my doorstep unlike the hospital, because they do not incur any expenses like transport.” P18, discordant negative female, age 36</p>
<p>“Okay, it [home testing] is still fair according to me, it is also good for those who find it difficult to go to the hospital, so when they come to know about it, they can have a change of mind [then test].” P1, discordant negative male, age 23</p>
<p>“I might not have time to go to the hospital, so when you make an appointment to come it is okay.” P14, discordant negative male, age 24</p>
<p>“I welcomed them, because I was even called to town, I went very fast and agreed, you cannot refuse these things because they can help you, not others, they just help those who are told, so when you tell others and they don’t want to listen, it is their fault.” P17, concordant positive male, age 46</p>
<p>“We had a chance of being tested together as a man and wife, leaving to go there [the hospital] is difficult, so I like that we were taught together. It was good because now everybody knows how he is and you are being taught how to stay and take care of yourselves.” P10, concordant negative female, age 29</p>
<p>“It [home testing] was nice because you know each other’s status, at least when one is positive, and you also know when one is positive and the other negative [discordant] you can avoid giving [infecting] the other person HIV and also you can plan the future of the kids.” P11, concordant negative female, age 27</p>
<p>“It is just that we tested together, so I was happy because I usually go alone but now we know status of each other. It was good because we both knew our status.” P19, discordant negative female, age 24</p>
<p>“It [home testing] is good because it is being done when we are few and there is no surprise so the man and the woman get to know their status just the two of them.” P7, concordant negative male, age 28</p>
<p>“I don’t always consent to testing, but she always tests when she goes to the clinic. At least I got to know our status.” P9, concordant negative male, age 23</p>
<p>“It [the visit] brought a difference and a good one because we knew our status after that and it made us take more care of ourselves more than we used to before.” P4, concordant negative male, age 23</p>

3.6.3.2 Home testing preference due to privacy and quality time

As was alluded to in the previous section, the majority of men and women preferred home testing and education compared to clinic or hospital testing and education, which was found to be due to more privacy in the home when probed further. One woman put it this way:

“The experience was nice, because you know you are free, you are in the house, you know at the hospital you fear those who are there, the nurses and the doctors, you will fear they may know that you are positive, or know your status and maybe they know you they will go to advertise, unlike in the house.” (P11, concordant negative female, age 27)

A man in a discordant partnership similarly expressed himself:

“Testing at home is good because it finds you are in a private place, only you, your wife and those who test, there are no other people who hear you, I found it good. The one at home was very good because we were free as compared to the hospital.” (P21, discordant negative male, age 28)

Quality time with the health advisors was another a major benefit of home compared to clinic-based testing. A man in a concordant positive partnership expressed privacy in the home as being a catalyst to being able to have quality time:

“It [home testing] is good because in the hospital people are many and somebody is afraid so this one is good because everybody takes his time to listen.” (P5, concordant positive male, age 29)

Health advisors having time to spend in the home versus hospital setting was also mentioned by many women and men. A woman in a discordant partnership stated:

“They [health advisors in the home] have the time to sit down and teach you, unlike the hospital which is just testing and you go, they do not sit with you down.” (P15, discordant positive female, age 28)

Furthermore, when asked about attending antenatal visits at the clinic, many men reported that they did not go.

Table 3.3 provides additional supporting quotes for privacy and quality time in home-based testing and education.

In speaking with couples, it became clear that while most had been visited at home and preferred home testing, a few of them had actually not been tested at home, but were seen by

study health advisors at the hospital due to preference of being tested outside the home. While the adaptability of the intervention location was not specifically asked about in the qualitative interviews or in the quantitative surveys of the parent study, the occurrence of this is worth noting as an adaptation of the program.

Table 3.3 Privacy and quality time in home-based testing and education

<p>“It [home testing] is good because you are tested alone without even the presence of the children, the way you have visited us here it will be private just you and us so that even if I have [HIV], I can go for the drugs without people noticing but they would know later on but nowadays it is difficult to know.” P4, concordant negative female, age 19</p>
<p>“That [home testing] is also good because there are people who are afraid to go to where people are.” P5, concordant positive male, age 29</p>
<p>“It is nice, I like it [home testing] because you are together, you are the only people and you are free.” P11, concordant negative male, age 35</p>
<p>“One done at the house is more appropriate for me than one done in the hospital...when done in the house you can talk it out better unlike in the hospital where you can end up not talking to each other.” P6, concordant negative female, age 31</p>
<p>“This [home visit] is better because you have enough time to ask questions and learn more.” P14, discordant negative male, age 24</p>
<p>“This is better because you have taken your time with me while in the clinic you cannot get the whole of the teaching.” P10, concordant negative female, age 29</p>

3.6.3.3 Fear of couple HIV testing overcome with counseling

Home-based couple testing was effective not only due to convenience, privacy, and quality time, but also in how fear of testing was alleviated with skilled and attentive counseling. Many men and some women expressed initial fear of couple HIV testing, due to the fear of personally being found HIV positive. Many times this fear was eased once health advisors explained what HIV is and how it can be managed successfully and the benefits of knowing one’s status. One man in a concordant positive partnership explained:

“I found that first of all you bring awareness because you make people feel free, so what I first put in mind as a human being is that I will not live forever, and I know that diseases

kill, but now if I can find something to sustain me in life that is good isn't it?" (P2, concordant positive male, age 38).

Many men and women also expressed fear of being HIV positive and their partner HIV negative. As part of pre-test counseling, health advisors asked couples to discuss the different scenarios of what they would do if they were found to be both positive, both negative or if only one of them was positive and worked out solutions to different scenarios. When asked what he would have felt if one or both of the results were positive, a man in a concordant negative partnership expressed:

"They taught us first before, that such thing happen and what we will do even if we have it so I went in confidently, with knowledge." (P6, concordant negative male, age 39)

For discordant couples, post-test counseling was particularly important in relieving the fear and worry of their discordant serostatus. Being asked about how it felt being part of the visit, one man in a discordant relationship responded:

"It was easy, I have had it easy considering the thoughts I had before this visit, after we were tested and knew our HIV status, we had many thoughts, but after the education we got from the visit, all these days, I lost the thoughts and felt light." (P1, discordant negative male, age 23)

Table 3.4 provides additional supporting quotes for fear of HIV testing overcome with counseling.

Table 3.4 Fear of HIV testing overcome with counseling

<p>“People are afraid of test, though if you approach somebody and request to do for them the test at home and counsel them properly they might agree some have negative attitude towards HIV test, sometimes they suspect themselves so it is not easy to take the test, but if somebody comes and tell you the benefits of it you will realize it is good to know whether you have it or not to be able to live a longer life.” P8, concordant negative male, age 38</p>
<p>“It was difficult at first but after the doctor told us about the advantages of the test for a while I agreed, but I don’t usually like.” P9, concordant negative male, age 23</p>
<p>“You talked to us well, your approach was better even the fear disappeared after you introduced yourselves” P6, concordant negative male, age 39</p>
<p>“It was good [being involved] because there are some things you cannot just talk about but it will force you to talk about them like when I was asked about my status which I do not like to discuss it with people but I discussed it freely with researchers who came.” P18, discordant positive male</p>
<p>“I was afraid for the first time but after the teaching I was courageous. [And after testing] I felt good because the results were negative and we were both there.” P6, concordant negative female, age 31</p>

3.6.3.4 Lack of fear of HIV testing

While not a major theme, it is interesting and important to note that a few men and some women expressed they were not afraid of testing, even those in discordant partnerships. A man in a discordant partnership explained:

“I did not find it difficult, it was very easy, because I wanted to be free with my wife, and together to know our status and how we live, I was very happy.” (P21, discordant positive male, age 28)

Other men who were not afraid cited that they had not had any external partnerships and were therefore at ease with testing. One man expressed:

“There is no problem, I felt nothing even before we went to the hospital when I met her I told her that we go for the test because I trusted myself, I knew how I have been, I was confident and some people are afraid because of their past life and if you know your past life you will be confident.” (P3, concordant negative male, age 24)

For women, some fear of testing was usually expressed, although not in as much detail and depth as male respondents. Most females expressed being only somewhat afraid of testing or being not afraid and being relieved or happy after receiving results, particularly if concordant negative but also if positive, concordant or discordant. A concordant positive female explained her lack of fear when testing:

“I was feeling nothing [before]. [And after] I felt nothing. After we were tested, I got tested to know my status, and after the test and knowing, I will now see on how I can help myself by taking drugs.” (P5, concordant positive female, age 25)

Three HIV negative females whose partners were HIV positive had very similar responses in that they were not scared, before or after the test. One woman stated: “I was not afraid. [And after] we were just free.” (P19, discordant negative female, age 24).

3.6.3.5 Usefulness of women testing alone at clinic prior to couple testing

As another important side note, most women tested alone at the clinic prior to being tested together with their partner (not disclosed to partners by study staff) and the qualitative component sought to determine how helpful this was for women. For some women, having tested beforehand at the antenatal clinic brought some relief, particularly if found to be negative, but even if positive, they felt more prepared going into couple testing. One woman stated:

“Yes, it was good that I was first tested, then he is called later so you tell him that I have not been tested so that we are tested together, so that we know so he looks at mine and I also look at his.” (P1, discordant positive female, age 20)

However, most women expressed that being tested alone was a benefit of knowing their own status personally for their own health. Some stated prior testing did not matter and that it was most important to have been tested together:

“It helped me to know my status, but I didn’t know the status of my husband, so I felt relief in testing together.” (P11, concordant negative female, age 27)

“It helped me know my status personally so when they came to the house I was aware of my status; I was only waiting to confirm his.” (P3, concordant negative female, age 20)

One woman did not test prior to being tested before and she expressed it would have been helpful (P13, concordant negative female, age 23) and another woman whose husband did not test expressed she was glad she at least knew her status (P15, positive female, age 28). Therefore,

testing before at the clinic does not seem necessary for some women but with no drawbacks, but seems to be an important step in the process for others.

3.6.3.6 Improved relationship due to disclosure

Men and women spoke of increased trust, improved confidence, and better communication as a result of home-based testing and education. Facilitation of HIV disclosure contributed to the improvement of many relationships. For concordant negative couples, their HIV status was used as a proxy of having no outside partnerships and reaffirmed the commitment they had to one another as they agreed to not have external partners. A woman in a concordant negative partnership noted:

“They [the teachings] helped us because I saw so many differences. Because if you have your husband and you don’t know your status, he would sometimes walk out and move around and after knowing our results we decided to maintain one partner each.” (P4, concordant negative female, age 19)

For discordant couples, their acceptance of their discordant status seemed to also improve upon their relationship as they resolved to stay together and help one another in preventing and managing the HIV infection. A man in a discordant partnership expressed:

“I did not see anything bad [in the visit], it was all good. First of all, I thought it would make us break up with my wife, but my wife also encouraged me, and encouraged the relationship because we have children so we should look at the life ahead, so there is nothing bad.” (P21, discordant positive male, age 28)

Similarly, another man in a discordant partnership explained:

“I found it easy and it also gave us an opportunity to be at peace with each other in our house, because I know her status and she also knows mine, what remained is us being together and remind each other, I was not jealous in any way, when she is supposed to take her medicine I remind her.” (P1, discordant negative male, age 23)

For concordant positive couples, a similar phenomenon of acceptance and peace as well as moving forward in order to live well was noted. A woman in a concordant positive partnership stated:

“It [the visit] has brought a good one [difference] because we are now staying with peace because everyone knows each other’s status so we live well.” (P17, concordant positive female, age 27)

Likewise, a man in a different concordant partnership noted:

“There was some peace because all of us had so they will not accuse somebody else that you are the one who has given him.” (P5, concordant positive male, age 29)

While most couples expressed an improved relationship, there were a few instances in our sample of non-testing, non-disclosure and relationship dissolution, as noted in the participant descriptions, although not attributed to study participation. The study intervention, while having an effect on many relationships, may not work for every couple. More supporting quotes for improved relationship due to disclosure are found in Table 3.5

Table 3.5 Improved relationship due to disclosure

“It [the visit] helped me because I stayed with him but [before] did not know his status and if I asked, we were disagreeing [arguing].” P9, concordant negative female, age 19
“[I liked] the way we have stayed with him since the visit and the agreement we have been having since. It was good because now everybody knows how he is and you are being taught how to stay and take care of yourselves.” P10, concordant negative female, age 29
“It is good because it makes us free with one another in the house.” P17, concordant positive male, age 46
“I was positive and he was negative, [after the test] he encouraged me.” P14, discordant positive female, age 18
“I realized that we are trustworthy -- we don’t walk in the wrong direction [...] after we were tested together I found out that I was clean and she was also clean that showed that we were faithful and no one was cheating on each other.” P4, concordant negative male, age 23
“We now know how to protect ourselves from getting the disease and to trust each other.” P3, concordant negative female, age 20
“It [having partner involved] was ok with me because we were together and were taught together the two of us. Secondly, we were tested both of us and after that love was too much because we knew our status.” P4, concordant negative female, age 19

3.6.4 *Experiences of partner involvement*

3.6.4.1 Efficiency and appropriateness of partner involvement and joint education

Women and men reported that male partner involvement and joint education, which included pregnancy, facility delivery, exclusive breastfeeding, and postpartum family planning, was both efficient and appropriate. Couples expressed mutual understanding and reinforcement of the health education and noted that topics were relevant to both members of the couple and promoted bonding. A man in a discordant partnership described the benefit of mutual understanding of health education:

“It is better when you are taught the two of you not that one will say that I was taught like this and I was taught like this so when you are taught together you take it once in a clear way.” (P18, discordant positive male, age 26)

Likewise, a woman in a discordant partnership put it this way:

“It was good because when we were taught together he also listens, not that we are taught separately, so we listen to the same thing.” (P17, concordant positive female, age 27)

Men also did not consider these topics to be only relevant or appropriate to women. A man expressed the importance of being involved in these matters:

“I felt good [being involved] because such programs should be taught both man and woman when they are together. They [the teachings] are useful because we knew in marriage it is important to get such teachings so that we can be able to take care of our children.” (P6, concordant negative male, age 39)

Furthermore, this mutual understanding and relevancy of health education went beyond to helping couples make actual joint health decisions. Expressing his views on mutual agreement on health decisions, a man stated:

“I think being with my wife is good because there are things which if we are told together we become aware and it will be easier to implement unlike individually, when she goes and get the teaching alone when she comes with the information, I will not agree to it because I am not aware of all that she is bringing along. So if we get the teaching together even if she wants to dispute I tell her ‘no’, it was said that we do like this because it only helps our lives and we can remind each other. So it is better to be taught together rather than separately. Just like we know people are different, some men cannot

implement what the woman has come up with, [but being taught together] he [would] also know the goodness of that information. After being taught together is when he can agree to do that in his house.” (P8, concordant negative male, age 38)

3.6.4.2 Partner support in pregnancy and postpartum

Some men expressed supporting their partners in previous pregnancies, but most mentioned they were encouraged by the intervention to support their partners. Support given was mainly in helping with providing a balanced diet in pregnancy and postpartum, taking the woman to the hospital for delivery, and helping around the house with chores. A man in a discordant partnership attributed his support to the visit:

“If this education did not take place, then it would not be well; it is because of this study that I now and have the confidence to give her support [...] for instance buying for her fruits, food that she wants, her coming to the hospital, you prepare early enough and ensure she does not miss transport, she comes in time and does not fail to attend, I also don’t refuse her [deny her permission] to come at the days of her appointment.” (P1, discordant negative male, age 23)

Another man explained his support as though they were now a team:

“I felt to be a part of this it was like we were carrying the pregnancy, we used to go to the clinic together when something is wrong we try and solve it together. I was more concerned [than before] because in this community where I come from, we believe pregnancy is for a woman and when she gives birth, your responsibility is to go to the hospital for the discharge and bring her to the house and look for some chicken and shed its blood. But even when she was going to give birth I took her to the hospital, besides that after giving birth I was checking on her on a daily basis and we were together in this concerning the child and even before she gave birth.” (P8, concordant negative male, age 38)

Most men reported giving this type of support and women spoke of getting this assistance and receiving empathy from the partner. A woman in a discordant partnership expressed:

“It was good according to the education we got together, there were some parts that he could know and help me [...] when I delivered, he now understood the difficulty I had.” (P19, discordant negative female, age 24)

3.6.5 *Intervention influence on health behaviors*

3.6.5.1 Learning/reinforcement of health behaviors

Women and men reporting learning a variety of things from the visit, including importance of facility delivery, exclusive breastfeeding until 6 months, postpartum family planning, how to have a healthy pregnancy, and how to take care of their newborn. Some couples expressed that the health topics were a review but reinforced behaviors, while others stated they had learned something, particularly in the realm of family planning. One woman expressed:

“I feared that when I give birth, ‘do I have breast milk to keep the child until 6 months?’ I learnt that a baby should be breastfed for six months before introducing another food, I learnt that I can even do family planning when we are staying with my husband , I was happy when we were told that we could use condoms when we were together.” (P6, concordant negative female, age 31)

Also, when querying their knowledge on topics of facility delivery, family planning and exclusive breastfeeding, most women and men demonstrated knowledge and retention of key messages given in the visit, which took place at least 6 months prior. Additionally, couples in discordant or concordant positive relationships also reported learning about their status, how to stay with one another, and prevent/manage the infection.

3.6.5.2 Knowledge affecting behaviors

For facility delivery and postpartum family planning, it appeared that knowledge was enough to influence behavior and these behaviors were high among the respondents. However, when probed, many couples reported having engaged in these behaviors prior to the intervention with previous pregnancies.

While exclusive breastfeeding knowledge was high, execution of the behavior was lower potentially due to difficulty in assuring this behavior when a baby had different caretakers, particularly outside the partnership, and when the female had other responsibilities to attend to. A woman noted:

“It [exclusive breastfeeding] is supposed to be for six months but due to the responsibilities I have I started giving him other food after three months.” (P10, concordant negative female, age 29)

Another couple discussed this issue in the broader family context:

Man: “She breastfed her but in the fourth month she started giving her water.” (P9, concordant negative male, age 23)

Woman: “I did not give her, my younger aunt gave her. I quarreled with her.” (P9, concordant negative female, age 19)

Also, some respondents worried their milk supply was low or that the baby needed water or did not violate the exclusive breastfeeding rules (extrapolated from other health knowledge or from misinformation). A woman noted:

“I started giving water when it was three months [because] (laughs shyly) milk was little.” (P19, discordant negative female, age 24)

A couple explained how milk might not be sufficient for the baby’s needs and that water is a good supplement:

Woman: “Water is necessary in the body they want it to be 70% of the body.” (P18, discordant negative female, age 36)

Man: “90% percent of blood is always water so if there is no water the blood can dry up that can be a mistake.” (P18, discordant positive male, age 26).

In summary, couples expressed different health behaviors that the visit had an influence on, demonstrating that couples took away different things from the visit depending on what they did not know before, individual experiences with the education and counseling, and their serostatus.

A woman in a concordant negative relationship noted:

“It [the visit] has really helped us we take care if the child well and after six months is when we start giving them food and us, we also take care of our family [and] we have not experienced any problem. And after I had given birth we decided that we should now go for family planning in order to give the child a chance to have a good life.” (P7, concordant negative female, age 22)

A woman in a concordant positive relationship described:

“I liked it [the visit] because we could be taught how we could live and eat and how we could use the drugs well and even on having sex, they encouraged us, so the visit also helped a lot.” (P17, concordant positive female, age 27)

3.6.6 *Feedback and suggestions for improvement*

3.6.6.1 Health advisor feedback

Couples were visited usually by two health advisors, one male and one female, from the study (based at the hospital); however, sometimes only one would conduct the visit due to scheduling. There were mixed preferences of having one or two health advisors conduct the visit, with some saying it is better to have one for clarity and increased privacy and others saying two were better for completeness of teaching and ability to have mixed gender health advisors. A concordant positive couple noted:

Man: “Even if it is one person, it is still good because it is someone who is learned about the research, so what s/he is telling you is what you focus on.” (P17, concordant positive male, age 46)

Woman: “You know two people, one will ask a question from the other end and you have not responded to this one so there will be confusion. So one person is better.” (P17, concordant positive female, age 27)

In general, women preferred female health advisors but men had mixed opinions on gender with some men preferring male health care workers due to relatability and some preferring female health workers due to knowledge on health topics. Most men said if only a female health advisor could be present, it would be fine as well if the teaching was the same quality. A man in a discordant relationship stated:

“I cannot lie about that because even if I say that they should be men because I am a man, I think that will be a mistake, so whether it is a woman or a man provided s/he does the visit, and the teaching they have brought is what is important.” (P18, discordant positive male, age 26)

However, both men and women strongly preferred having a non-local health advisor, rather than someone from the community (a local community health worker or midwife), conduct the visit due to privacy concerns and some concerns of the quality of education provided. Only a few men stated they would agree to be visited by someone based locally. A man in a discordant partnership expressed:

“Those from the community will just help you with advice but they cannot give you much information like those from the hospital tell you. I would not like someone from the

community, because they come out with it openly. They would put it in a different way to spoil your name. I prefer someone who comes from a place where I don't know [a stranger]. Someone who knows you will speak about it [your status] to others but those who come from outside [far from the community] will keep your secret." (P21, discordant positive male, age 28)

Table 3.6 gives further supporting quotes for local community health workers vs. non-local health advisors.

Table 3.6 Local community health worker (CHW) vs. non-local health advisors

<p>"It [a local CHW] is not good. It is better with a health worker who knows [knowledgeable]. [Also] some can keep your secret but some cannot." P12, discordant positive female, age 26</p>
<p>"That [being visited by a local CHW] is difficult for anyone to accept, because those who come to the house are people from around so after they test you they go to tell others" P1, discordant positive female, age 20</p>
<p>"Somebody who knows me can share it with some other people who know me unlike somebody who do not know me, so I prefer somebody who doesn't know me totally." P10, concordant negative female, age 29</p>
<p>"I am not sure if the health workers in our community have the right education or knowledge of what is right, but someone known to me would also not be acceptable, I will not be happy with it because we may know each other in many ways, and we may also be meeting at different places that may make us have a disagreement one day, and then they tell my secret." P1, discordant negative male, age 23</p>
<p>"That [being visited by local CHWs] would be... we would not be that free to talk to them. Even when it comes to testing... may be this is somebody who knows me, you don't feel it can be private, they may say 'I went to so and so' you may feel uneasy." P11, concordant negative male, age 35</p>
<p>"Those ones are good [local CHWs], they can teach you according to the knowledge they have and how they see it or how they have been doing it all along. But in the hospital, you are taught according to the experience they have acquired and they have also done it practically so they know both theory and practical and so if one does not go according to plan, they always have another option that is why the hospital is better than midwife [local CHW]." P4, concordant negative male, age 23</p>
<p>"Midwives [and local health workers] do not even have gadgets to measure people. It [the visits] needs somebody who has the knowledge; midwives mostly have no knowledge because the ones I see in the nearby dispensary I don't see them having enough skills concerning treatment unless they will have good training." P9, concordant negative male, age 23</p>

3.6.6.2 Positive reviews of the intervention

Overall, couples gave positive reviews of their visits. They were pleased with the adequacy of topics and the way the health education was taught. They rarely had suggestions for improvement or listed anything they did not like about the visit. Couples were also asked if other couples would participate in the intervention without study compensation (300 Kenyan shillings per couple, which is approximately 3 U.S. dollars), and most stated that the education was valuable in and of itself. Others expressed that compensation would be appreciated and that some couples may even expect it. Couples were supportive of program expansion, although some cautioned they could not speak too knowledgeably about how their neighbors would receive the intervention. In general, couples thought the program should continue and reach more couples as they had positive experiences with their own visits.

3.7 DISCUSSION

The results of this qualitative study suggest that home-based couple testing during pregnancy facilitates male partner testing and disclosure and that home testing affords more privacy and quality time with health advisors than clinic-based testing. Overall, couples preferred home testing to clinic testing and appreciated being tested and educated together as a couple rather than as individuals. Home-based couple testing has been found to be acceptable and even favored by clients to clinic-based testing in other studies as well [10, 24-28]. While initial fear of testing was prevalent, it was overcome with skillful counseling of trained health advisors. In qualitative interviews with health advisors in the study, they explained that it took skill and good communication of the benefits of couple HIV testing to have couples more willing to test. Additionally, couples reported that the intervention resulted in partner support during pregnancy and postpartum and that disclosure improved their relationships.

These qualitative outcomes in the parent study support and add to our understanding of the quantitative results regarding HIV testing uptake among partners in this study, as male partners were more than twice as likely to have been tested in the HOPE (home-based partner education and testing) arm (n=233, 87%) as the INVITE (clinic invitation for the partner) arm (n=108, 39%) by 6 months postpartum per their own self-report. Furthermore, women in the HOPE arm were also twice as likely to know their partner's HIV status as the INVITE arm (n=217, 88% vs. n=98, 39%); mainly because couples in the HOPE arm (n=192, 77%), were

more than three times more likely to have been tested as a couple as the INVITE arm (n=62, 24%). Additionally, home-based couple testing was more effective at reaching and testing discordant couples, as more were identified in the HOPE arm (n=33, 13%) than the INVITE arm (n=10, 4%). As consistent with the qualitative results, women in the HOPE arm (n=157, 61%) also reported an improved relationship compared to the INVITE arm (n=44, 17%).

Most men and women demonstrated high comprehension of facility delivery, postpartum family planning and exclusive breastfeeding. Furthermore, couples reported learning new material or reinforcing pre-existing health knowledge during the visit, and this knowledge assisted them in making decisions and engaging in those behaviors. However, breastfeeding remained a challenge as couples cited difficulty due to other responsibilities of the woman, family caretaking of the infant, and concerns of exclusive breastfeeding being sufficient for the baby's needs, suggesting that a one-time visit during pregnancy may not be sufficient and that counseling and support during the exclusive breastfeeding period is needed.

These qualitative results are consistent with high uptake of facility delivery and postpartum family planning in the quantitative parent study among those in the HOPE arm. However, high rates of uptake were seen overall in both arms, with nearly all women in the study having delivered in a health facility (n=504, 97%) and three-quarters of all women using a hormonal method, IUD or sterilization by 6 months postpartum (n=398, 75.8%). Reasons for a high uptake rate in the INVITE arm includes a recent introduction to free maternity care including delivery in Kenya, as well as the implementation of a direct physical family planning referral after having visited the immunization clinic for infants, and a possible contamination effect from those in the HOPE arm to the INVITE arm. In addition, when probed in qualitative interviews, many couples who attributed the intervention to these health behaviors, also reported having engaged in these behaviors in prior pregnancies. The intervention may have had more of an impact had there been more room to improve or in a location where free maternal care or strong referral systems do not exist. For exclusive breastfeeding, the qualitative results validate the challenges couples faced in achieving this behavior, as only a third of women in the parent study exclusively breastfed to 6 months postpartum (n=176, 33.5%), supporting the idea that different interventions need to be considered for supporting exclusive breastfeeding.

While couples had a variety of views on health advisor preferences in regards to gender or being visited by one or two advisors, couples were overall strongly opposed to having a local

community health worker conduct home-based couple HIV testing and education mostly due to a fear of a breach of confidentiality and some adequate training concerns. Couples preferred having health advisors outside the community conduct these visits as was done in the study. In their own qualitative interviews, study health advisors also expressed that their anonymity was partly responsible for their success in conducting home-based HIV testing and education. Programs considering home-based testing and education should take this into account and try to address these concerns if using community health workers. Additionally, because of the variety of gender preferences, programs may want to accommodate the preferences of the couple receiving the intervention, which was a sentiment also echoed by study health advisors. Study health advisors also expressed that programs need to plan for odd working hours of the health advisors, as many visits occurred during the evening, early mornings or on weekends, and when they did go alone without the assistance of a colleague due to a scheduling issue, it was more challenging and they did fewer visits in a day. Lastly, while home testing was overall preferred to clinic-based testing, some couples did choose to have their appointment with their partner at the program office at the hospital and this location preference should also be accommodated when possible, which was an idea also supported by health advisors. This flexible model of couple preferences may also include invitations with follow-up and partner tracing, as both have also demonstrated effectiveness in reaching men in two recent studies [32, 33]. Perhaps these methods may be included as part of a comprehensive strategy of male partner involvement, starting with invitations, then tracing and home-based visits for those who are not reached with the first methods.

This qualitative study had several strengths including interviewing both women and men as individuals and as couples in order to collect potentially sensitive information as well as joint health decision-making. Also, half of couples were either in discordant or concordant positive partnerships. The parent study is a randomized clinical trial studying the quantitative effectiveness of home-based partner testing, so it was possible to compare the results from the qualitative study to explain phenomena and to quantify the impact. The qualitative in-depth interviews also provide feedback on potential modifications to the intervention, which will be useful in future scale-up studies. A limitation of our study includes not interviewing those who had not received the intervention in order to compare their perspectives and experiences during pregnancy, although we have quantitative data on their outcomes and behavior. Furthermore, the

purpose of the qualitative in-depth interviews was to understand home-based testing and education among couples who received the intervention rather than explore the experiences of those who had not. Another limitation to our study is potentially limited generalizability, as both the qualitative and quantitative study was conducted in one site in western Kenya. Qualitative understanding of interventions aimed at engaging and testing the male partner during pregnancy is particularly lacking and this type of data and feedback would be useful to include in studies and programs planning to implement these interventions.

3.8 CONCLUSION

Home-based couple HIV testing and education was identified as having many benefits to couples receiving the intervention, which is supported by the study's quantitative results. Antenatal programs should consider engaging male partners with home-based testing and education in order to facilitate partner testing and disclosure, potentially averting MTCT, and to improve partner support during the time of pregnancy.

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Chapter 4. CONCLUSION: NEXT STEPS IN HOPE

4.1 USING MIXED METHODS TO INCREASE UNDERSTANDING

The Home-based Partner Education and Testing (HOPE) Study used quantitative methods to determine the effectiveness of the intervention and qualitative data to understand the perspectives and experiences of those who had received the intervention. Utilizing both methods in a mixed methods approach, rather than doing one or the other, can provide many functions. Specifically, mixed methods can serve five purposes [1]: triangulation, initiation, complementarity, development, and expansion. “Triangulation” seeks convergent validation, in that the qualitative and quantitative methods both are used to validate an intervention or hypothesis whereas “initiation” carefully analyzes quantitative and qualitative results to find areas of discordance, and uses those comparisons to gain new insight and understanding. “Complementarity” uses mixed methods to clarify, explain or elaborate on what the other method may have already shown in order to increase meaningfulness and interpretability. “Expansion” applies quantitative and qualitative methods for different research questions in order to extend the bounds of the study and understand these questions from different methodological perspectives as appropriate whereas “development” utilizes either qualitative or quantitative methods to guide the development and use of additional data collection for the other method.

The mixed methods in the HOPE Study primarily serves the purpose of complementarity, in that the qualitative results enhance and provide illustration for the quantitative outcomes observed. For the quantitative results of the effectiveness of home-based couple testing, we understand this approach is successful from the qualitative data because couples reported this intervention finds those who would otherwise not test, since hospital- or clinic-based testing is inconvenient or may cause apprehension and home testing is preferable due to privacy and quality time spent with health advisors. Qualitative results also describe how skillful one-on-one counseling can convince partners to test and overcome their fear of testing. Furthermore, home-based couple testing facilitates disclosure as couples who test individually may have trouble disclosing to their partner without the help of health advisors. For quantitative results of improved relationship, the qualitative data provide illustrations of how disclosure actually brings

peace and understanding among couples, and how women felt supported during their pregnancy and postpartum due to the joint education they received on pregnancy, which both men and women felt to be beneficial and relevant.

In regards to facility delivery and postpartum family planning uptake, which were not quantitatively different between those who received home-based education and testing due to high uptake in both arms, the qualitative results provide some clues as to why this may have been. Many couples expressed having learned something new in regards to these health topics, but some admitted they were a review and only served as reinforcement. Couples did express that this knowledge influenced into their decisions to have a facility delivery and to start postpartum family planning, although when probed, many couples had done these things prior to being in the study with their last pregnancies. For exclusive breastfeeding, which had lower rates in both arms of the study, the qualitative results point to some barriers in achieving this behavior, including competing responsibilities of the mother and other caretakers as well as perceptions of water being acceptable as a supplement to breastmilk, suggesting further guidance and support is needed for couples.

For feedback and suggestions for improvement for the intervention, the qualitative component served more of an “expansion” role for mixed methods research [1]. While couples gave positive reviews of the intervention, they did have varying preferences of health advisors, including gender and being visited by one or more advisors and were overall united in not wanting to have local health advisors from the community conduct the visits. These research questions were not studied in the quantitative surveys and were a new area of inquiry. The qualitative results suggest future studies and programs considering home-based testing and education may want to use individual preferences to accommodate women and their partners in regards to gender and number of health advisors, and should address concerns of privacy and adequate training if wanting to use existing local health advisors/community health workers.

One of the major unanswered questions in the HOPE Study is whether to keep or drop the educational component for facility delivery, postpartum family planning and exclusive breastfeeding since there was no evidence for improved outcomes in the quantitative data. Thus, the intervention will most likely change in regards to this health education component and the original results of the trial will be most interpretable for the HIV testing aspect, although the results should still be used with caution if the intervention changes as even some HIV testing

outcomes could have been influenced by other aspects of the intervention. For example, if education on other health topics were done prior to HIV testing and this warmed the couple up to the idea of testing and in being comfortable with the health advisors, then taking this component away may result in a decrease in testing. However, in the pilot study of the same intervention without the health education component [2], similar high uptake of testing were observed.

In the HOPE Study, qualitative data was used to illuminate quantitative study findings, providing context and answers to understand behaviors and to further refine the intervention. If the Kenya Ministry of Health will pursue roll-out as a collaborator in the next steps, the qualitative results are invaluable in understanding and optimizing the intervention as we move forward not only to study but to begin providing this intervention to more communities. Qualitative components may become part of this wave of on-going fieldwork and study, where quantitative and qualitative inform one another [3].

4.2 REFINING THE INTERVENTION WITH NEW EVIDENCE

The next step having completed the HOPE Study is to determine how to refine the intervention for further study and scale-up to antenatal clinics. One way to maximize the intervention's efficiency would be to use a multi-component approach of invitations, phone calling, and home testing, given that recent studies have reported success in partner invitations and partner tracing. Understanding these recent studies further would be helpful in guiding the next steps for the HOPE intervention. Additional ways to maximize efficiency include targeting certain populations for home testing and tailoring health messages based on what is needed for each couple.

In both the HOPE Study and pilot study, invitations regarding couple counseling and testing at the antenatal clinic resulted in about a third of men coming to clinic for testing [2]. An implementation study using clinic invitations for male partners in Tanzania in 2013 published this year resulted in half of men returning to clinic with about eighty percent accepting couple testing [4]. This study was not a randomized trial, but was an implementation study with pre- and post- measures of couple testing (pre-study couple testing rates during antenatal care 2-19%). Community sensitization campaigns of HIV and PMTCT occurred during the study period as part of government public health initiatives, which may have contributed to its success. Also, the study was conducted in an overall lower prevalence area of HIV than the HOPE study, which

may have also aided in high rates of return (9% in compared to 15.1% in Nyanza province where the HOPE study was conducted) [5]. Furthermore, rates of male attendance were much higher in rural than urban areas (three-quarters versus about a third of men, respectively). The urban result is more applicable to HOPE Study setting of Kisumu, and correlates well with the invitation arm results. Overall, self-reported HIV positive status was negatively associated with partner return, and three-quarters who were HIV positive concordant or discordant relationships who did attend reported problems during mutual disclosure, signifying that clinic-based testing of these couples with standard of care procedures may not have been able to provide adequate counseling due to lack of skill or time. Lastly, the invitation used in this study did not mention testing, but rather invited the partner for a clinic information session that would cover pregnancy, parenthood and other health issues. Also, a follow-up letter was given to those not attending the second antenatal visit with a new appointment for the partner session; the first invitation yielded 79% of men returning, with the remaining 21% returning after the second invitation.

In a different study published this year, a randomized trial of partner invitations (n=100) in Malawi also yielded about half of men presenting to the clinic and undergoing couple testing [6]. This study only included HIV positive women with the rationale that disclosing to male partners would increase PMTCT adherence, specifically Option B+. In the partner invitation plus tracing arm (n=100), in which partners had three phone call attempts and three in-person location attempts to schedule an appointment at the clinic, about three-quarters of men presented to clinic and were tested as a couple. Phone tracing had the most gains in tracing the partners for clinic attendance, with 18% presenting after phone tracing, and 5% presented with additional in-person tracing. By comparison, the pilot study for HOPE called women in both the home testing and invitation arm as needed to reschedule appointments [2], while phone follow-up calls were only made to the home testing arm in the HOPE Study; however, both had home locator visits for study follow-up purposes and may have had an influence on partner involvement. Invitations in the Malawi study also did not mention testing, but rather invited the man for family-focused health education and included an appointment date which was determined with input from the woman, but women were told they could come back with their partners at any time. In addition, a transport allowance was given for each study visit which may have had an influence in partner attendance. Also, women were excluded if their partner was not living in the area (98 out of 336 women screened) and this exclusion may have influenced high partner attendance (in the HOPE

Study, this was not an exclusion criteria). Of partners who did not attend, women reported that the partner had no time, did not want to come to clinic or receive education as the reasons for nonattendance. Also, women who were afraid of partner reactions were less likely to have partners attend as well as women who already knew of their partner's HIV positive status. In maximizing efficiency and thus reducing cost, the next phase in HOPE may try invitation and phone calling approaches first but instead of three in-person location attempts, would utilize home testing.

With this new evidence and invitation arm results from the HOPE Study and pilot study, invitations could be used as a first attempt to test male partners, with follow-up calling if not at first successful, and home visits for those who have not been reached and tested by the first two methods. This integrated model could be more efficient and less costly while maximizing the effectiveness of all approaches. However, some couples could be targeted for home testing without the first attempts of invitations and calling. Target populations for home testing may include HIV positive women, those who report their partners would be too busy or unwilling to come to the clinic, those who anticipate issues with testing and disclosure and need additional skilled time and counseling that home testing can provide, and couples' personal preference of visit location. Couples to be visited at home may be asked about additional preferences, including gender and number of health advisors, and may result in a visit with two opposite gender advisors. In addition, the intervention could be refined by tailoring educational messages to couples by evaluating behaviors they have already engaged in and assessing what additional education they may need and want, as the qualitative component in HOPE identified many couples already had achieved these health behaviors in the past.

The antenatal clinic would remain the method of identifying pregnant women, to test women on their own initially so at the very least they know their own status and be prepared for couple testing, and be used as a base for distributing invitations to women, making phone calls and conducting clinic visits, and planning home-based visits that would extend from this location with dedicated staff as needed. This type of program would need to rely on a skilled work force with time to dedicate to male involvement, partner calling, couple testing and home visits with focus on quality counseling for disclosure. Training in couple testing, HIV counseling as well as marital counseling would be needed among health workers in this program. In addition, time would need to set aside for engaging male partners rather than adding this task into an already

strapped and busy clinic setting. The acceptance of couple testing also hinges on the presence of a strong HIV comprehensive care and antiretroviral therapy program, with the added benefit of clinic testing being able to refer more directly to these programs than home-based testing.

There are a few other aspects that still needed to be considered. First, the question of compensating for clients' time remains unanswered, as the HOPE Study and the pilot study gave compensation [2], the partner tracing study in Malawi provided a travel allowance [4] and the partner invitation implementation study in Tanzania did not specify [6]. In the qualitative study in HOPE, couples reported that the education was more valuable than compensation, but that couples may expect or be more willing to be involved if some form of compensation or incentive was given. Also, scheduled appointments were important in home-based visits, but it was not clear how well these two studies with clinic-based visits were able to honor these scheduled appointments. Thus, it was unclear if couples had short or no waiting times or if couples were in queue if they did not come during their appointment times. These aspects need further consideration in the next step of the intervention.

4.3 USING IMPLEMENTATION SCIENCE TO SCALE-UP HOPE

Once refinements to the intervention have been considered, the next step is to determine the best way to examine and scale-up the intervention to antenatal clinics. Before the HOPE Study began, many steps were taken to maximize the potential post-trial scale-up of the intervention in Kenya including thoroughly understanding the observational literature, conducting a pilot study of home testing, receiving buy-in from the Ministry of Health and other stakeholders, and including a cost-effectiveness component and qualitative study as part of a randomized clinical trial design. Utilizing implementation science methods to study and scale-up the intervention would be a logical next step. A stepped wedge design may be the most appropriate and forward-looking design to pursue next as it simultaneously allows for further examination of effectiveness in different settings and allows for the benefits of the program to begin taking effect in communities in a pragmatic way.

There is no question that in any design chosen as the next step, more sites would need to be involved. Having more than one site would be advantageous as it would provide not only more generalizable results, but also experience in how to implement the intervention in different settings. Kisumu, the third largest city in Kenya, is located in the west on the shore of Lake Victoria in

Nyanza province, where HIV is considered hyperendemic with adult prevalence around 15.1% [5]. The clients are from a mix of urban, peri-urban and some rural areas. It is not known how the intervention would do in a completely rural site, although the pilot study was based in a more rural area, thus having multiple sites would provide stronger evidence for further scale-up. However, knowing how well something can work can be a useful tool for program managers and implementers as they aim for high efficiency and productivity in settings similar to Kisumu.

A design that could be considered instead of a stepped wedge trial would be a multi-site trial, but this design still allocates the intervention to individuals rather than communities and is less appropriate for implementation science objectives. A cluster randomized trial is another study design that could be considered, in which the intervention is implemented to randomly chosen sites and other sites, where no intervention is implemented, serve as the controls at the same time. The cluster randomized trial addresses the problem of contamination, that is, the potential for the effects of the intervention to spread beyond the individuals and into the population, including the controls [7]. The HOPE Study may be subject to some contamination, as women or men may share what they learned from the educational component of the intervention with others in their community or exhibit different behaviors which may influence others as well. Another benefit of cluster randomized trials is that a whole facility would be on board with the intervention, therefore, you would learn the effect of introducing an intervention into the clinic. For scale-up, this is a useful design as it provides knowledge of facility-level effectiveness.

Similar to cluster randomized trials, a stepped wedge design may be even better suited to study and scale-up interventions. This design actually represents the way many interventions are rolled out, in waves where sites are added on at different times because it is logistically difficult to deliver the intervention to all sites at once [8]. Comparisons are made between the times in which sites which are implementing the intervention against times when the other sites are not. Importantly, the order in which the sites receive the intervention should be randomized. This design is practical when the intervention is well predicted to be beneficial, thereby having a parallel control arm would be unethical and against the concept of equipoise [8]. With the benefits seen in HOPE, equipoise may not be achieved by randomizing individuals or even sites. The benefit of rolling out the intervention sequentially ensures that all participants receive the intervention at some point. This ethical consideration was also considered in the HOPE Study, and it was decided

that all control participants will receive home-based testing and education at the end of the follow-up period.

Currently, we are looking for grant opportunities and have begun drafting a proposal that would study and implement the intervention to additional sites. This proposal also has aims that are more in line with implementation science goals, including 1) assessing effectiveness rather than efficacy, 2) defining start-up time, staffing needs, training, and cost, 3) performing time-motion and flow-mapping studies to increase efficiency and performance and 4) using existing staff and resources to create a sustainable implementation model. Given the setting of dedicated study nurses and health advisor staff and intensive follow-up, the HOPE Study likely estimated efficacy, rather than effectiveness, the latter of which uses more flexible, everyday practices with relatively unselected participants in order to test the intervention in more real world circumstances. A determination of effectiveness would be an important next step in how well the intervention stands up to these conditions. Start-up time, staffing needs, training and cost would also be important to assess as even the cost-effectiveness component in the HOPE Study had to use a few assumptions in estimating costs, particularly the cost of using community health workers rather than dedicated and more trained research staff and health advisors. However, given that couples had privacy and adequate training concerns with local community health workers, this may need to be addressed by using community health workers from outside the area or dedicated home visit staff from the clinic and training them appropriately. Time-motion and flow-mapping studies would help identify bottlenecks or inefficient parts of the system of identifying pregnant women at the antenatal clinic, speaking with them about home-based testing, scheduling appointments, tracking couples and following through with appointments. A potential inefficiency that could be even be improved upon is working hours of health advisors and scheduling home visits on the same day that are in near proximity to one another. And finally, using existing staff and resources with less support from study grants would give an idea of how much the system would be able to handle as is and how much it would have to invest to conduct the intervention so that it can become a sustainable part of antenatal care in Kenya.

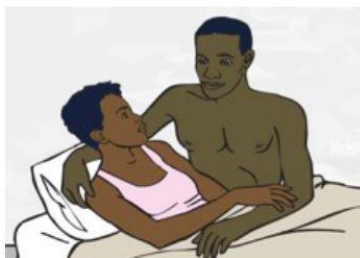
There are many combinations of kinds of interventions, trials and study designs. Given implementation science is a relatively new field, and is just becoming more standardized in terms of nomenclature and tools, randomized clinical trials have remained predominant while other methods evolve. The HOPE Study, during its inception and roll-out, utilized what was feasible in

terms of budget constraints and what was useful in determining efficacy and acceptability in designing the study. As a randomized clinical trial with elements of implementation research, including cost-effectiveness and qualitative assessment, the HOPE Study provides valuable information to the next phases of adding additional sites, with the larger goal of nationwide roll-out. Furthermore, the quantitative and qualitative results demonstrate that this intervention is highly acceptable, effective and feasible and has implications for PMTCT and overall HIV testing strategies. A stepped wedge design as a next step would not only maximize on a research and implementation science goals, but would also confer the benefits of the intervention to a wider population as the intervention begins to scale-up in Kenya.

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APPENDIX A



Preventing STIs

Test for syphilis* and receive treatment at the clinic if needed.
Seek medical treatment if you notice symptoms of STIs (sexually transmitted infections)

Testing for syphilis is at the same time as HIV. Can use the same 1 finger-prick as HIV test. Treatment cures and it protects your baby.

Recognize STI symptoms and seek medical treatment early if you have...

Discharge
Abdominal pain
Painful urination (burning)
Genital ulcer (pain / no pain)*

Treatment for STIs can help avoid...

Miscarriage, stillbirth, child death *
Babies born too small *
Baby's illness (eyes, brain, lungs, etc) *
Mother's future infertility

Warning! Do not self-medicate. If an STI is not properly treated, symptoms may disappear but the infection is still present.



Family Planning

It is best for a woman's health to wait 2 years between pregnancies. To accomplish this you will need to:

Make a plan NOW

- 1) Discuss how many children you desire
- 2) Decide which contraceptives to use

Avoid Sex for 6 weeks after Delivery. This is important to ensure a mother's recovery from childbirth.

Use multiple types of Contraceptive for 2 years after your a child is born

- 1) **Progestin (Injections or Pills) + Condoms** OR
- 2) **IUDs + Condoms**

Warning! Condoms alone are **NOT** enough to prevent pregnancy. Combine them with another contraceptive.



Home-Based Partner Education & Testing (HOPE) Checklist

- ✓ Talk to your partner about Family Planning
- ✓ Plan to Deliver at a Health Facility
- ✓ Breastfeed Exclusively
- ✓ Consider using Contraceptives
- ✓ Know your partner's HIV status
- ✓ Seek clinic treatment for STIs
- ✓ Use condoms if your partner could be HIV-positive
- ✓ Be Faithful to your partner
- ✓ Consider Male Circumcision

HOPE Study Contact Information:
Dr. Alfred Osoti, 073-726-3000 ext. 44138



Facility Delivery

The hospital is the best place to deliver your baby. Health workers **WANT** to help you deliver your baby safely.

Make a plan for delivery

- 1) Where will I deliver?
- 2) How will I get there?
- 3) Who will go with me?
- 4) Who will take care of my children?
- 5) How much money will the facility delivery cost? the travel?

Facility Delivery Helps:

1) Protect both mother and child during delivery.

If anything goes wrong, skilled health workers will assist you.

2) Prevent infection

Health Facilities are clean and safe.

3) Protect your baby from HIV

If you are HIV+, you will be given medicine to protect your baby from HIV.



Infant Feeding

Breastfeeding **ONLY** during the first 6 months of life is the best way to feed your baby.

Exclusive Breastfeeding means no formula or sugar water; only breast milk.

- 1) Breast milk provides exactly the right nutrients that your baby needs to grow.
- 2) Breast milk helps prevent infection.
- 3) Breast milk is free, always available, and safe, but formula may not be.
- 4) Exclusive breastfeeding provides short-term protection against another pregnancy, which gives mothers time to recover after delivering a child.
- 5) If you are HIV+ Breastfeeding is **NOT** dangerous for your baby if you take your ART pills regularly.

Note: **Formula feeding** without clean, boiled water can make your baby very sick.

Warning! If you are **HIV-positive**, using formula and breast milk together might give your baby HIV, but **Breastfeeding Exclusively** will help protect your baby.



Preventing HIV

Women are at high risk for HIV infection after giving birth. Take these steps to protect your partner.

1) Know your Partners' Status.

Get tested for HIV!

2) Always **use condoms** during sex if your partner is HIV-positive or you do not know their HIV status.

3) Men and women should Give up Outside partners

Your risk of HIV infection is **HIGHEST** if you have other sexual partners outside of this relationship.

4) Consider Voluntary Medical Male Circumcision

Male circumcision will reduce a man's risk of being infected with HIV, and will help protect his female partner. Being circumcised around the time when your partner gives birth is a perfect time because your partner needs a break from sex after delivering a baby anyway.

VITA

Daisy Krakowiak, MPH, PhD, earned her doctoral degree in Epidemiology at the University of Washington in 2015 and has been a part of the Kenya Research and Training Center since 2011. The focus of her dissertation has been working on a randomized clinical trial of home-based education and HIV testing of partners of pregnant women in western Kenya (The HOPE Study) with Carey Farquhar, MD, MPH, as the PI on the project and the chair of her committee. She spent time in Kenya in Fall 2014 to implement a qualitative component to capture user perspectives and experiences of the intervention and has also been involved in survey development, study management, data cleaning and analysis. She presented baseline findings of the association of past antenatal attendance and partner HIV testing at the International AIDS Society (IAS) Conference in Vancouver in July 2015 and the main quantitative results of the study have been selected for an oral presentation for the Conference on Retroviruses and Opportunistic Infections (CROI) in February 2016 as well as for publication in a supplement in the Journal of Acquired Immunodeficiency Syndromes (JAIDS).

Prior to coming to University of Washington, Daisy earned her MPH and a graduate certificate in Global Health from the University of Utah in 2010. From 2010 to 2011, Daisy was involved in the Berekuma Collaborative Community Development Project in Kumasi, Ghana, where she led a family planning assessment and disseminated findings from previous assessments back to participating communities. Daisy is interested in research and program implementation in the areas of partner involvement, maternal and child health, reproductive health, and HIV.