CORRELATES AND BARRIERS OF CONTRACEPTIVE USE AMONG HIV DISCORDANT COUPLES IN KENYA

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Correlates and Barriers of Contraceptive Use among HIV Discordant Couples in Kenya

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DECLARATION

This Thesis is my original work and has not been presented for a degree in any other university.

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DEDICATION

This work is dedicated to my parents Mr. Eliud Ngure and Mrs. Teresia Ngure and to my wife Ruth Wairimu and daughters Teresia Njeri and Sarah Wambui.

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LIST OF ABBREVIATIONS/ ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome.
ANC	Antenatal Care
APHRC	African Population and Health Center
ARV	Anti-Retroviral
ART	Anti-Retroviral Therapy
CBS	Central Bureau of Statistics
CEDPA	Center for Development and Population activities
СНСТ	Couples HIV Counselling and Testing
COC	Combined Oral Contraceptive
EDA	Exploratory Data Analysis
ERC	Ethical research Committee
FAN	Formal Approval Number
FGDs	Focus Group Discussions.
FHI	Family Health International
FP	Family Planning.
GEE	Generalised Estimating Equations
GoK	Government of Kenya.
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus.
HSV	Herpes Simplex Virus
	V.V.

ICPD International Conference on Population and Development IAS International AIDS Society ICF Inner City Fund **IDRC** International Development Research Center IEC Information Education and Communication IDI In depth Interviews IQR Interquartile Range **IREC** Institutional Research and Ethical Committee **IUCD** Intra Uterine Contraceptive Device KAIS Kenya AIDS Indicator Survey **KDHS** Kenya Demographic Health Survey. **KEMRI** Kenya Medical Research Institute KII Key Informant Interviews **KNBS** Kenya National Bureau of Statistics Kshs. Kenya shillings MOH Ministry of Health. MTCT Mother to Child Transmission NACC National AIDS Control Council NASCOP National AIDS and STI Control Program NCAPD National Coordination Agency for Population and Development PEPFAR President's Emergency Plan for AIDS Relief

PIPS	Partners in Prevention Study
РМТСТ	Prevention of Mother to Child Transmission
PTID	Participant Identification Numbers
SSC	Scientific Steering Committee
STDs	Sexually Transmitted Diseases
STIs	Sexually Transmitted Infections.
WHO	World Health Organisation.
UN	United Nations
UNFPA	United Nations Population Fund
UNAIDS	The Joint United Nations Programme on HIV/AIDS
USAID	United States Aid for International Development
VCT	Voluntary Counselling and Testing

DEFINITION OF OPERATIONAL TERMS USED IN THIS STUDY

Barrier Contraception Barrier methods of birth control include methods that present a physical barrier when having sex. They include male condoms, female condoms and diaphragm

CD4 (Cluster ofThis is a glycoprotein expressed on the surface of T helperDifferentiation 4)cells. HIV infection leads to a progressive reduction in the
number of T cells expressing CD4. Health professionals
refer to the CD4 count to decide when to begin treatment
during HIV infection. Normal blood values are 500-1200
cells/ mm3. CD4 count test measures the number of T
cells expressing CD4. Patients often undergo treatments
when the CD4 count reach a level of 350 cells/ mm3; less
than 200 cells/ mm3 in an HIV positive individual is
diagnosed as AIDS (Staszewski *et al.*, 1999).

Contraception This is the practice or methods used to deliberately prevent a woman becoming pregnant as a result of having sex (Ngure *et al.* 2009).

Contraceptive use Number of positive responses to the questions indicating past, present use and future intentions to use

contraception. Defined as any current use of an intrauterine device (IUD), tubal ligation or hysterectomy, or an oral, injectable, or implanted hormonal method (other than condoms) (Ngure *et al.* 2009).

Contraceptive User Any respondent reporting use of any contraceptive methods during the study follow up period.

Gender "Gender" refers to the different roles that men and women play in society and also to the rights and responsibilities that come with these roles. It differs from "sex" which refers to the physical and biological differences between men and women (Brett, 1991, CEDPA, 1996, Riley, 1997, Williams *et al.*, 1994).

Knowledge The individual's level of awareness as represented by their answers to simple questions such as side effects associated with contraception. This can also be referred to as awareness.

- Non BarrierNon barrier methods of birth control include methods thatContraceptiondo not present a physical barrier when having sex. They
include intrauterine contraceptive devices (IUDs) and
hormonal contraceptives.
- Self-reportedUse of contraception other than condoms, defined asContraception usecurrent use of an intrauterine device, surgical method,
depot medroxyprogesterone acetate, implants, or oral
hormonal methods.
- Sero-discordant Couples One partner is HIV-1 infected and the other is HIV-1 uninfected – making these couples a high-risk population for HIV-1 transmission and a key group for targeting HIV-1 prevention strategies

ABSTRACT

Unwanted pregnancies among HIV discordant couples are a surrogate marker for high risk sexual intercourse. Among HIV discordant couples there is an ever present risk of HIV transmission to the infants born of the HIV positive women as well as to the HIV negative partner. Mother to Child transmission (MTCT) is the main mode of HIV transmission to infants. Avoiding unwanted pregnancies among HIV-infected women would avert or reduce the number of HIV positive births. Contraceptive use among HIV positive women is highly recommended through counselling and awareness creation. Some contraceptive methods such as male and female condoms can also prevent HIV infection to the negative partner. The main objective of this study was to determine the factors associated with contraceptive use in a clinical trial cohort of HIV serodiscordant couples based in Thika and Eldoret Districts in Kenya. Additionally, this study sought to explore barriers to contraceptive use among the same cohort of HIV discordant couples. Data was collected from of 481 HIV discordant couples enrolled in the Partners in Prevention HSV/HIV Transmission Study at Thika and Eldoret sites. Contraceptive use was measured through self report at baseline, every 3 months and at the 24 month study visit. Additionally, qualitative data was collected through 32 in depth interviews, 8 focus group discussions among HIV discordant couples and 8 key informant interviews among clinicians and counselors working at the two clinical trial sites.

At baseline the prevalence of non-barrier contraceptive methods among the HIV positive women was 24.3% and 25.7% among the HIV negative women. At month 24 of follow up the prevalence of contraceptive use was 38.6% among the HIV positive and 18.2% among the HIV negative women. Using logistic regression models, the estimated odds of contraceptive use among HIV positive women was 1.61 (95% confidence interval (CI) 1.0-2.5). Additionally, being married (odds ratio (OR) = 2.4, 95% CI 1.2-5.0), attending Thika site clinic (OR = 6.1, 95% CI 4.2-9.0), and having two or more children (OR = 1.9, 95% CI 1.3-2.8) were associated with increased use of non barrier contraceptives. The main barriers to contraceptive use among the couples identified qualitatively were; (1) lack of adequate knowledge on modern contraception among both men and women leading to myths and misconceptions; (2) side effects associated with the methods either experienced or perceived; (3) male partners reported opposition to contraception methods available to their partners. Most women believed that male partners expected to be consulted before women started or changed a contraceptive method. The implications of these findings are that future programs should focus on interventions to increase contraceptive use among women in HIV discordant relationships, with a special emphasis on HIV negative single women with 2 or fewer children and their male partners. Additionally, emphasis on educating couples on contraceptive methods would reduce barriers associated with misconceptions associated with modern methods as well as building skills for women to negotiate contraceptive use with their male partners.

CHAPTER ONE:

1.0 INTRODUCTION

1.1 Background information

Kenya has witnessed a steady rise in contraceptive use since the early 1980s reaching 46% in 2008-9. Consequently the total fertility rate declined from 8.1 births per woman in the 1970s to 4.6 births per woman between 2006 and 2008 (Kenya National Bureau of Statistics (KNBS) & Inner City Fund (ICF) Macro, 2010). However, according to Central Bureau of Statistics (CBS) 2003, there is still a large unmet need for contraceptives estimated at 25% this has remained unchanged since 2003 (KNBS & ICF Macro, 2010 and CBS, 2003). This unmet need for family planning has been further compounded by the HIV/AIDS epidemic with regions with high HIV prevalence also being the same with high fertility levels. For example in sub Saharan Africa, women experience an average of 5.6 births, meaning they spend a considerable part of their life pregnant (Morrison *et al.*, 2007).

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that by December 2008, 33.4 million people worldwide were living with HIV/AIDS, 31.3 million adults, 15.7 million women and 2.1 million children under 15 years. A total of 2.7 million people were infected in 2008, 2. 3 million adults and 430,000 children. In addition, about two thirds (63%) of all adults and children living with HIV globally were

in sub-Saharan Africa. A significant number of children are infected through mother to child transmission of HIV. UNAIDS further estimated 1.7 million adult deaths and 280,000 children under 15 year olds deaths (UNAIDS, 2009).

In sub Saharan Africa It is estimated that one quarter of all births are unintended, applying the same estimate to the HIV positive births, therefore 25% of all HIV positive births are unintended. Contraceptive use would therefore prevent these births which have been estimated at 120,000 HIV positive births per year (Reynolds, 2005). The National AIDS Control Committee (NACC) and National AIDS and STI Control Program (NASCOP) estimate infections in children are calculated from HIV infection among adults thus projecting the number of children likely to be infected through mother to child transmission. The mother to child transmission of HIV can be greatly reduced by prevention of mother to child transmission (PMTCT) programs. There were an estimated 83,000 births from HIV positive women in Kenya, resulting in 29,022 HIV positive births in 2006 (MOH, 2005).

The 2007, Kenya AIDS indicator survey (KAIS), indicated that 7.1% or about 1.3 million Kenyans are infected with HIV with the highest prevalence being in Nyanza at 14.9% and lowest being North Eastern Province at 0.8%. Nyanza and Rift Valley provinces are home to more than 50% of HIV infected persons in Kenya. In addition about 10% of HIV positive women aged between 15-49 were pregnant at the time of the survey (NASCOP, 2008).

Among married individuals in Kenya who are HIV infected, 45% have a partner who is not currently infected. In addition 10% of monogamous married couples and 14% of polygamous couples are in serodiscordant relationships (NASCOP, 2008). Recent population surveys and mathematical modelling studies have found that stable HIV-1 serodiscordant couples (in which one partner is HIV-1 infected and the other is HIV-1 uninfected) may be responsible for a majority of new HIV-1 transmissions in Africa (Dunkle *et al.*, 2008). Thus, HIV-1 serodiscordant couples should be considered a high priority population for both HIV-1 prevention efforts and family planning interventions.

Factors that influence contraceptive use especially among HIV positive and HIV negative women in discordant relationships need to be studied to give insights that may help increase contraceptive usage among this group. In addition, use of condoms may help reduce the prevalence of HIV among the general populace.

1.2 Problem Statement

Pregnancy among HIV positive women presents a risk of mother to child transmission (MTCT). Even when MTCT of HIV does not occur there is the ever-increasing risk of the infant being orphaned and becoming vulnerable to sexual abuse and HIV infection. HIV positive infants are a burden not only to individual women but also to medical institutions and society as a whole. Treating HIV related opportunistic infections and complications is expensive and not affordable in many developing countries. This is more so when meeting the basic needs of maternal and child health is in itself a burden. Additionally, the HIV negative partner within the discordant couple is at an ever increasing risk of acquiring HIV infection from the HIV positive partner further compounding the situation. With women who acquire HIV during pregnancy being at the highest risk of transmitting HIV to their infants.

Gender has a tremendous influence on reproductive health decision making and behaviour. Such decision making can include use of family planning (Blanc *et al.*, 1996). This study seeks to explore gender –based factors that may influence contraceptive uptake among HIV positive and HIV negative women in sero- discordant relationships in Thika and Eldoret Districts.

The limited information regarding the factors that influence contraceptive use among HIV discordant couples is a major barrier to developing effective programs. Such programs can support positive behaviour and attitudes such as increased condom use and decreased unsafe sexual behaviour and decision making in relevant issues with regard to contraception. Findings from this study will guide development of policies to increase contraceptive use among HIV discordant couples in Kenya.

1.3 Justification for the Study

Family planning is of critical importance in HIV prevention, and is often an overlooked HIV prevention strategy (Cates, 2006). Averting unintended pregnancies for women will reduce MTCT for those who are positive. Adding family planning to HIV care programs will reduce future unintended pregnancies for HIV positive women.

Infants born to HIV positive women even when they do not contract HIV are at a risk of orphan hood and many of the women infected with HIV are unaware of their status. Orphans present a challenge to the society and are vulnerable to sexual abuse which further compounds the HIV/AIDS problem (Richey & Setty, 2007).

Contraceptive use among the HIV positive women needs to be established in order to provide the support necessary to avoid unintended pregnancy and to adopt safer sexual behaviors. Preventing unintended pregnancies will reduce the chances of HIV positive births and would eventually reduce the prevalence of HIV/AIDS (Cates, 2006).

Thika and Eldoret sites were selected for this study purposefully to give a representation from diverse geographical regions in Kenya. Additionally the two of these sites had cohorts of HIV-1 serodiscordant couples, this being special group is difficult to find cohorts of discordant couples in many regions of Kenya. At the time of the study only 4 large cohorts of HIV-1 discordant couples existed in Kenya, in Thika , Eldoret, Kisumu and Nairobi.

This study sought to identify factors that influence reproductive decision making among HIV discordant couples. Especially since stable HIV serodiscordant couples have been recently reported to be responsible for a majority of new HIV-1 transmissions in Africa (Dunkle *et al.*, 2008). Determinants and barriers to contraceptive use, and factors that contribute to successful contraceptive use in this population should be understood if efforts to reduce the number of unintended pregnancies are to be successful. In addition understanding the role of gender in contraceptive uptake in this population would provide invaluable insights.

HIV discordant couples have been neglected by policy makers in the past in family planning issues, with no policy on contraceptive choices for HIV serodiscordant couples in Kenya. Such a policy would guide health care providers in addressing the unique contraceptive issues among HIV serodiscordant couples.

1.4 Research Questions

- i. What are the factors influencing contraceptive use among HIV discordant couples within Thika and Eldoret Districts?
- ii. What are the barriers to effective contraceptive use among HIV discordant couples within Thika and Eldoret Districts?

1.5 Null Hypotheses

- a) The HIV status of women in serodiscordant relationships does not significantly influence their contraceptive use.
- b) The social demographic characteristics of women in serodiscordant relationships does not significantly influence their contraceptive use.

1.6 Study Objectives

1.6.1 Overall Objective

To determine the correlates and barriers of contraceptive use among HIV discordant couples in Thika and Eldoret Districts.

1.6.2 Specific Objectives

- a. To evaluate the contraceptive choices and trends among HIV positive and negative women in discordant relationships during follow up in Thika and Eldoret Districts.
- b. To determine the correlation between HIV status, health status and social demographic characteristics of the women and their male partners on non-barrier contraceptive use.
- c. To identify the barriers to contraceptive use among HIV discordant couples.

CHAPTER TWO:

2.0 LITERATURE REVIEW

2.1 HIV Discordance

Among married individuals in Kenya who are HIV infected, 45% have a partner who is not currently infected. In addition 10% of monogamous married couples and 14% of polygamous couples are HIV serodiscordant (KAIS., 2008). There have been numerous reports that have demonstrated that stable HIV discordant couples may be responsible for a majority of HIV infections in Africa (Lingappa et al, 2008; Dunkle et al., 2008). It has been recently demonstrated that the risk of HIV acquisition rises during pregnancy (Mugo *et al.*, 2010). This change is unlikely to be due to sexual risk behaviors, but might be attributable to hormonal changes affecting the genital tract mucosa or immune responses. HIV prevention efforts are needed during pregnancy to protect mothers and their infants, this is more so for HIV discordant couples, where HIV negative women with HIV positive male partners are at an increased risk (Gray *et al.*, 2005).

2.2 Family planning in Kenya

Family planning allows individuals and couples to anticipate and attain their desired number of children and the spacing and timing of their births. It is achieved through use of contraceptive methods and the treatment of involuntary infertility. A woman's ability to space and limit her pregnancies has a direct impact on her health and well-being as well as on the outcome of each pregnancy.

According to KNBS and ICF Macro (2010), the uptake of family planning in Kenya is relatively high. The contraceptive use among married women is estimated at 46%, with most using a modern method (39% of married women) while 6% use traditional methods. Injectables, pills and periodic abstinence are the most commonly used contraceptive methods, used by 22%, 7% and 5% of married women respectively. One quarter of currently married women in Kenya have an unmet need for family planning that has remained unchanged since 2003. About 50% of unmet need is composed of women who want to wait for two or more years before having their next child (spacers), while 40% is composed of women who want no more children (limiters) (CBS, 2003, KNBS & ICF Macro, 2010).

Despite a relatively high level of contraceptive use, unplanned pregnancies are common in Kenya. Overall 17% of births in Kenya are unwanted, while 26% are mistimed (wanted later) (KNBS & ICF Macro, 2010). The percentage of births considered mistimed or unwanted has decreased slightly compared with the 2003 Kenya Demographic and Health Survey (KDHS), however trends show a sizeable increase in percentage of births that are unwanted and a comparable reduction in those that are mistimed (CBS, 2003, KNBS & ICF Macro, 2010). Trends in contraceptive use in Kenya show a slight increase since 2003 (39 to 46%) among married women. This was a 7 % increase experienced between 2003 and 2008. There was also an increased trend towards use of injectable contraceptives and a decrease in the use of the pill (CBS, 2003, KNBS & ICF Macro, 2010).

Further KNBS and ICF Macro, (2010) reports that 36% of women discontinue a method within 12 months of embarking on use. The one year discontinuation rate as follows, injectables (29%), periodic abstinence (33%), the pill (43%) and male condom (59%). In a study among women in HIV counselling and testing clinics, a substantial majority in Kenya (59%), Tanzania (66%), Zimbabwe (77%) and Haiti (92%) reported they did not want another child in the next two years (Cohen, 2008).

2.3 Approaches to preventing Paediatric HIV infection

In the absence of any HIV prevention intervention, a mother who is infected with HIV will transmit the virus to her baby (30 to 40%) of the time. NASCOP estimates that approximately 100,000 infants and children are living with HIV in Kenya and many more have already died of AIDS related complications. The majority of these children acquired the infection from their mothers at or around the time of birth, with a small number infected during pregnancy. Between 25 to 50% of the infected children are probably infected through breast milk (MOH, 2001).

The World Health Organization and its United Nations (U.N.) partners have been promoting four main approaches to prevent mother to child transmission of HIV (WHO, 2003a). These approaches were identified by the U.N. in the Glion Call on Family Planning and HIV/AIDS in Women and Children to provide health care workers with opportunities to reduce mother to child transmission (UNFPA, 2004). The first approach referred to as primary prevention of HIV infection in women involves preventing the woman from becoming infected by delaying the sexual debut of teenage girls, keeping girls in school and providing HIV prevention counselling. This can reduce the number of young women who are infected during pregnancy.

The second approach involves reducing the number of HIV-exposed pregnancies, by encouraging sexually active women to avoid unwanted pregnancies by using effective methods of contraception. It would thus be important to investigate factors that influence contraceptive use among HIV positive women with an aim of increasing contraceptive uptake to reduce unwanted pregnancies.

The third approach involves reducing transmission from HIV infected women by voluntary counselling and testing (VCT) for HIV during pregnancy and for women who test positive by provision of antiretroviral (ARV) drug prophylaxis during delivery and to their newborns. Other practices in this approach include activities that reduce trauma and shorten exposure to the virus during labour and delivery can reduce HIV transmission. These include avoiding prolonged rupture of the membranes for more than

four hours and routine episiotomy and elective caesarean delivery. The fourth approach encourages provision of care and support for HIV –infected women, infants and their families.

Currently, the main approach to preventing mother to child transmission has primarily focused on provision of ARVs to mothers and their neonates. However, many HIV positive births could be prevented by preventing primary HIV infection in young women of child bearing age and preventing unintended pregnancies by using contraceptives among HIV positive women (O'Reilly, 2003).

2.4 Family planning as a HIV prevention Strategy

Family Health International (FHI) estimates that current contraceptive use by HIV positive women prevents over 173,000 HIV positive births each year in Sub-Saharan Africa. This report further suggests that effective contraceptive use has a potential of preventing more than 160,000 additional paediatric HIV infections annually (Cates, 2006).

Researchers from World Health Organization (WHO) and the Johns Hopkins University found that a reduction of 16% in unintended pregnancy rates in the 8 countries studied would reduce HIV positive births as much as the current PMTCT initiatives among HIV infected women (Sweat *et al.*, 2004).

The data demonstrates that even a modest decline in the number of unintended pregnancies among HIV positive women in Botswana, Cote d'Ivoire, Kenya, Rwanda, Tanzania, Uganda, Zambia and Zimbabwe could lead to the prevention of the same number of HIV positive births as prevented by the current PMTCT programs in these countries (Sweat *et al.*, 2004).

According to Connor (1994), the benefit of maternal antepartum and intrapartum zidovudine therapy followed by newborn zidovudine therapy for the first six weeks after birth reduced the risk of MTCT by approximately two thirds with this therapy (from 25 to 8%) subsequently, the vertical transmission rate was further reduced to < 2% with the use of highly active antiretroviral therapy (HAART) and scheduled caesarean delivery in select HIV positive women. The proven benefit of such therapies in the reduction of vertical transmission of HIV, along with the fact that HIV has become a manageable chronic disease, may influence the postpartum contraceptive choice of women with HIV. For example, more HIV positive women may choose reversible forms of contraception instead of choosing permanent sterilization which limits future pregnancies (Tuuli, 2006).

According to Stover (2003) and Sweat *et al;* (2004) preventing unintended pregnancies is a cost effective strategy to prevent new HIV infections among infants. Models have demonstrated that for the same expenditure, increasing contraceptive use averts more HIV positive births than a traditional PMTCT strategy of ARV prophylaxis. A study conducted in eight African countries estimated that the same number of infections averted by providing niverapine to all women with HIV giving birth could be averted at a less cost by moderate reductions in the number of unintended pregnancies from 6% to 35% in Kenya and Rwanda, respectively, (Sweat *et al.*, 2004).

2.5 Family planning practices among HIV positive women

There is little information about factors that influence contraceptive use among HIV positive women. Limited studies have been conducted in Kenya and even fewer studies have been conducted among HIV discordant couples.

A study among HIV positive women enrolled in care in USA, found that HIV positive women have reproductive patterns similar to those of HIV negative women with the majority having given birth to children and many wanting more children in the future. Potent antiretroviral therapy has greatly improved the outlook for HIV –infected women even those with an AIDS diagnosis (Stanwood *et al.*, 2007).

Four studies (two in developed and two in developing countries) on HIV positive women and contraceptive use reported increased condom use in sero-discordant couples and an increase in contraception among HIV positive women with children after learning their HIV status. In the studies from developed countries, an association was found between knowing HIV positive status and decreased pregnancy rates through increased contraception or increased termination of pregnancy prior to the
introduction of highly effective antiretroviral therapy but not after, while no such dampening effect of HIV status on pregnancy rates was found in developing countries (Delvaux & Nostlinger).

It is estimated that if the HIV – positive women in Sub Saharan Africa who are currently using modern contraceptive methods to prevent unintended pregnancy were not able to do so, the number of HIV positive births in the region would be 31% higher than it is now, translating to 153,000 more HIV –infected births unplanned births each year (Cohen, 2008).

A qualitative study which explored pregnancy decision-making among HIV-positive women in four US cities revealed that this was influenced by factors such as: perceived risk of vertical transmission, beliefs about vertical transmission risk reduction strategies, desire for motherhood, stigma, religious values , attitudes of partners and health care providers and the impact of the mother's health and longevity of the child. Most women who did not desire children after their diagnosis cited the risk of vertical transmission as the primary reason for not wanting children. Those who became pregnant after their diagnosis seemed more confident in the efficacy of risk reduction strategies (Kirshenbaum, 2004).

One in four married women in Sub – Saharan Africa is sexually active and does not want to have a child or another child in the next two years, yet not using any method of contraception. This results in many unintended births, which occur in the very

countries in which HIV prevalence is high and 60% of all adults living with HIV are women (Cohen, 2008).

Studies have reported diverse rates of dual method use for pregnancy and STI/HIV prevention, rates ranging from (3-42%), but few data are available regarding people living with HIV and women in sero-discordant couples (Delvaux & Nostlinger, 2007).

Research has shown that regions with high HIV-1 prevalence are also the same where women experience high levels of fertility. For example, in sub-Saharan Africa, women experience an average of 5.6 births, thus spending a considerable portion of their reproductive years pregnant (Morrison *et al.*, 2007).

Little is known about how initiatives to offer ARV drugs to HIV infected women may affect a woman's desire for pregnancy. But HIV-infected women may be less interested in limiting childbearing in response to their HIV-infected status if ARV treatment promises better health, quality of life, and survival (Preble *et al.*, 2003). In the U.S., abortion rates among HIV infected women fell after ARV drug therapy (Massad *et al.*, 2004).

Studies into the HIV/AIDS health care system revealed that the unmet need for contraception among HIV-positive women and women at high risk of HIV is even greater than among women in the general population . A study conducted among women in three PMTCT programs in South Africa in 2006, established that 84% of the

pregnancies were unintended. A similar study reported that 93% of the pregnancies among pregnant women receiving antiretroviral therapy in Uganda were unintended (Cohen, 2008).

A breastfeeding study in Kenya that examined contraceptive use and factors that were associated with use of reliable contraceptives found that women with sero-discordant partners were more likely to use reliable contraceptive methods. The study also found an 86% of women reported reliable contraceptive use, however a significant number of the women reported subsequent pregnancies (Mbori-Ngacha *et al.*, 1998).

2.6 Contraceptive use and Gender Roles

Gender has a dominant influence on reproductive decision making and behaviour (McCauley, 1994; Moser, 1993; USAID, 1997). These decisions include whether to practice family planning, choosing when and how to have sexual relations, engaging in extramarital sexual relations and using condoms to prevent STDs (Beckman 1983, Blanc *et al.*, 1996, Magnani 1997). In many developing countries such as Kenya men are the primary decision makers in matters of fertility and contraceptive use (Green *et al.*, 1995). They are often referred to as "gatekeepers" because of the multiple powerful roles they play in society. In the many roles men can control access to information, finances, transportation and other resources (Robey *et al.*, 1990; Mbizvo *et al.*, 1996).

Male involvement in reproductive health is important in enabling millions of women avoid unintended pregnancies (Population report, 1998). Global estimates suggest that out of the 175 million pregnancies each year, 75 million are unintended (UNFPA, 1997).

A study conducted by Isiugo-Abanihe (1994) among 3,000 urban Nigerian couples found that, while men do not dominate decision making, they still wield more power than women. Approximately 60% of men interviewed reported that they decided on matters of family size, when to have sex and how long periods of abstinence should last, 40-50% of women agreed that men decide. A study of one South Indian family found that the men tended to control contraceptive use and make fertility decisions (Karra *et al.*, 1997).

In addition, it is difficult for women in many places to gain compliance with safe sex from their male partners. Many women are uncomfortable or afraid to ask their sexual partners to use condoms. This poses the risk of disclosing their HIV status and casting doubts in the partner's fidelity, both of which may be seen as courting conflict, violence or abandonment.

According to Mantell *et al.* (1998) successful integration of family planning (FP), HIV and STI prevention services requires consideration of the following issues; concurrent protection from pregnancy and HIV/STIs, the social forces and gender relations affecting sexual negotiations between women and men, the need for reorganization of FP programs; and improvement in STI diagnosis and treatment among asymptomatic clients.

"A gender perspective should be adopted in all processes of policy formulation and implementation and in the delivery of services especially in sexual and reproductive health including family planning" (UN, 1999). Understanding gender relations is important in reproductive health programs for both men and women. Programs that understand gender roles of both men and women are more likely to avoid roles that would reinforce negative gender roles. This will enable them to design programs that would maximize communication strategies that in the long term facilitate more equality between men and women, resulting in positive outcomes in the reproductive health arena (Pfennenschimidt *et al.*, 1997).

Cognitive models have been extended to the study of behavior change for a wide variety of behaviors, ranging from smoking cessation to the adoption of new computer technologies, from weight control to condom use, and from the acceptance of novel agricultural techniques to using clean needles when injecting drugs. With extended applications, several models have been extensively revised and refined. Yet, particularly within the last decade, a number of scholars have leveled criticisms, most prolifically and thoughtfully with respect to HIV prevention (Parker, 2004, Davies *et al.*, 1992, Ingham *et al.*, 1992, Melkote *et al.*, 2000, Yoder, 1997, Yoder, 2001).

Behavioural interventions to control the transmission of HIV have largely centered on risk reduction through abstinence, being faithful, or condom use (the so-called ABC's of HIV prevention). Several scholars have argued that cognitive theories and models of health behavior do not provide an adequate framework for promoting the adoption of safe sex.

Yoder (2001) highlights two key assumptions common to cognitive models of behavior change: 1) the capacity for behavior change is viewed as being in control of the individual, and it is assumed that if individuals are educated about health risks they will be motivated to change their behavior; and 2) individuals act rationally in assessing information and risk, and are empowered to take action to protect themselves. Unlike smoking cessation or the adoption of preventive medical care, safe sex (except for the case of abstinence) is not something that individuals engage in alone. Airhihenbuwa and colleagues (Parker, 2004) argue that the assumption that individuals can or will exercise total control over their behavior has led to a focus on the individual rather than on the social context in which the individual functions. This viewpoint has been dubbed the "individualist fallacy" by Davies *et al.*, (1992), who also points out that the interpersonal activity is preceded by a "complex social negotiation, which we understand poorly."

According to Davies *et al.*, (1992) "it is more fruitful to seek the causes of a particular sexual behavior in the interaction between individuals," rather than in characteristics of the individual. This suggests that the unit of analysis is more appropriately the

interaction in a sexual session, as opposed to specific cognitive characteristics of an individual (Yoder, 2001). Emphasis on the negotiating aspects of sexual encounters draws attention to the dynamics of interpersonal power, and raises the issue of self efficacy, the extent to which individuals have control over the course of events (Yoder, 1997) emphasizes that, in cognitive models, "most social behavior is assumed to be based on volition, and very closely linked to intention to perform that behavior." Yet for sexual encounters, this may not be the case. As Parker (2004) notes, "Sexual interactions take place in a wide range of contexts and along a continuum of consent that extends from willed or conscious engagement in sexual activity through to unwilled non-consensual sex, that include the use of coercion and possibly physical violence." With respect to consensual sex, Davies *et al.*, (1992) notes that sexual negotiation is not necessarily between equals. Instead, there exist situations in which one individual becomes more able to decide the course of events than the other, and the decisionmaking power is not fixed over time, but continuously renegotiated, even between the same two individuals. As Yoder (2001) points out, however, most cognitive models "assume individuals make a once-and-for-all decision to have safe sex ... (and) minimize the negotiating aspects of sexual acts." Similarly Parker 2004 argues that behavior change cannot be assumed to be consistently maintained, and emphasizes that the "complexity of sexual relationships and interactions over a lifetime....are influenced by diverse changing contexts – for example changing partnerships, changing relative empowerment/ disempowerment." Consequently, individual intention is mediated by this shifting power dynamic, influenced by interpersonal actors, as well as fluctuating social and political realities (Mason, 1994).

The second broad assumption of cognitive behavior change models – that individuals educated about risks will act rationally – has also been called into question. Ingham *et al.*, (1992) points out the narrow use of the concept of rationality in behavior change theory: "Campaigns and interventions rest on the assumption that 'correcting' false beliefs and misconceptions will enable any 'rational' person to alter their behavior in the 'desired' direction." Missing from this formulation of rationality is the fact that individuals may have valid reasons for not complying with the advice, or may have other factors constraining or motivating their behavior. Ingham *et al.*, 1992 thus describe "varied rationalities" that may be "at odds with and counteract the 'received rationality' of official biomedical wisdom." This, again, points to the fact that also influence decision-making. While some models have been extended to address this by adding socio-demographic variables, Yoder (1997) concludes that "factors of social relations and ecological context are given short shrift."

Along with Davies *et al.*, (1992), Yoder (2001), emphasizes the utility of focusing on social interaction for understanding behavior change, and elucidating contexts in which specific actions are negotiated or imposed. He concludes that focused ethnographic methods are essential to understanding behavior in its social contexts.

CHAPTER THREE:

3.0 MATERIALS AND METHODS

3.1 Study Sites

The study was conducted as an ancillary study to the "Phase III Randomized Placebo-Controlled Trial of HSV-2 Suppression to Prevent HIV transmission among HIV – Discordant Couples." This study was also known as "Partners HSV-2/HIV-1 Transmission Study" (Lingappa *et al*, 2009). It was conducted in two of the fourteen sites Partners in Prevention study sites, Thika and Eldoret. The other sites were Gaborone (Botswana), Kisumu, Nairobi (Kenya), Kigali (Rwanda), Cape Town, Johannesburg-Orange Farm, Johannesburg-Soweto (South Africa), Moshi (Tanzania), Kampala (Uganda), Ndola, Kitwe, Lusaka(Zambia). Thika and Eldoret sites were purposively selected. Both sites enrolled a total of 481 HIV discordant couples and followed them for up to 24 months.

3.1.1 Thika Site

Thika site is located in Thika District, in Central Province of Kenya (appendix 11) and has a HIV prevalence of 3.6% (NASCOP, 2008; appendix 12). Thika site recruited HIV discordant couples mainly from the expansive Thika District and enrolled 213 women from July 2006 to April 2007. Among these women 160 were HIV positive while 53

were HIV negative. Baseline data on contraceptive use among HIV positive and HIV negative women was collected at enrolment.

Thika District is one of the seven districts in Central Province. The district covers an area of 1,960.2 sq Km². It borders Nairobi City to the south, Kiambu District to the west, Maragua District to the north and Machakos District to the east. The district lies between latitudes 3°53' and 1° 45' south of Equator and longitudes 36° 35' and 37° 25' east. The district's population stood at 575,968 in 1999 for the then Gatundu and Thika Divisions. Growing at rate of 2.56%, the population increased to 670,265 persons in 2000 with Gatundu and Thika Divisions having been hived off to form part of the new Thika District. The district population is projected to reach 674,868 in 2010 as HIV/AIDs in Thika is a major health problem with the prevalence averaging 3.4%. With regard to bed occupancy, about 60% of the hospital beds are occupied by patients with HIV/AIDs related diseases. The age group 20-49 years is the most affected, majority of whom are females (NCAPD, 2005). This has resulted in high increase in number of HIV/AIDs orphans in the district and loss of families' incomes which is directed towards addressing the pandemic in the household. The main causes of the spread of HIV/AIDs in the district include unsafe sexual behavior, drug abuse especially drinking of illicit brews, high levels of peer pressure and ignorance of facts, family breakdowns and others (NCAPD, 2005a).

3.1.2 Eldoret Site

Eldoret site is located in Uasin Gishu district located in Rift valley Province of Kenya (appendix 11) and has a HIV prevalence of 6.3% (NASCOP, 2008; appendix 12). Eldoret site recruited couples mainly from the expansive Eldoret/ Trans Nzoia district and enrolled 268 women from November 2004 to April 2007. Among these 200 were HIV positive while 83 were HIV negative. Baseline data on contraceptive use among HIV positive and HIV negative women was collected at enrolment.

Uasin Gishu District is one of the Seventeen (17) districts in Rift Valley Province (RVP), with a total area of 3,327.8 Sq.Km. It extends between longitude 34° 50' and 35° 37' east and 0° 03' and 0° 55' north. The district shares common borders with Trans Nzoia District to the north, Marakwet and Keiyo to the east, Koibatek District to the southeast, Kericho District to the south, Nandi to the west and Lugari District to the North West. The district is divided into six divisions namely Kapsaret, Ainabkoi, Kesses, Soy, Turbo and Moiben. The 1999 population census showed that Uasin Gishu District had a population of 622, 705 with a growth rate of 3.35% per annum. The population growth rate is on a general decline from the inter-censal rate of 3.93% per annum for the period 1979 – 1989. HIV/AIDS has become a major threat as prevalence rates are on the general increase and 72% of women surveyed (CBS, 1998) indicated that they are at little risk of getting the virus (low risk perception). Uasin Gishu recorded a HIV/AIDs prevalence of 12.1% in year 2001. Both males and females are affected in equal proportions of 1:1. Condom use is very low in the district with only 5% of the

women and 23% of the men reporting use of the method (NCAPD, 2005b). It is imperative that more targeted IEC be put in place to give information on the pandemic. The high-risk groups like the truck-drivers that pass through the main urban centres in the district need to be sensitized. The social and economic consequences of HIV/AIDs are enormous. Children as young as 10-12 years have been left to fend for themselves and their siblings, leading to school drop outs and increase in child labour and abuse (NCAPD, 2005b)

3.2 Study Design

This was a descriptive cross-sectional study that utilized a combination of quantitative and qualitative techniques to gather data from the study population. Quantitative data was abstracted from the case report forms and medical records of all the 481 female and 481 male study participants enrolled in the Partners in Prevention trial. This data included relevant demographic information such as the participant's age, education, marital status, employment status, obstetric history, and parity, number of living children, medical history- CD4 count, ARV status and contraceptive choice at enrolment, quarterly and the exit visits. In the Partners in Prevention trial data on contraceptive use was collected from the HIV positive women on monthly basis, while data was collected from the HIV negative women on quarterly basis. However, only contraceptive data collected at quarterly visits was extracted to have equal data points for both HIV positive and HIV negative women. All discordant couples were followed for up to 24 months.

Additionally, cross sectional design was employed to gather qualitative data by use of in- depth interviews, focus group discussions among HIV positive women and HIV negative women and their male partners and key informant among health care workers (clinicians and counsellors), working at the two clinical trial sites.

3.3 Study Population

The study population comprised HIV discordant couples enrolled in the Partners in Prevention clinical trial, a collaborative project by the University of Washington and Kenyatta National Hospital. At baseline all the 481 HIV discordant couples were sexually active, were part of a heterosexual couples and had reported at least 3 sexual contacts in the 3 months prior to enrollment. During follow up HIV positive women came to the study clinic on monthly basis while the HIV negative women came to the clinic quarterly.

Quantitative data was collected from all the 481 HIV discordant couples, while the qualitative data followed a specified inclusion and exclusion criteria.

3.3.1 Inclusion Criteria

- i. HIV discordant couples aged over 18 years (legal age of consent in Kenya).
- ii. Enrolled participant at the Partners in Prevention study at Eldoret and Thika sites.
- iii. HIV discordant couples who consented to the study.

3.3.2 Exclusion Criteria

- i. HIV discordant couples aged below 18 years.
- ii. HIV positive participants who may be too sick to answer questions.
- iii. HIV discordant couples who declined to participate in the study.
- iv. Being on antiretroviral therapy.

3.4 Study Variables

3.4.1 Dependent Variables

These variables related to the use of barrier and non barrier contraceptives. These included contraceptive use at enrollment and contraceptive use at every quarterly and exit visits (trends).

3.4.2 Independent Variables

These variables related to demographic characteristics such as; age, educational level, marital status, HIV Status of male partner, barrier contraceptive methods, economic status, number of children, history of verbal or physical abuse, CD4 cell count, pregnancy status throughout the follow up period and ARV use during study follow up.

3.5 Sampling Procedure

Quantitative data from all the participants enrolled at the Thika and Eldoret sites were analyzed. Participants for the focus group discussions (FGDs) and in depth interviews (IDIs) of this study were selected purposively (also known as judgement sample) according to the study eligibility criteria and the most productive sample to answer the research question. This involved development of a framework of variables that might have influenced an individual's contribution. Couples were identified from the Partners in Prevention Study cohort while counselors and clinicians were purposively selected from the staff of the Partners in Prevention Study at both Thika and Eldoret clinical trial sites.

3.5.1 Sample size determination

Sample size was determined using a formula (as recommended by Fisher et al., 1998)

$$n = \frac{z^2 pq}{d^2}$$

Where,

n= desired sample size

z= standard normal deviate which is equal to 1.96 corresponding to the 95% confidence limit.

p= prevalence of contraceptive use among discordant couples was hypothesized to be 39%

p= 0.39

q=1.0- p = 0.61

d= the confidence limit of the prevalence (p) at 95% confidence interval

= 1 – Confidence interval = 1 – 0.95 = 0.05

Degree of accuracy desired for the study was hence set at ± 0.05

Thus

$$n = \frac{(1.96)^2 \times 0.39 \times 0.61}{0.05 \times 0.05} = 365.6$$

The minimum sample size for this study was **366** couples

However, data from all the 481 (25% more) couples was available and was abstracted. This translates to data from **962** individuals. This increased the power of this study and limited bias associated with inadequate sample size.

3.6 Data Collection Methods

Quantitative data was obtained from the Partners in Prevention database using a structured questionnaire (Appendix 1).

Discordant Couples who had participated in the Partners in Prevention trial were recruited for participation in in-depth interviews and focus group discussions. Participants also responded to a brief structured face to face questionnaire that assessed their socio demographic characteristics and contraceptive method use.

Focus group discussions (FGDs), key informant interviews and in-depth interview guides were used to elicit qualitative data (Appendices 2, 3 and 4). Guiding the discussion, the principal investigator elicited views on barriers contraceptive from the group members. This was also useful in eliciting views that were not obvious from the structured questionnaires and helped in clarifying issues that emerged from the quantitative data.

Focus group discussions (FGDs) were useful in eliciting information on shared understandings of constructs by specific subpopulations, revealing the degree of consensus or contestation and disagreement among members of that subpopulation or across comparative groups (Knodel, 1993;Bernard,1995). A total 8 focus group discussions were conducted at both sites, 2 among HIV positive women, 2 among HIV negative women, 2 among HIV negative men and 2 among HIV positive men. A minimum of 8 and a maximum of 12 participants were recruited for each FGD. Eligible participants for the FGDs were HIV positive and HIV negative women and their male partners. The sample size and study were designed using the principles of qualitative methods research (Bernard &Ryan, 2010;Miles & Huberman, 1994; Sandelowski, 1994; Straus & Corbin , 2008)

In-depth interviews were conducted among women and their male partners, who were not using any contraception during their participation in Partners in Prevention study to explore factors associated with non use of family planning method. According to Barnard (1995) and Miles *et al.*, (1994), in-depth interviews are most appropriate to focus research on personal experience, behavior, motivations and attitudes. In total 32 in - depth interviews were conducted to explore barriers of women and their male partners who were not using contraceptives stratified by HIV status. The participants who participated in the in-depth interviews did not participate in the FGDs and vice versa.

Key Informant Interviews (Appendix 4) were employed to gather data from family planning counsellors and study clinicians at both the Thika and Eldoret clinical trial sites. A total of 8 key informant interviews were conducted. All the qualitative interview guides were pre-tested before the commencement of the study. This was done after drafting the interview guide. Pretesting helped the investigator to assess the time it took to complete the interview and helped to identify and amend confusing questions. After pretesting the investigator developed the final interview guide.

The qualitative interviews were conducted by the Investigator and two trained research assistants. This was after training the research assistants thoroughly on how to conduct and transcribe the interviews. The quantitative data was extracted and analysed by a biostastician under the guidance of the of the investigator.

3.7 Data Analysis

3.7.1 Quantitative data analysis

A computer based data file was developed using STATA version 10 for analyses of the quantitative data from the questionnaires. For inferential analysis, a longitudinal analysis of the contraceptive use at each follow-up month was done. Data analysis began by graphically exploring the data to determine crude trends in the data guided by the study objectives. This kind of longitudinal data, determined if the data were linear in time or curvilinear so as to inform the analysis method.

The following approaches addressed the research questions.

1. Exploratory data analysis (EDA):

Exploratory data analysis were used to crudely assess the relationship between HIV status and the chance contraceptive use over time as measured in months since enrolment by;

- a) Graphical and tabular presentation of longitudinal data.
- b) Fitting smooth curves to longitudinal data.
- 2. Confirmatory analysis via longitudinal logistic model based on GEE.

This way the scientific question involved, not only how the prevalence of contraceptive use differed, but also how the change in prevalence of contraceptive use overtime. This included the relationship between prevalence of contraceptive use and HIV status other factors such as age, marital status, site, number of children among others. Basically this involved characterizing the changes in the prevalence of contraceptive use overtime.

Longitudinal logistic model was considered appropriate for carrying out the primary analysis of the study addressing this primary scientific question. Specifically, letting be the contraceptive use indicator (=0 or 1) on the patient at the follow-up month. The following logistic model for marginal probability of contraceptive use at each follow-up month using a generalized estimating equations (GEE) approach.

The model includes a squared term for time (months) to account for the curvilinear trend in contraceptive use. An adjustment for other potentially confounding variables was done to allow for the analysis of their possible role on the association between contraceptive use and the risk (likelihood) of contraceptive use and changes in this risk over the time. Using the XTGEE command in STATA V10.1, the above logistic model was run for the likelihood of contraceptive use.

The focus of this question was the inferences about the population-average likelihood ("risk" here refers to likelihood of using any form of contraceptive) of contraceptive use and the effect of baseline HIV status on this risk, as well as to determine whether changes in the risk of contraceptive use during follow-up. Therefore, longitudinal logistic model was considered appropriate for carrying out the primary analysis of the study addressing this primary scientific question. Specifically, Letting Y_{ij} be the contraceptive use indicator (=0 or 1) on the *i*th patient at the t_{ij} follow-up month, the following logistic model for marginal probability of contraceptive use at each follow-up month was fitted using a generalized estimating equations (GEE) approach.

$$\log it(\Pr(Y_{ij}=1)) = \beta_0 + \beta_1 HIV_i + \beta_2 age_i + \beta_3 t_{ij} + \beta_4 t_{ij}^2 + \beta_5 marital_i + \beta_7 Site_i + \beta_8 No.child_i$$

The model includes a squared term for time (months) to account for the curvilinear trend in contraceptive use.

3.7.2 Qualitative Data Analysis

Audio-taped IDIs, KIIs and FGDs were transcribed, translated and coded for predetermined and emerging themes. Qualitative data from FGDs, IDIs interviews and KIIs were analyzed thematically in five main stages as follows;

- 1) Transcription and review of notes and tapes.
- 2) Analyses of the notes by themes for location of key words.
- 3) Development of an analysis framework.
- 4) Summary of results by themes (for each discussion).
- 5) Summary of results for all discussions and interviews conducted.
- 6) Data was presented in summaries and quotations.

3.8 Ethical considerations

Only participants' identification numbers (PTID) were used in all the databases to maintain confidentiality. The database was only accessed by passwords. Publications from these data will not bear name identifiers. Additional written consent was sought from all participants for the qualitative component of this study using informed consent forms (Appendices 5, 6, 7). This study was approved by Moi University Institutional Research and Ethics Committee (Ref. FAN: IREC 000450; Appendix 8). In addition,

the KEMRI National Ethics Review Committee approved this study (Ref. KEMRI/ RES/7/3/1; Appendix 9). This study was also approved by the KEMRI Scientific Steering Committee (Ref. SSC. No 1617, Appendix 10).

CHAPTER FOUR:

4.0 RESULTS

4.1 Baseline Characteristics of the Study Participants

Data from a total of 481 HIV discordant couples from Thika and Eldoret sites were analyzed. Depending on the type of variables, appropriate standard descriptive (summary) statistics such as means for continuous variables; counts and proportions for categorical variables. The median duration of follow-up was 18 months (IQR 15-24) for HIV-1 seropositive women and 18 months (IQR 18-24) for HIV-1 seronegative women, and HIV-1 seropositive and seronegative women each completed a median of 6 visits (IQR 5-7 and IQR 6-7, respectively).

4.1.1 Distribution of study participants by site and by HIV status

More than half (55.7%) of the participants were from the Eldoret site (Table 4.1).

Table 4. 1: Distribution of study participants by site and by HIV status

Site	Ν	HIV-	HIV+	Р
Eldoret	268 (55.7%)	86(61.4%)	182(53.4%)	0.106
Thika	213 (44.3%)	54(38.6%)	159(46.6%)	0.100

The proportion of HIV positive and negative women from both the Eldoret and Thika sites were statistically similar (p=0.106) by chi-squared test.

4.1.2 Distribution of participants by age

The median age was 30.5 years for HIV negative and 30 years for HIV positive women. The highest proportion of the participants (53.2%) were aged 25-34 years (Figure 4.1). The proportion of age categories for HIV positive and negative women were statistically similar (p=0.083).



Figure 4. 1: Proportion of participants in various age categories by HIV Status

4.1.3 Marital status of the participants by HIV status

In this couples' study, most (94.2%) of the participants reported being married (Table 4.2). The remaining participants (5.8%) reported to be single (with a regular sexual partner) or cohabiting. The proportion of participants by marital status for HIV positive and negative women were statistically similar (p=0.357).

Table 4. 2: Distribution of study participants by marital status

Marital Status	Ν	HIV-	HIV+	Р	
Single	28	6(4.3)	22(6.5)	0 257	
Married	453	134(95.7)	319(93.5)	0.337	

4.1.4 Distribution of participants by number of children

Overall, most (71.9%) of the HIV positive participants had two or more children while a small (10.4%) proportion of participants did not have any children (Figure 4.2).



Figure 4. 2: Distribution of participants by number of children

The proportion of participants by number of children for HIV positive and negative women were statistically similar (p=0.064).

4.1.5 Baseline CD4 cell count of the participants at baseline

About half (50.1%) of the HIV positive participants had a CD4 of more than 500 cells/ mm^3 (Figure 4.3).



Figure 4. 3: CD4 cell count of the HIV positive participants at baseline

At baseline all the participants had a CD4 of above 250 cell/ mm3. A (Partners in Prevention study inclusion criteria).

4.1.6 Prevalence of contraceptive methods at baseline

At baseline 74.3% and 75.7% of HIV positive and HIV negative women respectively were not on any non barrier contraceptive method. Among the contraceptive users,

injectable methods were the most commonly used by both HIV negative (15%) and HIV positive (14.7%) women (Figure 4.4). The proportion of participants by contraceptive choices for HIV positive and negative women were statistically similar (p=0.685).



Figure 4. 4: Prevalence of contraceptive methods at baseline

4.2 Comparison of contraceptive choices and trends among HIV positive and negative Women

Contraceptive use was compared between HIV positive and HIV negative women during follow-up.

4.2.1 Proportion of participants using contraceptives during follow-up by HIV status.

Cross-sectionally, the prevalence of contraceptive use was significantly (P=0.032) higher among the HIV positive women at each month relative to the HIV negative women. Table 4.3 shows the proportion of participants using contraceptives during follow-up by baseline HIV status.

Table 4. 3: Prevalence of contraceptive use during follow-up

		Follow-up visit Month								
		0	3	6	9	12	15	18	21	24
HIV-	N	140	134	127	112	100	76	59	31	22
	count(%)	36(25.7)	31(23.1)	32(25.2)	28(25)	26(26)	21(27.6)	17(28.8)	7(22.6)	4(18.2)
HIV+	N	341	329	323	315	297	272	204	125	88
	Count (%)	83(24.3)	88(26.7)	107(33.1)	130(41.3)	132(44.4)	127(46.7)	88(43.1)	45(36)	34(38.6)

4.2.2 Prevalence of Contraceptive use among women during follow-up in Thika site

At Thika site the baseline contraceptive use among the HIV positive women was 29.6% and 37% among the HIV negative women. The HIV positive participants reported a higher contraceptive use than the HIV negative participants throughout the 24 month follow -up (Figure 4.5).



Figure 4.5: Contraceptive methods used during follow-up at Thika

4.2.3 Prevalence of Contraceptive use among women during follow-up in Eldoret site

At Eldoret site the baseline contraceptive use among HIV positive women was 19.8% and 18.6% among the HIV negative women.

The HIV positive participants reported a higher contraceptive use than the HIV negative participants throughout the 24 month follow -up (Figure 4.6).



Figure 4.6: Prevalence of Contraceptive methods used during follow-up in Eldoret

4.2.4 Prevalence of contraceptive methods used during follow-up

Among those using contraceptives, over 55% used injectables compared to other forms of contraceptives at each time- points during follow-up. It was observed that at any follow-up month, at least 60% of the participants were not using any form of contraception. IUDs were the least popular method with less than 10% of participants using them at anytime during the follow up visit.

Figure 4.7 shows the proportion of participants using various forms of non-condom contraceptives during follow-up among all women by method chosen.



Figure 4.7: Prevalence of various Contraceptive methods used during follow-up by all women

4.2.5 Prevalence of various contraceptive methods during follow-up among HIV positive women

The most common contraceptive method used by the HIV positive women was injectable method (reported by 60% of the women at baseline and by 67.3% at month 24) followed by oral methods at 13.3% at baseline and by 15.4% at month 24, IUD and implants 8.4% at baseline and by 7.7% at month 24. A number (18.1%) reported to have undergone hysterectomy (Figure 4.8).



Figure 4.8: Prevalence of various contraceptive methods by HIV positive women during follow-up.

The IUD (*coil*) was the least popular method through all the months of follow up. In the qualitative interviews numerous myths were associated with the IUD.

4.2.6 Prevalence of various contraceptive methods used during follow-up among HIV negative women.

Among the HIV negative women, the most common contraceptive methods used were; injectable methods (reported by 58.3% of the women at baseline and by 62.8% at month 24) followed by oral methods at 13.9% at baseline and by 0% at month 24, IUD and implants 13.9% at baseline and by 25% at month 24. A number (13.9%) reported to have undergone hysterectomy (Figure 4.9)



Figure 4.9: Prevalence of various contraceptive methods by HIV negative women during follow-up

Among the HIV negative women, injectable contraceptive methods were the most commonly used followed by the oral contraceptives. In the qualitative interviews women reported that injectables methods were easy to use and could be used discreetly that is, without their male partners knowing.

4.2.7 Reported Condom use among HIV discordant couples

Reported condom use was high throughout the follow up period for sex with study and non study partners (study partner sexual partners who they enrolled with in the Partners in Prevention clinical trial). This arose from 75.47% at baseline to 94.02% at month 24 of follow up for sex with study partners and remained >95% throughout follow up for sex with other partners (Table 4.4).

Month of Visit	N		Study Partner	Other partners			
		Count	%	count	%		
0	481	118	24.53	16	3.33		
3	453	46	10.15	6	1.32		
6	441	34	7.71	8	1.81		
9	421	31	7.36	14	3.33		
12	419	33	7.88	14	3.34		
15	410	26	6.34	20	4.88		
18	349	20	5.73	16	4.58		
21	238	20	8.40	11	4.62		
24	184	11	5.98	8	4.35		

 Table 4. 4: Prevalence of Unprotected Sex by women with Study and Non

 Study partners

Although reported condom use among women was high, it was associated with numerous negative sentiments which were reported in the qualitative interviews. These views included that the condoms were not appropriate for couples but their HIV serodiscordant status 'forced' them to use them.

"The condom is not good for men, it is only because of the problems that we have that we use it. It also hurts us." 46 year old HIV negative male participant.

Condoms were also reported to cause reduced sexual pleasure.

"we are fed in our minds that condoms make sex tasteless, also you see condom is something strange, so inserting a condom and using a condom is something that is not in our practice. It has an element of dissatisfaction," 46 year old HIV positive male participant.

4.3 Correlates of contraceptive use

The focus of this question was the inferences about the population-average likelihood ("risk" here refers to likelihood of using any form of contraceptive) of contraceptive use and the effect of baseline HIV status on this risk, as well as to determine whether changes in the risk of contraceptive during follow-up.

In the first model, the estimate odds of contraceptive use for the HIV positive relative to the HIV negative women are 1.61 (p= 0.032). That is the odds of contraceptive use are 1.61 times greater among the HIV positive women than in those who were HIV negative. This association of contraceptive use with HIV status was statistically significant.

Further the model revealed statistically significant associations between contraceptive use and marital status (P=0.015), site (P <0.001) and number of children (P =0.003). Specifically, being married, coming from Thika, having two or more children were significantly associated with increased likelihood of using contraceptives (Table 4.5).
Table 4.5:Marginal logistic regression analysis of baseline factors and
longitudinal Contraceptive use using GEE Approach. Model 1

Covariate	N	OR	Р	95%CI
HIV status at enrolment				
Negative*	801	1		
Positive	2294	1.605	0.032	(1.042-2.472)
Month of Visit	3095	1.117	< 0.001	(1.073-1.162)
Married to study partner				
No*	181	1		
Yes	2914	2.431	0.015	(1.188-4.976)
Age	3095	0.949	< 0.001	(0.922-0.977)
Site				
Eldoret*	1696	1		
Thika	1399	6.116	< 0.001	(4.156-9.002)
Pregnant during follow up				
No*	2421	1		
Yes	674	0.888	0.591	(0.576-1.369)
Number of Children				
1*	809	1		
>=2	2286	1.868	0.003	(1.245-2.804)
* Baseline category				

In the qualitative interviews one participant commented,

"they want a baby, that makes them stop the family planning because you cannot continue with it and yet you want a baby you cannot get so that makes you stop," 40 year old HIV positive woman.

Similar comments were made by other participants in the IDIs and FGDs and supported by KIIs.

The second model included additional variables, these were, Female CD4, Female on ART, Male CD4, male on ART, female's age, male's age, male earns income, male's average income, female's years of education, male's years of education, female earns income, female's average income, female ever abused and male ever abused were not significantly associated with contraceptive use.

In this second model statistically significant associations remained between contraceptive use and female HIV status at enrolment, marital status, site and number of children. Being married, coming from Thika, having two or more children were significantly associated with increased likelihood of using contraceptives. Table 4.6 contains the results of these analyses, because of the non-convergence of the model, some variables were excluded from the model.

Table 4.6:Marginal logistic regression analysis of baseline factors and
longitudinal Contraceptive use using GEE Approach. Model 2

Covariate	Ν	OR	Р	95% CI
HIV status at enrolment				
Negative*	974	1		
Positive	2393	2.002	0.002	(1.281-3.128)
Month of visit	3367	1.086	< 0.001	(1.045-1.128)
Married to study partner				
No*	189	1		
Yes	3178	2.301	0.026	(1.106-4.785)
Age	3367	0.942	0.001	(0.909-0.975)
Male age	3367	1.015	0.243	(0.990-1.041)
Site				
Eldoret*	1867	1		
Thika	1500	7.149	< 0.001	(4.701-10.874)
Pregnant during follow up				
No*	2570	1		
Yes	797	0.932	0.765	(0.588-1.478)
Male partner's years of education	3367	0.997	0.912	(0.942-1.055)
Male partner's years of education	3367	0.975	0.403	(0.918-1.035)
Number of Children				
0*	314	1		
1	554	2.474	0.018	(1.172-5.222)
>=2	2499	2.885	0.003	(1.446-5.756)
Ever abused				
No*	2963	1		
Yes	404	0.658	0.165	(0.364-1.188)
Male ever abused				
No*	3325	1		
Yes	42	0.479	0.071	(0.216-1.064)
Male earns income				
1*	2134	1		
2	1233	1.052	0.809	(0.699-1.583)
Female earns income				
1*	924	1		
2	2443	1.192	0.435	(0.767-1.853)
* Baseline category				

The third model included additional variables, these were, female and male being on ART, both the male's and female's CD4 . These additional variables were not significantly associated with contraceptive use (Table 4.7). Also not associated with contraceptive use was whether or not both male and female earned income, whether or not male or female had been physically abused by their sexual partner, years of education for both male and female and female being pregnant during follow-up (Table 4.7).

Table 4.7:Marginal logistic regression analysis of baseline factors and
longitudinal Contraceptive use using GEE Approach. Model 3

Covariate	Ν	OR	P>z	95% CI
Month of visit	2329	1.118	< 0.001	(1.066-1.173)
Married to study partner				
No*	149	1		
Yes	2180	2.327	0.055	(0.981-5.520)
Female Age	2329	0.935	0.002	(0.896-0.975)
Male age	2329	1.016	0.275	(0.987-1.046)
Site				
Eldoret*	1246	1		
Thika	1083	10.074	< 0.001	(5.848-17.352)
Pregnant during follow up				
No*	1826	1		
Yes	503	1.457	0.257	(0.760-2.792)
Male education	2329	0.987	0.698	(0.924-1.054)
Female education	2329	0.975	0.474	(0.908-1.046)
Number of Children				
0*	255	1		
1	416	2.161	0.079	(0.915-5.104)
>=2	1658	2.174	0.052	(0.993-4.760)
Female Ever abused				
No*	2024	1		
Yes	305	0.666	0.267	(0.324-1.366)
Male ever abused				
No*	2296	1		
Yes	33	0.269	0.189	(0.038-1.907)
Male earns income				
1*	1549	1		
2	780	1.007	0.979	(0.604-1.680)
Earns income				
No*	661	1		
Yes	1668	1.293	0.353	(0.752-2.224)
Female On ART				
No*	2227	1		
Yes	102	0.7	0.311	(0.352-1.395)
Female CD4				
<=250*	179	1		
250-349	475	1.07	0.759	(0.695-1.647)
350-499	707	1.003	0.991	(0.621-1.618)
>=500	968	1.169	0.53	(0.717-1.906)
* Baseline category				

The fourth model focused on the male partners' variables. This demonstrated that male

partner HIV positive status was associated with a 30% reduced likelihood of

contraceptive use (p=0.028) (Table 4.8).

Table 4.8:	Marginal	logistic	regression	analysis	of	Male	partners'	baseline
factors and lo	ongitudinal	Contrac	eptive use u	sing GEE	Ar	proacl	n. Model 4	

Covariate	Ν	OR	Р	95% CI
Month of visit	3367	1.085	< 0.001	(1.045-1.127)
Married to study partner				
No*	189	1		
Yes	3178	2.249	0.03	(1.082-4.675)
Age	3367	0.941	0.001	(0.909-0.975)
Male Age	3367	1.013	0.323	(0.988-1.039)
Site				
Eldoret*	1867	1		
Thika	1500	7.159	< 0.001	(4.752-10.787)
Male education years	3367	1	0.989	(0.946-1.056)
Education years (woman)	3367	0.973	0.36	(0.916-1.032)
Number of Children				
0*	314	1		
1	554	2.372	0.026	(1.110-5.066)
>=2	2499	2.815	0.004	(1.388-5.706)
Ever abused				
No*	2963	1		
Yes	404	0.68	0.196	(0.379-1.220)
Male ever abused				
No*	3325	1		
Yes	42	0.54	0.115	(0.251-1.161)
Male earns income				
1*	2134	1		
2	1233	1.024	0.909	(0.685-1.529)
Earnincome				
1*	924	1		
2	2443	1.193	0.428	(0.771-1.848)
Male HIV+				
No*	2474	1		
Yes	893	0.702	0.028	(0.512-0.962)
* Baseline category				

Notably, the investigator's interest in statistical modeling was in parsimonious modeling; which sought a minimum set of X variables to predict variation in (Y=contraceptive) response variable. The goal was to reduce the number of predictor variables to arrive at a more parsimonious description of the data.

4.4 Barriers of contraceptive use among HIV discordant couples

4.4.1 Social Demographic characteristics of qualitative study participants

Barriers of contraceptive use among HIV discordant couples were explored using qualitative research methods (IDIs, FGDs, KIIs). A total of 32 couples in depth interviews 8 FGDs were also conducted among HIV positive and negative women and their male in serodiscordant relationships. Additionally, 8 key informant interviews were conducted among the health care workers (Table 4.9).

Table 4.9:Description of Participants for qualitative study

Participants	FGDs	IDI and KII	
HIV positive women in an HIV discordant partnership	2 FGDs		
HIV positive men an HIV discordant partnership	2 FGDs	16 discordant couples	
HIV negative women an HIV discordant partnership	2 FGDs	in-depth interviews	
HIV negative men an HIV discordant partnership	2 FGDs		
Total Sample Size:	8	8 Key informant interviews	

A total of 13 serodiscordant couples were interviewed through IDI. In the IDIs all the women were married, with all women except one being in the reproductive age group (Table 4.10). Each member of the couple was interviewed separately. In the FGDs all

the women were married with more than half (64%) of them having more than 3 children. In addition, 57% of the participants were women (Table 4.10).

	In-depth Interviews		FGDs		
Characteristic	Males n=13	Females n=13	Males n=29	Females n=39	
Age					
20 - 24	0	0	0	2	
25 - 34	2	6	4	17	
35 - 44	6	6	14	15	
45 & Over	5	1	11	4	
Marital Status	13	13	28	39	
(Married)					
HIV Status					
Positive	10	5	14	22	
Negative	3	8	15	17	
Level of Education					
Primary incomplete	0	6	1	1	
Primary Complete	5	2	7	12	
Secondary	7	4	18	25	
College	1	1	1	1	
No. of children					
1	1	1	0	1	
2	4	3	4	13	
3 or more	8	9	11	25	

 Table 4.10:
 Socio Demographic characteristics of couples in IDIs and FGDs

Most (53.8%) of the women in the in - depth interviews reported using condoms only as a method of contraception. This is shown in Figure 4.10



Figure 4.10: Contraceptive use among women who participated in the IDI

Most (54%) of the women in the focus group discussions used condoms only as a method of contraception, followed by injectables at 15% (Figure 4.11).



Figure 4.11: Contraceptive use among women who participated in the FGDs

Key informant interviews were conducted among 4 clinicians and 4 HIV counsellors at the Thika and Eldoret sites. More than half (5/8) of the KII were conducted among females below the age of 34. Almost all (7/8) the informants had at least a College Diploma (Table 4.11).

Characteristic	Males $n = 3$	Females $n = 5$
Age		
25 - 34	1	4
30 - 39	1	0
40 - 49	1	1
Gender	3	5
Marital Status		
Married	3	2
Widowed	0	1
Single	0	2
Highest Level of Education		
Certificate		
Diploma	0	1
University	2	4
	1	0
No. of children		
0	0	1
1	0	3
2	1	1
4	2	0

 Table 4.11:
 Socio demographic information of Key Informant Interviews

4.4.2 Specific Barriers to Contraceptive use among HIV discordant couples

The results of the qualitative interviews are presented by the most salient themes, with illustrative quotes from IDIs, FGDs and KIIs. The reported barriers to contraceptive use are broadly divided into 3 main barriers and 4 less common barriers. In addition, this study was also able to identify the reasons why HIV serodiscordant couples frequently changed or stopped using contraceptive methods.

4.4.2.1 Myths and Misconceptions about contraceptive methods

Among the main reported barriers to modern contraceptive use among HIV discordant couples were myths and misconceptions associated with the contraceptive methods. These myths and misconceptions were widely reported by both female and male participants. There was a general consensus among HIV positive and negative women and their male partners that they had heard that contraceptive methods made the women to be "cold." This was especially after initiating the injectable contraceptives. Interestingly there was no consensus on the meaning of the word "cold" some thought it was actually becoming physically cold while others reported it as losing interest in sex, others did not know what being "cold" meant although they had heard about it. The women reported that their main fear in being 'cold' was that their male partners would abandon them. Mostly these misconceptions were reportedly heard from other women.

"I do not know what they mean by being 'cold', but you can hear it from other women. I have heard from three women one was my brother in laws wife, he kept throwing her things outside, he used to tell her when I sleep with you it is like I am sleeping with my brother you are so cold."... 36 years old HIV negative female participant.

"There is also another one whose husband married another wife and when she asked him why he married another wife, he told her take water to the bathroom and while she was there, he told her feel the water, he told her you are like that water. I do not know how the coldness comes to our side."... 32 years old HIV positive female participant.

"The man and the woman are not interested in that thing (sex) any more and it also has shame." ...49 year old HIV negative male participant

Similar misconceptions associated with the injectable methods were reported by the KII, especially the misconception that contraceptive methods made women become 'cold', which to many participants meant a reduction in libido.

"Most of them believed that family planning methods made their women to be 'cold'. "Men believe that the family planning makes their women become 'cold' and they believe that one so much."...KII Thika

"There are several fears expressed by women for contraceptives: one is the issue of them becoming 'cold' having a lowered sexual urge."... KII Eldoret.

Some women in both IDIs and FGDs reportedly believed that the IUCD could move or disappear inside the woman's body. Additionally, some women reported that their male partners complained that the IUCD pricked them during sexual intercourse. Notably, participants commonly referred to IUCD as the coil possibly because of the shape of the earlier IUCDs which were coil shaped.

"Like the coil, when having sex with your partner, he will feel it."... 26 year old HIV negative female participant.

"The problem with coil is when it is inserted while your husband is away; during sex he says it is not comfortable it pricks him."...36 year old HIV negative female participant.

"There is another method called the coil, I asked people and they told me it is not used by fat people it can disappear inside." ...38 year old HIV negative female participant.

The IUCD was also commonly reported to have a high failure rate leading to unwanted pregnancies mainly after it reportedly 'disappeared' inside a woman's body.

"The coil can move while you are having sex, there are three women I know who got pregnant while having the coil. She found the coil had disappeared in the stomach. until today the coil has not been found and the baby she gave birth to is 4 years." ...36 year old HIV negative female participant.

Similar myths and misconceptions associated with the IUCD were reported by the male participants. Additionally, some male participants also admitted to have heard from women that the IUCD caused cancer.

"Women say it can bring diseases like cancer although when we were taught we were told it is not that way but many believe it is like that." ... 40 year old HIV positive male participant.

Key Informants from Thika and Eldoret sites reported similar misconceptions associated with the IUCDs. They also reported that couples said that the IUCD limited the styles by which they could practice sexual intercourse thereby reducing their sexual enjoyment for fear that it could disappear in the women's bodies.

".....and for IUCD, what I have heard the clients sharing some say it fattens the body leading to weight gain these are some of them that I have heard clients sharing." ... KII Thika

Another commonly held myth associated with IUCD reported by women in both IDIs and FGDs and corroborated by KIIs was it could get stuck on the baby during pregnancy.

"Like the IUCD the participants will feel that when you use the IUCD it disappears in the uterus and will cause damage or you might conceive when it is there and it comes out stuck in the head of the baby (long laugh) that's a myth and it comes out often."... KII Eldoret.

Some of the women in both the IDIs and FGDs reported that the oral contraceptive pill it did not get dissolved completely in the body which left crystals which were claimed to be the cause of fibroids.

"There are those ones who complain and say that drugs lodge in the stomach" ... 40 year old HIV positive female participant.

"I hear people say about it, they said there is a lady where I come from who was operated and when she went to the theatre they found some drugs which had lodged in uterus."... 28 year old HIV positive women.

"It depends on how people talk about them. Most of the time people say those drugs for taking all the time makes women develop growth. That's why some fear.".... 35 year old HIV negative female participant.

Similar misconceptions were reported by some men in the IDIs and FGDs. Additionally some men reported that they had heard from the women that the coil and oral contraceptive pills caused cancer. This led to most of the participants reporting that they were better without family planning to avoid health problems that came with the modern contraceptive methods.

"Some claim that those are not needed in their bodies, it pollutes the body one should stay the way they were born." ... 40 year old positive male participant.

"Others think if you use family planning you may have a baby who is deformed, so those

are some of the myths."... KII Eldoret

One of the misconceptions of the male condom reported by a few women was that it increased the amount of vaginal discharge in women. This was possibly because of the lubrication in the condoms.

"There is another one who is a friend of mine she told me the husband was complaining he does not want to use the condom, her reproductive part was having discharge so the man felt that if he uses the condom he will not satisfy her but he will add more water from the condom. I do not know whether those who do not have that problem enjoy." ... 31 year old HIV positive female participant.

There were a few women who had reportedly used the female condom, one of the main myths expressed by these women was the fear that the female condom would disappear into their female genital tract.

"Okay, the challenges which are there, now for the new users, they say the ring that is there. It makes them to be uncomfortable, so we have those who are opting like after they have inserted, they get the ring and remove it can be better and others say they fear because it can go inside."... KII Thika.

4.4.2.2 Fear of Adverse Events of Contraceptive Methods

A second common theme reported as a barrier to the use of modern contraceptive methods was fear of side effects. These side effects were either experienced by the women themselves or heard from others.

There was a general consensus among women and men in IDIs and FGDs was that the

use of family planning resulted in multiple health complications in women.

"She had tried using pills, she was not comfortable with it then she stopped, she used to complain of health problems sometimes she could have a discharge and she was also not comfortable when having sex." ... 31 year old HIV positive male participant.

Contraceptive methods were reportedly associated with experiences of back pains and also losing or gaining weight. Mainly these were the hormonal contraceptive methods.

"There is one woman who told me she had it and when she stopped she was thin, she had back pains, You can take them and you become thin until you stop them." ... 35 year old HIV negative female participant.

"I have witnessed about two or three, you find the body fattening uncontrollably, overweight, the other one she starts getting pain in her body." ... 46 year old HIV positive female participant.

"One of my friends was inserted Norplant and she was thin like me, there is a time she became too fat she couldn't even walk and there was a time she was sick and her hand got paralyzed and then she stopped that is what made get scared of it." ... 31 year old HIV positive female participant

Another additional reported theme reported by some women and KIIs was that women feared that when they suffered some side effects such as excessive bleeding or reduced libido, their male partners would seek other sexual partners. This was expressed mainly by female participants from Eldoret.

"The fears they have mostly I find them sharing is the prolonged bleeding, you see like she will become anaemic especially those who have started on a method of like injection we have heard that coming in as a report and then some other fear is that of weight gain, gaining a lot of weight. He will say that I am cold, she has that fear that he start looking for someone else and other women to satisfy him because she cold. "... KII Thika

There were a few women who reported that the male condom caused with vaginal itchiness. Some male partners also reported similar observations that their female partners had itchiness after using the male condom.

"Like the condom there are some who say it has an allergy when they use it when having sex; some are left itching after sex. There is some itchiness that they feel." ... 40 year old HIV positive female participant.

An additional side effect reported by some women in the IDIs and FGDS was that contraceptive methods were caused increased heartbeats and nausea.

"Some say they have increased heart beat there are others who I hear when they take the medicine they become nauseated." ... 40 year old HIV negative female participant.

Study participants especially the male partners reported that the condom reduced sexual pleasure, this reduced their motivation to use the condoms.

"Many men have not accepted to use the condom, there is a saying that they equated it to "it is like eating a sweet in a paper" there is a mentality that they have that because its not body on the other it is like there is no sex." ... 40 year old HIV positive male participant.

"You will hear them say it is eating a sweet with the wrapper, men's cases are many, I also read in an article, even those who are in a discordant relationship." ... 42 year old

HIV positive female participant

Similarly, some women especially in the FGDs reported that using a condom reduced sexual pleasure.

"It cannot be the same if he does not have the condom and I also do not have it, the pleasure cannot be the same." ... 35 year old negative female participant.

Additionally, both male and female participants, especially from the FGDs reported that condoms broke often.

"The problem of using the condom comes in when the condom bursts because the condom bursts when you are in dreamland before you finish what you are doing." ... 35 year old HIV positive male participant IDI.

Both female and male participants admitted that information on the side effects from the other men and women made them to make a decision on whether to use contraception and the kind of method to use.

"Like what I have said about my wife, believing that a certain complication is brought by family planning it makes one stop the family planning even if it was not caused by that." ... 40 year old HIV positive male participant

"Health problems, side effects, in fact I have heard this lady who decided never to take contraceptive methods." ... 40 year old HIV positive male participant.

Although family planning had the side effects that they had heard from other people, the male participants were left little choice on the methods.

"I have heard the family planning methods have side effects, but because you do not know any other method, it makes you use those ones, some experience over bleeding." ... 40 year old HIV positive male participant.

The theme of women making decision not to take up contraception based on what they had heard from others was also reported by KIIs at both Thika and Eldoret. For example in an interview with a KII in Eldoret the following came out;

"I: any other fears that you have heard about?

R: Generally what we call peer influence I really don't have a reason but because I heard my neighbour or relative talking bad about it then I just take it to be bad.

I: and how influential is the peer influence?

R: Very, very influential, very influential indeed."... KII Eldoret

Many of the female participants expressed fear when using family planning methods because of side effects and convenience when using them. Some said the injection caused excessive bleeding while others said pills were not convenient as one can forget to take them as advised. These are some of the comments they put across:

"They fear the pills because one forgets all the time. You could forget after coming from the office and go to sleep. Not many people use them."... 40 year old HIV negative female participant.

"The injection increases bleeding, you could have more days to your monthly period. Some have problems of bending and standing up."... 40 year old HIV negative female participant. "The side effects, like the ones I got from the pills and the injection even when someone says anything you tend to believe it will be the same." ... 31 year old HIV negative female participant.

Most of the women in both the IDIs and FGDs reportedly feared the permanent methods especially tubal ligation because they could be reversed and in the event you experience the side effects the health workers could not do anything about it, while for the other methods you could discontinue. Additionally others reported that some methods led to delayed return to fertility.

"Tubal ligation is not reversible and you cannot stop it, when your husband comes and tells you that you are cold because of the injection you can stop it. Many people fear being operated if you tell someone about it they will tell you that is your own problem and your husband will run away." ... 36 year HIV negative female participant.

"Women have side effects, then at times when you want to get a baby, you cannot conceive, you stay for along time without getting pregnant." ... 40 year old HIV positive male participant .

"The other thing is reversibility of other methods they feel that I have been put on a certain method probably if I want to get a child at some point I would not be able to have."... KII Eldoret.

4.4.2.3 Reluctance by the male Partners

Reluctance by the male partners were reported to be another barrier to contraceptive use by many women in both IDIs and FGDs. This made some women use contraceptive methods in secret or avoid using the methods all together. Women reportedly feared some men who were not easily approachable and therefore it became hard for them to discuss family planning with them.

"They are so authoritative; a woman might not have that environment to discuss with him about family planning because normally they usually say they are the workers, the bread winners for that family, in fact there was one who said he wanted as many as 15 children so that at his home he has 15 electoral votes." ... 46 year old female participant.

Most of the men disagreed with the female participants views that they were opposed to their female partners using contraception. For example a number of men said that the women did not like the condom, while others were using the natural method and this is what one participant said.

"Most of the time I hear the women are the ones who do not like using the condom especially in the rural areas it is hard to find a home where they are using those things." ... 49 year HIV positive male participant.

"Maybe they are learned people who can be able to know when they have safe days in their menstrual cycle, if they do not want to plan and they want children according to what they have planned they have to use this follow up method of knowing when they are okay." ... 42 year old HIV negative male participant.

In one of the FGD with HIV negative women from Thika the following was reported;

I : "are there times you use contraceptive methods without him knowing?

R2: Yes you can't tell him.

R: All, laugh

I: Why?

R1: When he sees those drugs he will throw them away

R7: He wants you to stay like that

R7 There are some who think you are doing other things (being promiscuous)"

R3 *Mine can throw them away*

R2 Some will tell you to stop completely

Men's role also came out clearly where many of the women said that the men also did not allow them to use family planning citing that they would become *cold*. Additionally some male participants (especially from Eldoret) reported that their female partners would become promiscuous if they used contraceptive methods. They thus prevented their female partners from using contraceptive methods. Additionally Key Informants reported that it was largely the women who made the decision whether women used contraception and when made the decision without the approval of their male partners they used the contraceptives in secret.

"Men say their women become cold they do not want them to use." ... 26 year old HIV negative male participant.

"Okay, aah most of this information comes from both, but majority of the clients who complain are male clients. They try to say that once a partner is initiated to a family planning, the partner becomes cold and the libido goes low and the other part, the figure part they dwell on it. They say that someone get pressure edema where if you press skin it goes in and doesn't come out. So they don't like that. Yeah." ... KII Thika "At times the client may tell you maybe the partner normally drinks so when he drinks, they don't use condom consistently or maybe they just feel like they don't want to use it." ... KII Eldoret

I: so how wide spread is the issue now, the issue of the male dominance as far as family planning is concerned and usage within the home.

R "Yea it is male dominance; we have heard issues of break ups because of family planning issues the husband who has said no to family planning finds out the wife is on one, as opposed to when it is the other way round."... KII Eldoret.

4.4.2.4 Additional barriers to contraceptive use among HIV discordant Couples

Other less common reported barriers to contraceptive use among HIV serodiscordant couples included;

Religion was also reported to be a barrier to the use of contraceptive methods, especially the Catholics who reportedly encouraged their followers to use natural methods and other religions which forbid their members from taking any form of medication such as the *Akorinos*.

"The faith of the people, There are some churches that do not accept using family planning, they use natural methods; there are those who do not accept use any method they say they will count the days. Some churches do not accept using the pills. Some are told to sign." ... 40 year old positive female participant.

"Among the couples who come here in our facilities there are these who are bound to the religion like aah some of the Akorinos religion and Catholics, they will tell you I will use natural method, the religion does not allow me to use any other method of family planning and I am comfortable with it. This is what I have been practicing and you see we respect the clients option, so we just leave it at that and continue encouraging maybe one day this participant will change and the Akorinos will say other things like taking other medications and what is not allowed in their religion. So it will belike initiating her on a family planning method is like going against the rule of their religion. So for them to remain clean before their God or their religion they refuse to be initiated on anything."... KII Thika

"There are women who have cited cases of religion where they say that their religion does not allow them to use contraceptive methods because that is tantamount to killing." ... KII Eldoret

Lack of information about discordance also played a part in the no contraceptive usage.

"Most of those who stop using the family planning when they are discordant they still have not yet believed that they can get a child when they are discordant." ... 40 year old HIV positive male participant.

There is also fear of getting a small number of children in case of death and also concerns on the society's perception of the couple.

"Some women fear their husbands, some do fear perception in the society especially those who are not exposed and also some just for fearing that you must give birth to a small number of children say three and then later on all of them die. She wants to have many of children so that if some die they will remain with others." ... 46 year old HIV positive female participant.

Some male partners reportedly associated condom use with immorality and therefore did not see the need of using the condoms with their regular partners. "Why would I use a condom with my wife it's for a prostitute or a commercial sex worker, they will have no problem with using the same condom with a commercial sex worker. And that becomes a challenge lets say the woman is negative and the man is positive, she is more at risk and the man does not want to use the condom." ... KII Eldoret

A number of couples reported that they saw no need to use non barrier contraception because they were already using condoms.

"And then again there is also another big issue of we are using condoms why do we have to use another method."... KII Eldoret

Some participants especially from Eldoret reported using herbal contraceptives to protect them from getting pregnant. These views were corroborated by KIIs. For example in an interview with a KII in Eldoret the following was reported;

Yes, tell us about the herbal family planning?

R: (Laughs) Okay that one I heard from my clients, do you use family planning? Yes. What do you use? Herbal. There are these traditional healers I don't know what they do but they have some herbal.

I: What do they call the plant?

R: I don't know they are just herbal. The concoction, I don't know what it is.

I: How wide spread is the usage.

R: In Western it is where there is lack of facilities that provide the conventional FP methods the woman will go for the herbal.

Some participants especially from Eldoret reported practicing some traditional practices

to protect them from getting pregnant. These traditional practices had been passed from generation to generation and were reported to work as illustrated by the interview below with a KII.

R "Yeah, the common one that we normally hear especially from western Kenya were by women do take their menses in a rug keep in above the fire place this is done by the mother in law, when she does that then you have permanent, it is family planning that is long lasting until you remove the rag from that place. It is the commonest".

I: Is it done voluntarily?

R: It is voluntary, you will get maybe five babies and you say those are enough and then you tell your mother in law, you will get the menses on the rag then she puts them there, unless it is removed from there by her, you will not conceive.

I: How widely used is this method?

R: It's widely used in western in Luhyaland that is."

4.4.2.5 Reason for stopping Contraceptive use

From the quantitative results it was clear that some women discontinued or changed their contraceptive choices frequently. Asked why couples stopped using contraceptive methods some of the comments that came from many respondents implied fears of side effects especially those associated with myths and misconceptions of contraceptives. There was a general consensus that family planning was necessary although they admitted that they would stop using them if they experienced the side effects that they suspected to be associated with the different family planning methods.

"Side effects can also make you stop."... said a 31 year old HIV positive woman.

"When you start using you heart beat increase."... said a 40 year old HIV positive woman.

The KIIs agreed with these views reporting that women stopped using contraceptive methods due to side effects that they experienced or those that were experienced by other women.

"Perceived side effects that's is one of them is the issues they report, the issues like I said before if a woman is put on Depo-Provera or Norplant they would come up and say they are having excessive bleeding there are women who would come up and say like the copper T, that men are complaining that they still can feel part of that gadget inside the vagina and their men are demanding they remove them, then of course there are those who hear stories from others, grapevine just like rumors spreads like bush fire."... KII Thika

Most of the participants also said that one could stop a method when they desired to conceive an additional child. This theme was mainly reported by the younger women.

"If you have planned to have a certain number of children you may stop so that you can add the more children." ... 31 year old HIV positive female participant,

"There are some who want another give birth again." ... 31 year old HIV negative female participant.

Some myths and misconceptions related to family planning methods were also a major reason why women discontinued using family planning.

"Like high blood pressure, others they hear rumours from like the coil brings cancer, even mine she had complications in the abdomen when she was using the injection and she believed it was the injection, I try to tell her from the teachings I had, it does not harm but she had believed it was the one. It reached a point she stopped it."..40 year old HIV positive male participant.

"They say if you take these pills they will ruin you. You will develop growths." ... 38 year old HIV negative female participant.

"When I was injected he heard over the radio that it brings cancer, he came and told me he does not want the injection I have heard it has side effects. I stopped it, then I stayed for a long time, and now I am not using anything."... 35 year old HIV negative female participant.

Some participants also stop using the non-barrier contraceptive methods once they become HIV discordant because of using condoms to prevent HIV transmission to the negative partner.

".....the others who know that they can get a baby they stop because they are using the condom." ... 40 year old HIV positive male participant.

"For some when they find that they are either discordant or both positive then you talk about using the condom every time then they decide to discontinue because they argue that now that they are using the condom they are not supposed to use any other family planning method." ...KII Eldoret

A number of female participants especially those over the age of 40 years reported that they would stop using the modern contraceptive methods if they felt that they were oldimplying if they reached the menopause.

"They would stop when they feel they are old." ... 45 year old positive participant.

"When you attain a certain age of menopause you can stop." ... 40 year old HIV positive female participant.

"Maybe if you are old, then there is no need of using family planning." ... 40 year old HIV negative female participant.

Another reason cited for stoppage of family planning given by some of the participants was that they stopped using modern methods because they were using the natural methods such counting the days to abstain from sex during their fertile period.

"They count their days; you agree with your wife that when it reaches some certain days you would not sleep together until a certain date." ... 40 year old male participant

A majority of the participants felt that what they heard from other people influenced their decisions on whether to use any of the family planning methods and their decisions were greatly affected. Some of the information they gathered were on the side effects and the myths related to these methods.

"When you listen to people it can also make you change you thinking. It can make you feel that that thing is not good. The injection is not good, even the pills, so you end up hating to use family planning method." ... 40 year old HIV positive female participant.

4.4.2.6 Summary of barriers to contraceptive use among HIV discordant couples

Three main barriers to contraceptive use among the couples identified were; lack of knowledge about range of modern contraception leading to myths and misconceptions, side effects associated with the methods either experienced or perceived and reported male partners were opposition to limiting fertility while others reported that their partners did not like their available contraception methods. Most women believed that male partners expected to be consulted before women started or changed a contraceptive method. Many women did not use contraception covertly because they were afraid that their male partners would discover it, which may have resulted in mistrust, conflict or separation. Figure 4.12 summarizes the main barriers to contraception use among HIV discordant couples in Thika and Eldoret districts.



Figure 4.12: Main barriers to contraceptive use among HIV discordant couples in Thika and Eldoret

CHAPTER FIVE

5.0 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Social Demographic characteristics of study participants

There were more (55.7%) participants enrolled in the quantitative part of this study from Eldoret site than from Thika site. This was because Eldoret site commenced the 'Partners in Prevention Study' in November 2004 while Thika commenced in July 2006, therefore Eldoret had a longer period of time to recruit HIV discordant couples in the parent trial from which this analysis was done (Lingappa *et al.*, 2009). The proportion of HIV positive and negative women from both the Eldoret and Thika sites were statistically similar (p=0.106).

Most of the women in this study were in the reproductive age with a median age of 30.5 years for HIV negative and 30 years for HIV positive women. The highest proportion of the participants were aged 25-34 years. Therefore, a study of correlates and barriers of contraceptive use was relevant to the study population.

In this couples' study, most (94.2%) of the participants reported being married, while the remaining participants (5.8%) reported to be single (with a regular sexual partner) or cohabiting. This was not an unexpected finding since an inclusion criteria for the

Partners in Prevention Study was that participants had to be in stable discordant couples partnership. The proportion of participants by marital status for HIV positive and negative women were statistically similar (p=0.357).

Most (71.9%) of the participants had two or more children. This finding is consistent with the KDHS (2003) which reported the total fertility rate in Kenya as 4.9 children per woman in the 3 years preceding the survey. The proportion of participants by number of children for HIV positive and negative women were statistically similar (p=0.064). One possible explanation was that most of the couples had known of the HIV status within a year to study enrollment.

At baseline 74.3% and 75.7% of HIV positive and HIV negative women respectively were not on any non barrier contraceptive method. This is similar to the KDHS (2003) which found 61% of women were not using any contraceptive methods. Among the contraceptive users, Injectable methods were the most commonly used by both HIV negative (58.4%) and HIV positive (60.1%) women. This finding is consistent with KNBS & ICF Macro,(2010), which reported that the most popular contraceptive method used nationally was the injectable with a prevalence of 46.6%. The proportion of participants by contraceptive choices for HIV positive and negative women were statistically similar (p=0.685).

5.1.2 Comparison of contraceptive choices and trends among HIV positive and negative women

Overall this study found that there was an inverse association between HIV status and contraceptive use with contraceptive use being lowest among the HIV negative participants compared to the HIV positive women at all times during follow-up. There was a sharp and consistent increase in proportion of participants using contraceptive until month 18 of follow up when contraceptive use declined in both groups. The proportion of those using contraceptive were higher for the HIV positive women at all visits. This result is similar to other studies conducted in resources poor countries that have found that HIV status may strongly influence contraceptive use, with HIV positive women reporting a significantly higher use (Elul *et al.*, 2009, Hoffman *et al.*, 2008, and Keogh *et al.*, 2009). Another possible explanation in this study, is that HIV positive women attended the clinic on monthly basis and thus received more contraceptive counselling compared to HIV negative women may also have been more motivated to use contraception to reduce the risk of MTCT of HIV.

Over half of the contraceptive users chose injectables compared to other forms of contraceptives at each time points during follow-up. However, in the qualitative interviews most of misconceptions and side effects were reportedly associated with the injectable contraceptives. This finding was similar to other studies that have found that hormonal contraception (injectables and pills) are popular in sub-Saharan Africa. One

advantage of the Injectables is the opportunity for discreet use (CBS 2004), for example in a study in Tanzania among women at antenatal clinics in Mwanza region, found that HIV positive women were more likely to use hormonal contraception (Keogh *et al.*, 2009). Data on the risk for HIV transmission or acquisition remains inconclusive, therefore dual contraceptive should be encouraged whenever possible (Lavreys *et al.*, 2004).

IUDs are extremely safe, effective, and economical, method of family planning. Once inserted, it requires little attention from the user and can provide protection against pregnancy for up to 10 years (Chiou *et al*, 2003; Thonneau *et al*, 2007; Grimes *et al*, 2007) and yet in this study IUDs had the lowest uptake with less than 2% of women using this method. The main reasons given for the poor uptake included that men complained that it pricked them and also it was believed that IUD could move and disappear inside the body especially in the '*fat*' women.

5.1.3 Correlates of contraceptive use among HIV discordant couples

This prospective study evaluated the correlates of contraceptive use among HIV

discordant couples in an HIV prevention trial setting in Kenya. This study found that being married was significantly associated with an increased likelihood of using contraceptives (P=0.015, OR, 2.4). Similar findings were reported among HIV positive women receiving PMTCT services in Rwanda and Cote d'Ivoire where women in a union were more likely to report a modern contraceptive method (Elul *et al.*, 2009; Desgrees *et al.*, 2002).

In this study, having a higher number of children was significantly associated with increased likelihood of using contraceptives (OR, 1.9). This has been reported in a study among HIV positive and negative PMTCT clients in South Africa and having a lower number of children were associated with pregnancy desire among the HIV negative women (Peltzer *et al.*, 2009). A study conducted among HIV positive and negative women in the national PMTCT program in Rwanda found women with fewer children had a stronger desire for additional children (Eluet *et al.*, 2009). In the qualitative interviews women reported not using contraceptives because they desired additional children, these views were mainly from the younger women.

Thika site had a significantly higher contraceptive use than Eldoret site (P<0.001). One possible explanation is that Thika site instituted a successful multipronged family planning strategy. This strategy involved; (1) provision of non-barrier contraceptive methods free of charge at the research clinic, (2) training of clinical and counselling staff on contraceptive methods, including practical demonstrations and discussions of common myths and barriers to contraceptive use, (3) provision of free contraceptive methods (oral contraceptive pills, injectables, implants, and intrauterine devices) to study participants at the research clinic, (4) discussion of challenges to contraceptive uptake with study couples individually and in psychosocial support groups. The insights
from these sessions were reported back to the study team to strengthen contraceptive messages for other couples and involvement of male partners during contraceptive counselling sessions during routine study visits (Ngure *et al*, 2009). In the qualitative interviews Eldoret site participants reported a higher use of herbal contraceptives as well as practicing traditional practices which could be another possible explanation why Eldoret site had a lower uptake of modern contraceptive methods.

In this study, male being on ART, both the male's and female's CD4 cell counts were not significantly associated with contraceptive use ($P \ge 0.05$). Also not associated with contraceptive use was whether or not both male and female earned income, whether or not male or female had been abused (physically or verbally), years of education for both male and female and female being pregnant during follow-up. It may be possible that a larger cohort or a longer period of follow up would have given more information on these variables. It could also be true that these factors were not associated with contraceptive use.

5.1.4 Barriers to contraceptive use among HIV discordant couples.

To the investigator's knowledge this is the first study to document barriers of contraception use among HIV discordant couples. This study identified several barriers to contraceptive use among the HIV serodiscordant couples interviewed. One of the barriers that was consistently raised was myths and misconceptions. These myths and misconceptions are commonly passed along by word of mouth from woman to woman.

The misperceptions that women have regarding individual methods can be divided into mistaken beliefs about the mechanisms and side effects. These myths and misconceptions were reported by both women and men in IDIs and FGDs and confirmed by KIIs. This is in agreement with a study by Kirkconnell-Hall *et al.* (2006) that reported that myths and misperceptions regarding different contraceptive methods limited women's interest in reversible methods of contraception in India.

Quantitative studies have highlighted that fear of side effects acts as a barrier to the use of modern methods, hormonal methods in particular; however this remains an ill defined and poorly understood concept (Bailey et al., 2008). Women's lack of correct knowledge regarding mechanisms and side effects directly affects the risks that they perceive in using contraceptive methods that are available to them. These perceptions are largely formed by the experiences other women relate to them, which in turn are colored by a lack of understanding and confusion about the mechanisms. This social learning process, though, also offers a potentially powerful way to educate women about contraception by training other women in the community to teach them (Kirkconnell-Hall et al. 2006). Similarly, in this study side effects associated with the contraceptive methods either experienced or perceived. The results show that fear of side effects was a term for a complex range of phenomena, both physiological and social, associated with the use of modern contraceptive methods. Women who have never practiced any form of contraception are unlikely to have ever actually discussed family planning with anyone but have received information from a variety of sources. The information women receive

and pass on to others is a mixture of negative and positive experiences but the negative information is more often passed verbally while positive experiences of family planning are more often observed but less often spoken about. A wide range of physical complaints and 'diseases' are attributed to the use of contraception however the exact cause and nature of these complaints is unclear in the minds of the women. This finding is similar to a study done in Ghana (Bailey and Matthews, 2008). Many studies show that when women cite fear of side effects as a reason for not using contraception is often attributed to misinformation and rumors regarding the possible effects of modern methods (Gutin *et al.*, 2011, Stringer *et al.*, 2007). There are clear practical and policy implications in understanding how the diffusion process influences reproductive behavior. Family planning education can then best utilize networks to disseminate information or understand how networks may work as a deterrent to individual contraceptive adoption.

This study found that male partners were opposed to limiting fertility while others reported that their partners did not like their available contraception methods. There was a general consensus among the women that male partners expected to be consulted before women started or changed a contraceptive method. Many women did not use contraception covertly because they were afraid that their partner would discover it, which may have resulted in mistrust, conflict or separation. Interestingly some men in the IDIs were not aware of the FP methods their female partners were using and would for example report their partner was on oral contraceptive pill while the female partner would report to be on IUD.

In Africa, child bearing is an important social milestone among couples. This study found that contraceptive use was reported as a barrier to having the desired number of children by the HIV serodiscordant couples. This finding is similar to studies conducted among HIV-1 positive women and men in Uganda and India that have reported desire for children as a barrier to condom use (Bunnell *et al.*,2008; Chakrapani *et al.*, 2010; Nakayiwa *et al.*, 2006). Couples also reported a need for information on safer ways of conception. In some cases there were contradictions between men and women on the number of children desired, implying a need for improved communication among couples on reproductive intentions.

Gender inequality has been reported as a barrier to contraceptive use in many studies (Starker, 2008). In this study there was a general consensus among the women that men were reluctant to use the condoms irrespective of their female partners HIV status. This was coupled with women's inability to negotiate condom use, especially because men were the 'bread winners.' This sometimes led to verbal, and in extreme cases, physical abuse. It is worth noting that only HIV negative women reported having tried to use female condoms implying a greater motivation for HIV prevention among this group hence, the need for female controlled methods. Unlike smoking cessation or the adoption of preventive medical care, contraceptive use especially the barrier methods such as condoms are not something that individuals engage in alone. The assumption

that individuals can or will exercise total control over their behavior has led to a focus on the individual rather than on the social context in which the individual functions. This viewpoint has been dubbed the "individualist fallacy" which points out that the interpersonal activity is preceded by a "complex social negotiation, which we understand poorly." (Davies *et al.*, 1992, Parker 2004, Yoder 2001). Therefore involving men in contraceptive counselling and provision would increase contraception uptake.

In this study, most of the women who were not using non-barrier contraception reported that they did not see a need to use these methods because they were using condoms regularly. This finding is supported by the quantitative findings of this study where reported condom use was high throughout the follow-up period rising from 75.47% at baseline to 94.02 % at month 24 of follow up. However, despite the high reported condom use a number of challenges were reported especially by the female participants. These challenges included male reluctance to use the condoms and condom breakages. This underscores the need to promote dual contraception among HIV serodiscordant couples (Ngure *et al*, 2009).

This study also found that women frequently changed methods due to hearing myths associated with the methods that they were using, side effects either experienced or heard from others and desire for children. This finding is similar to the findings from KNBS & ICF Macro, (2010) that 36% of women discontinue a method within 12

months of embarking on use - with the following discontinuation rates-, injectables (29%), periodic abstinence (33%), the pill (43%) and male condom (59%).

5.1.5 Strengths of this study

The strengths of this study include a relatively large prospective cohort; this provided an opportunity to observe contraceptive use over time up-to 24 months of follow-up for each couple. This was a study of couples study, providing a unique opportunity to assess contraceptive use among HIV positive and HIV negative women and having data on male partners to accompany data on the behaviours of both HIV negative and HIV positive women. Having information on male partners has been a limitation in many contraceptive studies (Wilson *et al*, 2003).

An additional strength of this study was the opportunity to interview HIV serodiscordant couples together, as well as separately. This study utilized both in-depth interviews and focus group discussions in a complementary manner to validate the findings. Separation of couples during in-depth interviews provided a greater range of responses; additionally this study utilized qualitative methods (IDIs, FGDs and KIIs) to complement the quantitative findings. Specifically these qualitative methods, provided a better understanding of the contraceptive choices and prevalence among the HIV discordant couples.

5.1.6 Limitations of the Study

This study was done in the context of clinical trial settings, where contraception was mainly provided free of charge at one of the study clinics (Thika), this may reduce the generalizability of the findings to the general Kenyan population.

Secondly, HIV positive participants were required to take study drug as per the HSV/HIV transmission clinical trial, (with pregnancy being discouraged as it would have meant that they stopped taking study drug), this may have biased the contraception counselling messages. Additionally, HIV positive women came to the research clinics on monthly basis while the HIV negative women came to the clinic on quarterly basis. This may have biased the outcome because the HIV positive women had more frequent clinic visits and hence received more contraceptive counselling.

5.2 Conclusions

The following conclusion have been made based on research findings and discussions.

5.2.1 Contraceptive use was lower among the HIV negative participants compared to the HIV positive participants at all times during follow-up with a sharp and consistent increase in proportion of participants using contraceptive until month 18 when contraceptive use declined in both groups to 18.2% among HIV negative women compared to 38.6% among the HIV positive women. Among those who used contraceptives, more than half used injectables compared to other forms of contraceptives at each time- points.

5.2.2 Statistically significant associations were observed between contraceptive use and female HIV status at enrolment, marital status, site and number of children. Being married, coming from Thika, having two or more children were significantly associated with increased likelihood of using contraceptives.

5.2.3 The main barriers to contraceptive use among the couples identified qualitatively were; lack of adequate knowledge on modern contraception among both men and women leading to myths and misconceptions; side effects associated with the methods either experienced or perceived and male partners reportedly opposed to limiting fertility while others did not like contraception methods available to their partners. Most women believed that male partners expected to be consulted before women started or changed a contraceptive method. Many women did not use contraception covertly because they were afraid that their partner would discover it, which could have resulted in mistrust, conflict or separation.

5.3 **Recommendations**

Based on the study findings the following recommendations can be made:

5.3.1 Comparison of contraceptive choices and trends among HIV positive and negative women

1) A high quality reproductive health program offering family planning methods education especially dual methods should be instituted. This could meet an important contraceptive need and hence prevent most of the unintended pregnancies and hence reduce the risk of MTCT and HIV transmission to the negative partner.

2) Further research should be directed towards the contraceptive use among HIV discordant couples to validate the findings from this study. Similar studies should be done on a country wide scale in order to facilitate formulation of policies on contraception among HIV discordant couples in Kenya (currently there is no policy on contraceptive among HIV discordant couples).

3) Studies on trends on contraceptive use among HIV discordant couples should be undertaken from time to time since the society is dynamic and could be included in the National Demographic and Health surveys.

5.3.2 Correlates of contraceptive use among HIV discordant Couples.

1) Future programs should focus on interventions to increase dual contraceptive use among HIV discordant couples, with a special emphasis on single women with few children. HIV positive and negative men should be given a special consideration. This should be done through a multipronged pronged strategy.

2) This study dealt exclusively with the correlates and barriers of contraceptive use enrolled in an HIV prevention clinical trial. More studies should be done focusing on the HIV discordant couples in the general population and in other settings such as in the comprehensive care clinics to check for any variations in contraceptive use.

3) Further studies need to be done to assess pregnancy intentions and fertility desires among HIV discordant couples. This is because effective contraceptive use should be used by couples to avoid unintended pregnancies.

5.3.3 Barriers to contraceptive use among HIV discordant couples

1) These findings indicated that family planning programs should improve HIV serodiscordant couples' knowledge of modern contraceptive methods and dispel misinformation and negative perceptions of methods. The strategy for achieving this aim includes a comprehensive, systematic, and culturally sensitive information, education and communication (IEC) programme to promote the use of family planning. This intervention should take advantage of the existing grapevine. These programs should be

guided by the new insights from this study.

2) Involvement of men will likely be a critical component of increased uptake of woman-controlled pregnancy prevention method for improved method. Though the increased and accessibility of woman-controlled contraceptive are vital for empowerment of women and improved reproductive health, alienation of men is a potentially a costly risk. Though the increased and accessibility of woman-controlled contraceptive are vital for empowerment of men will likely be a critical component of increased uptake of woman-controlled pregnancy prevention method for improved methods.

3) Specifically, women need support in ways of negotiating contraceptive use for women, further information on HIV discordance, skills building on effective condom use and disclosing HIV status to new sexual partners. Additionally, information on safe and effective ways of childbearing for couples who need children need to be incorporated into the counselling of HIV discordant couples. This support should be couples centric and may be offered through support groups where couples who are successfully using condoms can share their experiences and provide an opportunity to address challenges and misconceptions on condom use.

Interventions to increase contraceptive uptake may benefit from follow-up visits to focus on factors that lead to early discontinuation of dual contraception, including myths, side effects, and changing fertility desires.

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APPENDICES

Appendix 1: Secondary Questionnaire
Questionnaire number
Date of Extraction
Participant ID
1. Date of Birth Or Age
2. Marital Status
3. Number of living children
4. Years of schooling (Do not count repeat levels)
5. Income
6. If yes what is the average monthly income
7. Does the participant live in a formal or informal settlement? _ Formal _ Informal _
Not sure
8. Study partner
a. Is the participant married to your study partner?

- b. Do the participant and their study partner live together?
- c. Number of living children with the study partner?
- **d.** When did this participant first have sex with your study partner?

Screening Laboratory results

9. HIV status _____

10. If positive CD4 Count _____

11. Result of pregnancy test _____(for HIV uninfected only)

12. HSV 2 results_____

Birth Control Methods at enrolment

13. Currently using birth control?

- No/none() Injectable () Tubal ligation/Hysterectomy ()
- Oral () Implants ()

other Specify _____

IUD () Condoms ()

14. Birth control method at month, M3

No/none () Injectable ()

Tubal ligation/Hysterectomy ()

Oral	()	Implants	()	Other Specify		
IUD	()		Condoms			
15. Birth control method at month M6,						
No/ne	one ()	Injectable	()	Tubal ligation/Hysterectomy ()		
Oral	()	Implants ())	other Specify		
IUD	()		Condoms			
16. Bi	irth cor	ntrol method at	t month ,M9)		
No/n	one ()	Injectable	()	Tubal ligation/Hysterectomy ()		
Oral	()	Implants ()	other Specify		
IUD	()		Condoms			
17. Bi	irth cor	ntrol method at	t month M1	2		
No/ne	one ()	Injectable	()	Tubal ligation/Hysterectomy ()		
Oral	()	Implants	()	Other Specify		
IUD	()		Condoms			

18. Birth control method at month , $\mathbf{M15}$

No/none ()	Injectable ()	Tubal ligation/Hysterectomy ()		
Oral ()	Implants ()	other Specify		
IUD ()	Condoms			
19. Birth contr	ol method at month, M18	,		
No/none ()	Injectable ()	Tubal ligation/Hysterectomy ()		
Oral ()	Implants ()	other Specify		
IUD ()	Condoms			
20. Birth control method at month , M21				
No/none ()	Injectable ()	Tubal ligation/Hysterectomy ()		
Oral ()	Implants ()	other Specify		
IUD ()	Condoms			
21. Birth control method at month ,M24				
No/none ()	Injectable ()	Tubal ligation/Hysterectomy ()		
Oral ()	Implants ()	other Specify		

IUD () Condoms

22. CD4 cell counts (For HIV positive women)

Enrolm	lent	
M6 _		
M12		
M18_		
M24		
23. Coi	ndom use at Enrolment	
a.	Number of sexual contacts with study partner	
b.	Of those times , number of times condom used	
с.	Number of times of intercourse with someone other than study partner	
d.	Of those time, how often was a condom used	
24. Condom use at M3		
a.	Number of sexual contacts with study partner	

b. Of those times , number of times condom used _____

c. Number of times of intercourse with someone other than study partner

d. Of those time, how often was a condom used _____

25. Condom use at M6

a. Number of sexual contacts with study partner _____

b. Of those times , number of times condom used _____

c. Number of times of intercourse with someone other than study partner

d. Of those time, how often was a condom used _____

26. Condom use at M9

a. Number of sexual contacts with study partner

b. Of those times , number of times condom used _____

c. Number of times of intercourse with someone other than study partner

d. Of those time, how often was a condom used _____

27. Condom use at M12

b.

a.	Number of sexual contacts with study partner	
b.	Of those times , number of times condom used	
с.	Number of times of intercourse with someone other than study partner	
d.	Of those time, how often was a condom used	
28. Conc	dom use at M15	
a.	Number of sexual contacts with study partner	
b.	Of those times , number of times condom used	
с.	Number of times of intercourse with someone other than study partner	
d.	Of those time, how often was a condom used	
29. Condom use at M18		
a.	Number of sexual contacts with study partner	

Of those times , number of times condom used _____

с.	Number of times of intercourse with someone other than study partner
d.	Of those time, how often was a condom used
30. Co	ondom use at M21
a.	Number of sexual contacts with study partner
b.	Of those times , number of times condom used
c.	Number of times of intercourse with someone other than study partner
	_
Of those	e time, how often was a condom used
31. Con	dom use at M24
a.	Number of sexual contacts with study partner
b.	Of those times, number of times condom used
c.	Number of times of intercourse with someone other than study partner
d.	Of those time, how often was a condom used
32. Histo	ory Verbal or physical abuse by partner

33. STI symptoms/Diagnosis in the last 6 months

34. Pregnancy

- Has the participant been pregnant at any time during follow up? Yes () No()
- Was the pregnancy intended? Yes () No()
- What was the outcome of pregnancy
- o Birth () Abortion()

35. ARV Status (this is for The HIV positive women only)

- a. M6 Yes () No()
- b. M12 Yes () No()
- c. M18 Yes () No()
- d. M24Yes () No()
- e. If yes Date of commencement _____
- f. If yes did it lead to a change in contraceptive use?

Appendix 2: In-Depth Interview Guide Moderator's Guide

Step 1. Obtain oral informed consent individually from each participant.

Step 2. Complete demographic questionnaire for each participant.

Step 3: Conduct the in depth interview.

Interviewer Script

Thank You for coming. I am Kenneth Ngure from Jomo Kenyatta University of Agriculture and Technology. With me is ------ from ------. The purpose of this interview today is to get your views on Family planning. The information you provide will help in planning for ways to increase contraceptive uptake and reduce unintended pregnancies.

I would encourage you to speak as freely and frankly as possible. The responses you give in this interview will be confidential. We would also like to record your answers both by writing and using a tape recorder to help in the analysis of your answers. Please do bear in mind that there is no harm in not participating nor is there a direct benefit in participating except that the information will be useful to policy makers. The interview will take about one to two hours. Do you all agree to participate in this discussion? Note that you may leave at any time during the discussion.

1. Preamble

• What are the common health problems faced by couples ? (Probe on problems faced by HIV discordant couples)

• What are the common reproductive health problems?

2. Contraceptive use

• Which are common family planning methods? Probe on advantages, disadvantages and myths of each mentioned method including Emergency contraception)

Which FP methods do you commonly use?

• Are contraceptive options different depending on the HIV status of the women ?Probe contraceptive options for HIV positive and negative women?

• Are contraceptive options different depending on the HIV status of the male partner ?Probe contraceptive options when the male partner is HIV positive and when the male partner is HIV negative.

• What are the barriers to consistent condom use? (female and male condoms) – Probe if condom use is different if male partner is positive and if male partner is negative.

• Where do you go to obtain contraceptive services? (Probe on cost, quality and accessibility)

- Do women change their contraceptive choice after positive HIV results (explain)
- Who decides whether a woman uses contraceptive method or not?
- Who do couples talk to get advice on how to plan their families?
- What is it that women fear about contraceptives? Probe fears among HIV positive and HIV negative women (for women participants only)
- What role do men play in contraceptives?
- What makes couples discontinue contraceptive use?
- What role do Health care worker play in contraceptives? Explain
- What makes couples not use contraceptives even when they do not want to get more children?
- What are your suggestions to increase contraceptive use by women/couples?

Appendix 3: Focus Group Discussion (FGD) Moderator's Guide

Step 1. Obtain oral informed consent individually from each focus group participant

Step 2. Complete demographic questionnaire for each participant.

Step 3: Conduct the focus group discussion.

Interviewer Script

Thank You for coming. I am Kenneth Ngure from the from Jomo Kenyatta University of Agriculture and Technology. With me is ------ from ------. The purpose of this discussion today is to get your views on FP. The information you provide will help in planning for ways to increase contraceptive uptake and reduce unintended pregnancies

I would encourage you to speak as freely and frankly as possible. The responses you give in this discussion will be confidential. We would also like to record your answers both by writing and using a tape recorder to help in the analysis of your answers.

Please do bear in mind that there is no harm in not participating nor is there a direct benefit in participating except that the information will be useful to policy makers.

The discussion will take about two hours. Do you all agree to participate in this discussion? Note that you may leave at any time during the discussion.

1. Preamble

- What are the common health problems faced by couples ? (Probe on problems faced by HIV discordant couples)
- What are the common reproductive health problems?

3. Contraceptive use

- Which are common family planning methods? Probe on advantages, disadvantages and myths of each mentioned method including Emergency contraception)
- Which FP methods do you commonly use?
- Are contraceptive options different depending on the HIV status of the women ?Probe contraceptive options for HIV positive and negative women?
- Are contraceptive options different depending on the HIV status of the male partner ?Probe contraceptive options when the male partner is HIV positive and when the male partner is HIV negative.
- What are the barriers to consistent condom use? (female and male condoms) Probe if condom use is different if male partner is positive and if male partner is negative.
- Where do you go to obtain contraceptive services? (Probe on cost, quality and accessibility)
- Do women change their contraceptive choice after positive HIV results (explain)
- Who decides whether a woman uses contraceptive method or not?
- Who do couples talk to get advice on how to plan their families?
- What is it that women fear about contraceptives? Probe fears among HIV positive and HIV negative women (for women participants only)
- What role do men play in contraceptives?
- What makes couples discontinue contraceptive use?
- What role do health care workers play in contraceptives? Explain
- What makes couples not use contraceptives even when they do not want to get more children?
- What are your suggestions to increase contraceptive use by women/couples?

Appendix 4: Key Informant Interview Guide Moderator's Guide

Step 1. Obtain oral informed consent individually from each participant.

Step 2. Complete demographic questionnaire for each participant.

Step 3: Conduct the in depth interview.

Interviewer Script

Thank You for coming. I am Kenneth Ngure from Jomo Kenyatta University of Agriculture and Technology. With me is ------ from -----. The purpose of this interview today is to get your views on Family planning The information you provide will help in planning for ways to increase contraceptive uptake and reduce unintended pregnancies

I would encourage you to speak as freely and frankly as possible. The responses you give in this interview will be confidential. We would also like to record your answers both by writing and using a tape recorder to help in the analysis of your answers.

Please do bear in mind that there is no harm in not participating nor is there a direct benefit in participating except that the information will be useful to policy makers.

The interview will take about one to two hours. Do you all agree to participate in this discussion? Note that you may leave at any time during the discussion.

1. Preamble

- What are the common health problems faced by couples ? (Probe on problems faced by HIV discordant couples)
- What are the common reproductive health problems?

4. Contraceptive use

• Which are common family planning methods? Probe on advantages, disadvantages and myths of each mentioned method including Emergency contraception)

- Which FP methods do women/couples commonly use?
- Which FP trainings have you received?
- Are there specific methods that you advocate for use by HIV positive women?
- Are contraceptive options different depending on the HIV status of the women?
 Probe contraceptive options for HIV positive and negative women?

Are contraceptive options different depending on the HIV status of the male partner?
 Probe contraceptive options when the male partner is HIV positive and when the male partner is HIV negative.

• What are the barriers to consistent condom use? (female and male condoms) – Probe if condom use is different if male partner is positive and if male partner is negative.

• Where do women/couples obtain contraceptive services? (Probe on cost, quality and accessibility)

- Do you advise change their contraceptive choice after positive HIV results (explain)
- In your opinion who decides whether a woman uses contraceptive method or not?
- Who do couples talk to get advice on how to plan their families?
- What is it that women fear about contraceptives? Probe fears among HIV positive and HIV negative women (for women participants only)
- What role do men play in contraceptives?
- What makes couples discontinue contraceptive use?
- What makes couples not use contraceptives even when they do not want to get more children?
- What are your suggestions to increase contraceptive use by women/couples? Probe on the role health workers can play to increase uptake

Appendix 5: Informed Consent Form

Couples in depth Interviews

TITLE: Correlates and Barriers of Contraceptive use Among HIV Discordant

Couples in Thika and Eldoret Districts, Kenya

Investigators	Institution	Contact address
Kenneth Ngure MPH	Jomo Kenyatta University of Agriculture and Technology	Box 19704-00202, Nairobi
Prof. Zipporah Ng'ang'a	Jomo Kenyatta University of Agriculture and Technology	Box 62,000-00200 , Nairobi
Dr. Samoel Khamadi	Center for Virus Research	Box 54840-00200, Nairobi
	Kenya Medical Research Institute	
Prof. Violet Kimani	University of Nairobi	Box 19676-00202 Nairobi
Dr. Nelly Mugo	Partners in Prevention Study	Box 19865-00202 Nairobi

Principal Investigator: Kenneth Ngure

Telephone: 067-22561 (Nairobi, Kenya)

Researchers Statement

We are asking you to volunteer to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully.

Purpose of the Study

We are asking you to take part in research to help us understand the issues surrounding contraceptive use among discordant couples. The information will also help us understand what prevents women who do not desire future pregnancies from using contraceptives (barriers)

In addition we are asking you to share your experience of using contraceptives. This information will enable health care workers and policy maker to gain additional understanding on ways of increasing contraceptive uptake.

Study Procedures:

We are asking you to share your experience on contraceptive use. A moderator will conduct the interview and a study staff member will be present to observe and tape record the interview, both will maintain your information confidential.

If you agree to be in the study, we shall ask that you answer some questions which will be tape recorded. Questions such as your age, marital status, and number of children will be written on a questionnaire it is possible that you may find some of the questions embarrassing.

What we shall ask of you today to sign or make your mark on this consent form, have an interview about your experience and views on contraceptive use. The interview will last for approximately one and half hours.

You do not have to answer any of the questions if you do not want.

Risks:

There is potential risk of other research staff involved in this study knowing your HIV status during the course of interviews and recordings. Every effort will be make to reduce this risk.

It is possible that other people knowing your HIV status or your contraceptive choice may cause you social discomfort

Benefits:

There are no direct personal benefits from participating in this study. However, we expect there will be benefits to society as information gathered from this study will help increase contraceptive use and hence prevent unwanted pregnancies.

Confidentiality

Only the consent form will have your name and personal information. A personal code will be used to identify the notes and tape recordings.

The recorded tapes and the link between your name and identifying code will be kept in a safe and secure place under lock and key with only the Principal Investigator having access. During the discussions we shall ask that you not use your full name.

The recordings, documents linking your name to the code number, will be destroyed as soon as the analysis is completed by the latest date 28th February 2012.

Other research materials such this consent form and the book that links your personal information to this form will be destroyed within a 5 year period.

Only the research team will have access to your information, with the following exception: ethical committee or university staff may sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at harm.

Your participation is voluntary.

You are free to decide if you want to be in this research study.

If you decide not to participate, your decision will not affect the health care you would normally receive. If you are enrolled in Partners in PrEP clinical trial, not taking part in this study will not affect your participation in the trial.

Leaving the Research

You may leave the research at any time. If you choose to take part, you can change your mind at any time and withdraw.

If You Have a Problem or Have Other Questions

If you have a problem that you think might be related to taking part in this research or any questions about the research, please call Kenneth Ngure Tel 0722362219.

Your Rights as a Participant

This research has been reviewed and approved by the Kenya Medical Research Institute (KEMRI) If you have any questions about your rights as a research participant you may contact KEMRI Ethical Committee Chair at telephone number 2722541.

Volunteer Agreement

I have been given an opportunity to have any questions about the research answered to my satisfaction.

STATEMENT OF CONSENT AND SIGNATURES

This document describing the benefits, risks and procedures for the research titled "Correlates and barriers of contraceptive use among HIV discordant couples in Thika and Eldoret Districts" has been read and explained to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to join the study I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

Participant Name	Participant Signature/Thumbprint	Date
(print)		
Study Staff Conducting	Study Staff Signature	Date
Consent Discussion (print)		
Witness Name	Witness Signature	Date

Copies to: 1. Investigator

2. Study participant

Appendix 6: Informed Consent Form

Couples – Focus Group Discussions

TITLE: Correlates and Barriers of Contraceptive Use Among HIV Discordant

Couples in Thika And Eldoret Districts, Kenya

Investigators	Institution	Contact address
Kenneth Ngure MPH	Jomo Kenyatta University of Agriculture and Technology	Box 19704-00202, Nairobi
Prof. Zipporah Ng'ang'a	Jomo Kenyatta University of Agriculture and Technology	Box 62,000-00200 , Nairobi
Dr. Samoel Khamadi	Center for Virus Research	Box 54840-00200, Nairobi
	Kenya Medical Research Institute	
Prof. Violet Kimani	University of Nairobi	Box 19676-00202 Nairobi
Dr. Nelly Mugo	Partners in Prevention Study	Box 19865-00202 Nairobi

Principal Investigator: Kenneth Ngure

Telephone: 067-22561 (Nairobi, Kenya)

Researcher's Statement

We are asking you to volunteer to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully.

Purpose of the Study

We are asking you to take part in research to help us understand the issues surrounding contraceptive use among discordant couples. The information will also help us understand what prevents couples who do not desire future pregnancies from using contraceptives (barriers)

Many women do not use contraception even when they do not want to get additional children.

In addition we are asking you to share your experience of using contraceptives. This information will enable health care workers and policy maker to gain additional understanding on ways of increasing contraceptive uptake.

Study Procedures

We are asking you to share your experience on contraceptive use. A moderator will conduct the interview and a study staff member will be present to observe and tape record the discussion, both will maintain your information confidential. If you agree to be in the study, we shall ask that you answer some questions which will be tape recorded. Questions such as your age, marital status, and number of children will be written on a questionnaire it is possible that you may find some of the questions embarrassing. What we shall ask of you today, to sign or make your mark on this consent form, have a discussion about your experience with using contraceptive methods. We shall only ask you to attend one single visit, unless we find missing information, with your permission, we would then contact you again to collect complete information. The discussion will last for approximately one and half hours.

You do not have to answer any of the questions if you are not comfortable.

Risks:

As the discussions will be in a group of 6 to 8 people, it is possible that other persons in the group who are not staff members may discuss the things that you say in the group outside the group setting.

There is potential risk of other research staff involved in this study knowing your contraceptive choice or HIV status during the course of the discussions and recordings. Every effort will be make to reduce this risk.

It is possible that other people knowing your contraceptive choice or HIV status may cause you social discomfort

Benefits:

There are no direct personal benefits from participating in this study. However, we expect there will be benefits to society as information gathered from this study will help increase contraceptive use and hence prevent unwanted pregnancies

Confidentiality

We shall ask those who take part in this group discussion not to discuss what they hear from each other outside this group. However, we cannot guarantee that everyone will keep to this promise.

Only the consent form will have your name and personal information. A personal code will be used to identify the notes and tape recordings.

The recorded tapes and the link between your name and identifying code will be kept in a safe and secure place under lock and key with only the Principal Investigator having access.

The tape recording will only be used to gather information which will later be written; no recording will be used in media or public presentation. The recordings, documents linking your name to the code number, will be destroyed as soon as the notes of discussions are analyzed or by the latest date 28 February 2012. Other research materials such this consent form will be destroyed within a 5 year period.

Only the research team will have access to your information, with the following exception: Government or university staff may sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at harm.

Your participation is voluntary

You are free to decide if you want to be in this research study.

If you decide not to participate, your decision will not affect the health care you would normally receive. If you are enrolled in Partners in PrEP clinical trial, not taking part in this study will not affect your participation in the trial.

Leaving the Study

You may leave the research at any time. If you choose to take part, you can change your mind at any time and withdraw.

If You Have A Problem with Any of the Questions

If you have a problem that you think might be related to taking part in this research or any questions about the research, please call Kenneth Ngure Tel 06722561.

Your Rights as a Participant

This research has been reviewed and approved by the Kenya Medical Research Institute (KEMRI). If you have any questions about your rights as a research participant you may contact KEMRI Ethical Committee Chair at telephone number 2722541.

STATEMENT OF CONSENT AND SIGNATURES

This document describing the benefits, risks and procedures for the research titled "Correlates and barriers of contraceptive use among HIV discordant couples in Thika and Eldoret Districts" has been read and explained to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to join the study I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name Participant Signature/Thumbprint Date (print)

Study Staff Conducting	Study Staff Signature	Date
	Consent Discussion (print)	
Witness Name	Witness Signature	Date
Copies to: 1. Investigator		

2. Study participant

Appendix 7: Informed Consent Form

Counselors and Clinicians Key Informant Interviews

Title: Correlates and Barriers of Contraceptive Use Among HIV Discordant Couples in Thika and Eldoret Districts, Kenya

Investigators	Institution	Contact address
Kenneth Ngure MPH	Jomo Kenyatta University of	Box 19704-00202, Nairobi
	Agriculture and Technology	
Prof. Zipporah Ng'ang'a	Jomo Kenyatta University of	Box 62,000-00200 ,
	Agriculture and Technology	Nairobi
Dr. Samoel Khamadi	Center for Virus Research	Box 54840-00200, Nairobi
	Kenya Medical Research Institute	
Prof. Violet Kimani	University of Nairobi	Box 19676-00202 Nairobi
Dr. Nelly Mugo	Partners in Prevention Study	Box 19865-00202 Nairobi

Principal Investigator: Kenneth Ngure

Telephone: 067-22561 (Nairobi, Kenya)

Researcher's Statement

We are asking you to volunteer to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully.

Purpose of the Study

We are asking you to take part in research to help us understand the issues surrounding contraceptive use among discordant couples. The information will also help us understand what prevents couples who do not desire future pregnancies from using contraceptives (barriers)

In addition we are asking you to share your experience of using contraceptives. This information will enable health care workers and policy maker to gain additional understanding on ways of increasing contraceptive uptake.

Study Procedures

If you agree to be in the study, we shall ask that you answer some questions. These will be recorded.

We will also ask that you answer some written questions. Some of the questions may be intrusive. You do not have to answer questions that you do not wish to answer. There will be at least two people during the course of the interview; a counselor will ask the questions and a study assistant will supervise the tape recording. We shall ask that you do not use your full name during the interview.

We shall only ask that you be in the study for only this visit. We shall not ask you to come back again, however we may follow you to ask for a clarification.

What we shall ask of you today is to sign or make your mark on this consent form and have a tape recorded interview about your experience testing couples for HIV. We estimate the interview may take approximately one to two hours. You are free to agree or decline to participate in the interview.

You are also free to decline to answer specific questions

A code number will be provided to identify the notes written and the tape recorded; there will be no name identifiers on these records. The tape and written materials will be placed in a safe and secure place under lock and key.

The tape recording and the file that links your name to the written materials will be destroyed as soon as the testimonials are written or at the latest February 28th 2012. Your name will not be written in the testimonials.

Risks:

It is possible that you may experience discomfort sharing your feelings about counselling sessions. We shall not ask for any name or other identifiers for clients you have attended.

Benefits:

There are no direct personal benefits from participating in this study. However, we expect there will be benefits to society as information gathered from this study will help increase contraceptive use and hence prevent unwanted pregnancies

Confidentiality:

Only the consent form will have your name and personal information. A personal code will be used to identify the notes and tape recordings.

Only the research team will have access to your information, with the following exception: Government or university staff may sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at harm.

If You Decide Not To Be In the Research

You are free to decide if you want to be in this research study.

If you decide not to participate, your decision will not affect you or your work at all.

Leaving the Research

You may leave the research at any time. If you choose to take part, you can change your mind at any time and withdraw.

If You Have a Problem or Have Additional Questions

If you have a problem that you think might be related to taking part in this research or any questions about the research, please call Kenneth Ngure 06722561 (Thika).

Your Rights as a Participant

Ethics Review Committee reviews research studies in order to help protect participants. This research has been reviewed and approved by the Kenya Medical Research Institute (KEMRI)

Ethics Review Committee (ERC) reviews research studies in order to help protect participants

If you have any questions about your rights as a research participant you may contact KEMRI Ethical Committee Chair at telephone number 2722541.

STATEMENT OF CONSENT AND SIGNATURES

This document describing the benefits, risks and procedures for the research titled "Correlates and barriers of contraceptive use among HIV discordant couples in Thika and Eldoret Districts" has been read and explained to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to join the study I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

Participant Name Participant Signature/Thumbprint Date

(Print)

Study Staff Conducting	Study Staff Signature	Date
Consent Discussion (print)		
XX 7' , X Y		
Witness Name	Witness Signature	Date

Copies to: 1. Investigator

2. Study participant

Appendix 8: Formal Approval by Institutional Research and Ethics Committee (IREC)

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Conta .	/			CONSIGNATION CONSIGNATION
Principal and an and	INSTITUT	IONAL RESEARCH	AND ETHICS COM	MITTEE (IREC)
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ELDORET Tel: 33471//2/3				ELDORET Tel: 33471/2/3
Reference: IR Approval Nut	EC/2009/109 nber: 000450			8 th December, 2009
Kenneth Ngur P.O. Box 1970	e,)4-00202,			
NAIROBI, KE	NYA.			
Dear Mr. Ngu	e,			
RE: FORMA	APPROVAL			
The Institution titled:	al Research a	nd Ethics Committee	has received your	request for approval of your study
"Correlates a Clinical Trial	nd Barriers of Sites, Kenya".	Contraceptive Use a	mong HIV Discord	dant Couples in Thika and Eldoret
On the basis is glad to info 8th October, 2	of your study re m you that you 009. You are the	view and approval by r study has been gran erefore permitted to co	the KEMRI Scienti ted a Formal Appro ntinue with your stu	fic Steering Committee (SSC), IREC oval Number: FAN: IREC 000450 on Jdy.
Note that this with this rese Secretariat tw	approval is for arch beyond th o months prior t	1 year; it will thus expire e expiry date, a reque o the expiry date.	re on 7 th December est for continuation	r, 2010. If it is necessary to continue should be made in writing to IREC
You are requ must notify th related to the a final report	ired to submit e Committee of conduct of the at the end of the	progress report(s) reg any proposal change study, or study termina study.	ularly as dictated (s) or amendment ation for any reason	by your proposal. Furthermore, you (s), serious or unexpected outcomes a. The Committee expects to receive
Yours Sincer	ely,			
PROF. D. HO CHAIRMAN	ARE	H AND ETHICS COMI	WITTEE	Select & ETHICS COMP
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Appendix 9: Ethics Review Approval (KEMRI)

P. D. BOX 54840 - 00200 NAIROBI, Kenya Ensil: kenri-hq@nairobi.mimcom.net: director @ kenri. org; website: www.kenri.org KEMRI/RES/7/3/1 October 2, 2009 TO: KENNETH NGURE (PRINCIPAL INVESTIGATOR) THRO: DR. FREDERICK OKOTH, THE DIRECTOR, CVR, MAIROBI RE: SSC PROTOCOL NO. 1617 (<i>ETHICS REVIEW</i>): CORRELATES AND BARRIERS OF CONTRACEPTIVE USE AMONG HIV DISCORDANT COUPLE IN THIKA AND ELDORET DISTRICTS, KENYA. Make reference to your letter dated September 24, 2009. Thank you for your prompt response to the issues raised at the 169 th meeting of KEMRI/National Ethics Review Committee held on Tuesday 1 st September 2009. Due consideration has been given to ethical issues and the study is hereby granted approva for implementation effective this 2 nd day of October 2009, for a period of twelve (12) months. Please note that authorization to conduct this study will automatically expire on Friday, 1 st August 2010 You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study. Yours sincerely, Matting Matting Matting Sc: SECRETARY, KEMRI/NALONAL ETHICS REVIEW COMMITTEE	<text><text><text><text><text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text></text></text></text></text>	KEN	YA MEDICAL	RESEARCH INSTITU	UTI
 KEMRI/RES/7/3/1 October 2, 2009 T: KENNETH NGURE (PRINCIPAL INVESTIGATOR) THC': DR. FREDERICK OKOTH, THE DIRECTOR, CVR, MAIROBI RE: SSC PROTOCOL NO. 1617 (<i>ETHICS REVIEW</i>): CORRELATES AND BARRIERS OF CONTRACEPTIVE USE AMONG HIV DISCORDANT COUPLE IN THIKA AND ELDORET DISTRICTS, KENYA. Make reference to your letter dated September 24, 2009. Thank you for your prompt response to the issues raised at the 169th meeting of KEMRI/National Ethics Review Committee held on Tuesday 1st September 2009. Due consideration has been given to ethical issues and the study is hereby granted approva for implementation effective this 2nd day of October 2009, for a period of twelve (12) months. Please note that authorization to conduct this study will automatically expire on Friday, 1st October 2010. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by Friday, 21st August 2010 You are required to submit any amendments to this protocol and other information pertinent study. Yours sincerely, MATINI, For: SECRETARY, KEMRI/NATIONAL ETHICS REVIEW COMMITTEE 	<text><text><text><text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text></text></text></text>		P.O.Box Tel: (254) (020) 2722541 , 271334 E-mail: kemri-hq@nairobi.mimo	54840 - 00200 NAIROBI, Kenya 49, 0722-205901, 0733-400003; Fax: (254) (020) 2720030 com.net: director @ kemri. org; website: www.kemri.org	
 TO: KENNETH NGURE (PRINCIPAL INVESTIGATOR) THRO: DR. FREDERICK OKOTH, THE DIRECTOR, CVR, MAIROBI RE: SSC PROTOCOL NO. 1617 (<i>ETHICS REVIEW</i>): CORRELATES AND BARRIERS OF CONTRACEPTIVE USE AMONG HIV DISCORDANT COUPLE IN THIKA AND ELDORET DISTRICTS, KENYA. Make reference to your letter dated September 24, 2009. Thank you for your prompt response to the issues raised at the 169th meeting of KEMRI/National Ethics Review Committee held on Tuesday 1st September 2009. Due consideration has been given to ethical issues and the study is hereby granted approva for implementation effective this 2nd day of October 2009, for a period of twelve (12) months. Please note that authorization to conduct this study will automatically expire on Friday, 1st October 2010. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by Friday, 21st August 2010 You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study. Yours sincerely, MAWWA R. C.K.ITHINJI, FOR: SECRETARY, KEMRI/NATIONAL ETHICS REVIEW COMMITTEE 	TO: KENNETH NGURE (PRINCIPAL INVESTIGATOR). THRO: DR. FREDERICK OKOTH, DIATROBU PRI DE DIRECTOR, CVR, DURDE PRI SC PROTOCOL NO. 1617 (FIHICS REVIEW): CORRELATES AND DE ARRIERS OF CONTRACEPTIVE USE AMONG HIV DISCORDANT COUPLE IN THIKA AND ELDORET DISTRICTS, KENYA. Make reference to your letter dated September 24, 2009. Thank you for your prompt response to the issues raised at the 169 th meeting of KEMRI/National Ethics Review Committee held on Tuesday 1 st September 2009. Due consideration has been given to ethical issues and the study is hereby granted approval for implementation effective this 2 nd day of October 2009, for a period of twelve (12) months. Please note that authorization to conduct this study will automatically expire on Friday, 1 st October 2010. If you plan to continuing approval to the ERC Secretariat by Friday, 21 st August 2010 You are required to submit any amendments to this protocol and other information pertinent ohuman participation in this study to the ERC prior to initiation. You may embark on the study. WMMM You sincerely, MMMM MATIONAL ETHICS REVIEW COMMITTEE	KEMR	I/RES/7/3/1	October 2, 2009	
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Appendix 10:

KEMRI Scientific Steering Committee (SCC) Approval

ESACIPAC/SSC/4734

8th July, 2009

Kenneth Kairu Ngure

Thro'

Director, CVR <u>NAIROBI</u>

REF: SSC No.1617 (Revised) – Correlates and barriers of contraceptive use among HIV discordant couples in Thika and Eldoret Districts, Kenya

I am pleased to inform you that the above mentioned proposal, in which you are the PI, was disscused by the KEMRI Scientific Steering Committee (SSC), during its 157th **meeting** held on 2nd June, 2009 and has since been approved for implementation by the SSC.

The proposal has been forwarded to the ERC and we advise that work on this project can only start when ERC approval is received.

DR. C. S. MWANDAWIRO

C. Mwandawiro, PhD SECRETARY SSC







Appendix 13: PlusNews Article – (KENYA: Contraceptive Concerns for HIV Discordant Couples)



Appendix 14: Abstract Submitted For Poster Presentation at the XVIII International Aids Conference On

	Abstract Preview - Step 3/4
Abstract category:	D79 Family planning and reproductive health services as entry point for HIV prevention, treatment, care and support
Title:	Correlates of contraceptive use among HIV discordant couples in Kenya
Authors:	K. Ngure ^{1,2} , Z. Nganga ³ , V. Kimani ⁴ , S. Khamadi ⁵ , E. Irungu ^{1,2} , S. Mburu ^{2,6} , R. Heffron ⁷ , E. Were ^{8,9} , N. Mugo ^{10,11}
Institute(s):	¹ Kenyatta National Hospital, Partners PrEP Study, Nairobi, Kenya, ² UW International Clinical Research Center, Seattle, United States, ³ Jorno Kenyatta University of Agriculture and Technology, Itromid, Nairobi, Kenya, ⁴ University of Nairobi, Community Health, Nairobi, Kenya, ⁵ Kenya Medical Research Institute (KEMRI), Nairobi, Kenya, ⁶ Kenyatta National Hospital, Nairobi, Kenya, ⁷ University of Washington, Department of Epidemiology, Seattle, United States, ⁸ Mo University, School of Public Health, Eldorat, Kenya, ⁹ Indiana University, Indiana, United States, ¹⁰ Kenyatta National Hospital, Department of Obstetrics and Gynecology, Nairobi, Kenya, ¹¹ University of Washington, Department of Global Health, Seattle, United States
Text: Keywords: Related to women and girls? Related to children?	Background: Contraceptive use is associated with reduced maternal mortality and increased childhod survival. Additionally, among HIV infected women, contraception is one of the four pillars for prevention of mother to child HIV transmission. The aim of this analysis is to determine the factors associated with contraceptive uspeak in a clinical trait cohort of Kernya HIV discordant couples. Methods: We analyzed data from a total of 481 HIV discordant couples (341 with HIV positive women and 140 with HIV negative women) enrolled in the Partners in Prevention HSV/HIV Transmission Study at the Thika and Eldoret, Kernyan sites. The primary study measure was self-reported use of contraceptive outpake more actuate, implaints, or oral instructions devices, surgical method, depd medroxyprogesterone actuates, angliants, or continuate the devices, surgical method, depd methods provide as current use of an intraductine devices, surgical method, depd methods, provide a data and tabaseline and at 24 month follow-up, twomen and 53.7% of HIV negative women and 182% anong HIV negative women. Jung marginal structural models, the estimated dodds or contraceptive outpake models. A the second of dept method used) increased from 41.7% to 28.3%. Additionally, being married [odds ratio (CR) = 2.4, 95% Cl 1.2-5.0, attending Thika site clinic (RP = 1.9, 95% Cl 1.2-3.2), and having two or more fuldere [OR = 1.9, 95% Cl 1.3-2.3], were associated with increased use of non barrier contraceptives. Contraceptive outpake and women (HIV discordant relationships, with a special emphasis on single women with few shuld version and women (HIV discordant relationships, with a special emphasis on single women with ew children. I. Contraceptives and women with few children. I. Contraceptives and women with the whildren. I. Contraceptives and women with the whildren. I. Contraceptives and women with the whildren.
Ethical research declaration: Applied for scholarship?	Yes Yes
Acceptance Status:	Poster exhibition
Presentation Date:	Thursday, 22 July 2010
Location:	Poster Exhibition Area
Conference: XVIII Intern	national AIDS Conference · Reference No: A-240-0274-14165 · Status: Submitted (checked)
F	Print Back

Appendix 15: Original Paper

African Population Studies Vol 26, 1 (April 2012)

Correlates of Contraceptive use among HIV Discordant Couples In Kenya

Kenneth Ngure^{1,2}, Zipporah Ng'ang'a², Violet Kimani³, Samoel Khamadi⁴, Frankline Onchiri⁵, Elizabeth Irungu¹, Renee Heffron^{6,} Edwin Were⁷ and Nelly Mugo^{1,6}

 ¹ Kenyatta National Hospital, Nairobi, Kenya
 ² Institute of Tropical Medicine and Infectious Diseases, Jomo Kenyatta University, Kenya
 ³ Department of Community Health, University of Nairobi, Kenya

⁴ Center for Virus Research, Kenya Medical Research Institute, Kenya

⁵ Center for Microbiology Research, Kenya Medical Research Institute,

Kenya

⁶ Departments of Epidemiology & Global Health, University of Washington, Seattle, USA

⁷ School of Public Health, Moi University, Kenya

Address for correspondence: Kenneth Ngure, Box 19704-00202 Nairobi, Kenya, Phone 254722362219, kngure@pipsthika.org

Despite risks of HIV transmission to infants born of the HIV positive women, contraceptive use is uncommon among women in HIV discordant partnerships. The aim of this study was to determine the factors associated with contraceptive use in a clinical trial cohort of HIV serodiscordant couples based in Thika and Eldoret, Kenya. Data were analyzed from 481 HIV discordant couples enrolled in the Partners in Prevention HSV/HIV Transmission Study at the Thika and Eldoret sites. The primary study outcome was self-reported use of contraception other than condoms. Using a marginal longitudinal logistic model based on generalized estimating equations (GEE) approach we assessed the association of various demographic and behavioral factors with contraceptive use. At baseline the prevalence of non barrier contraceptive use among HIV positive and negative women was 24.3% and 25.7%, respectively. At month 12 of follow-up, the prevalence of contraceptive use was 44.4% among the HIV positive and 26% among the HIV negative women while at month 24, the prevalence of contraceptive use was 38.6% among the HIV positive and 18.2% among the HIV negative women. HIV positive women were more likely to report using contraception than HIV negative women (odds ratio (OR) 1.61 95% confidence interval (CI) 1.04-2.47). Additionally, being married (OR 2.4, 95% CI 1.2-5.0), attending Thika site clinic (OR 6.1, 95% CI 4.2-9.0), and having two or more children (OR 1.9, 95% CI 1.3-2.8) were significantly associated with use of non barrier contraceptives. Future programs should focus on interventions to increase contraceptive use among HIV serodiscordant couples, with a special emphasis on HIV negative women, unmarried women and women with few children.