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Approval Sheet

Family Planning for Women with HIV on Antiretroviral therapy in Lilongwe, Malawi

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Abstract Cover Page

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An abstract of

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

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in Global Epidemiology

2011

Abstract

Family Planning for Women with HIV on Antiretroviral therapy in Lilongwe, Malawi

By Lisa Haddad

Introduction: Preventing unintended pregnancy among women with HIV is essential to decrease unnecessary pregnancy-related morbidity and mortality and maternal to child HIV transmission. Given the high failure rate of condoms alone, promoting dual protection with additional forms of effective long-acting contraception is crucial. Our goal was to determine contraceptive medical eligibility, contraceptive preference, acceptance of the IUD, condom use, fertility intentions and contraceptive use among a cohort of HIV-infected women on antiretroviral therapy seeking contraceptive services. *Methods:* All women presenting for family planning services at the Lighthouse Clinic, an HIV/ART clinic in Lilongwe, Malawi, between August and December 2010 were invited to participate in a structured interview to assess eligibility for a prospective contraceptive study. A screening questionnaire assessed contraceptive medical eligibility and contraceptive choice. An enrollment questionnaire assessed fertility intentions, contraceptive and condom use. *Results:* 281 women were screened and200 women were enrolled in the study. Of these women, all non-pregnant women met eligibility for at least 3 contraceptive methods, with 87% eligible for all 5 methods evaluated. After counseling, 34.9% of the women selected an IUD as their first choice contraceptive method with 222 (79%) willing to have an IUD placed even if not their first choice method. Most women (95%) did not desire future fertility. Contraceptive and condom use was inadequate and prior reported unintended pregnancy rates were high. Inconsistent condom use was often due to partner's refusal to use. *Discussion:* We successfully demonstrated that contraceptive services can be integrated into HIV care and that women in this setting are receptive to enrolling into a randomized contraceptive study that included the IUD. Most methods of contraception are safe for use by HIV+ women who present for family planning services. Although more women chose DMPA as a first choice for contraception, almost 80% of the women were willing to receive an IUD. Efforts must be made to increase access to long-acting reversible methods. We need to improve contraceptive and condom use in this setting, with efforts to enlist partners in programs aimed at increasing use.

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Table of Abbreviations

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
CBC	Complete blood count
CDC	Centers for Disease Control and Prevention
CHC	Combined hormonal contraception
CI	Confidence Interval
COC	Combined oral contraception
CRF	Clinical research form
DHS	Demographic and health Surveys
DMPA	Depo medroxyprogesterone acetate, Depo Provera
FP	Family planning
HAART	Highly active antiretroviral therapy
HBG	Hemoglobin
HIV	Human immunodeficiency virus
NHSRC	National health sciences research committee
IRB	Institutional review board
IUD	Intrauterine device
LARC	Long-acting reversible contraception
OR	Odds ratio
PID	Pelvic inflammatory disease
STI	Sexually transmitted infection
UNC	University of North Carolina
UPT	Urine pregnancy test
WHO	World Health Organization

Background/Literature Review

Family Planning in Malawi:

There is a large unmet need for family planning services in Malawi. According to Malawi's 2010 DHS [1], the contraceptive prevalence rate (CPR) is now 42% among currently married women using any form of modern birth control. This marks an increase from 33% reported by the 2004 DHS. Although the total fertility rate in Malawi appears to be declining (5.7 in 2010, down from 6.0 in 2004, DHS 2010) an estimated 40.6% of pregnancies are unintended [1] with about one third of unintended pregnancies attributed to contraceptive method failure [2]. Studies to reduce unintended pregnancy must therefore recognize that efforts must be taken to both improve contraceptive utilization and move individuals toward consistently using more effective forms of contraception.

Currently, the most common modern method of birth control used in Malawi is depo-medroxyprogesterone acetate (DMPA). DMPA is a progestin (synthetic progesterone) given as an intramuscular injection in the buttock or upper arm once every 3 months (13 weeks). The efficacy of DMPA depends on adherence to the recommended dosage schedule (every 13 weeks). The percentage of women experiencing an unintended pregnancy based on data from the United States within the first year with typical use is 3% and 0.3% with perfect use [3]. In Malawi, over 60% of the married women who use a modern contraceptive method are using DMPA, with 26% of married women currently using DMPA. As many as 80% of HIV infected women using modern contraception use DMPA [4]. Despite its widespread use, DMPA may not be acceptable for all individuals; therefore, the needs of these women need to be met with other contraceptive methods.

Estimated failure rates among women in the United States in the first year with typical use with other contraceptive methods are 15% for condoms, 8% for oral contraceptive pills, and <1% for the IUD and implant [5, 6]. It may not be appropriate to generalize data on typical-use failure rates for contraception from a United States cohort to a Malawian cohort of women. Data from southern Africa suggest that failure rates in studies are much higher than these typical use rates reported for US women. In some HIV prevention studies [7], annual pregnancy rates of up to 50% have been observed despite monthly contraceptive counseling and/or use[8, 9]. A recent study with intensive efforts to prevent unintended pregnancy reported a 20% annual pregnancy rate [10]. Contraceptive method failures often occur because they require adherence on a daily or monthly basis by the user [2]. In developing countries, difficulties with these shorter-acting methods are compounded given that they require repeat clinic visits that can create obstacles for patients with limited resources for reliable transportation, or when supply chains are interrupted at the clinics.

The most effective non-permanent means of preventing pregnancy are long-acting reversible contraceptive methods or LARCs, including copper and progestin-only intrauterine devices (IUD) and progestin-only contraceptive implants. These methods are ideal because they do not require daily action and offer effective long-term protection from pregnancy, for 3-5 years for implants and up to 12 years for the copper IUD. Furthermore, LARC methods tend to be the most cost effective over time with an average direct cost per year of protection against unplanned pregnancy lowest for the copper IUD

($1.64) and sino-implant (a 2-rod progestin releasing contraceptive implant) ($4.02) compared to DMPA, OCPs, and Jadelle (a different 2-rod progestin contraceptive implant) ($7.90 to $8.70)[11]. The reduced efficacy noted with contraception in studies in southern Africa strengthens the arguments that programs need to be promoting the use of LARC methods. Unfortunately, despite its high efficacy, safety, ease of use, cost-effectiveness, and reversibility, less than 1% of African women use the IUD [12], and specifically only 0.2% of Malawian women using contraception use the IUD [1].

Barriers to family planning in sub-Saharan Africa

Studies among discordant couples in two African countries found that despite high knowledge of contraceptive methods, use of contraception remained low [13]. There is also strong evidence indicating poor utilization of dual protection with condoms to prevent STI and HIV transmission in addition to a contraceptive method to prevent pregnancy [14]. Barriers to family planning that could contribute to contraceptive non-use in sub-Saharan Africa include: reduced contraception availability, lack of knowledge about available contraceptive methods, poor economic resources [15], fear of side-effects, low quality care at family planning services, and social, cultural and religious practices discouraging contraception use and encouraging childbearing [16-18]. Gender-related power structures may also pose barriers to family planning in this region. For example, it is typically the woman's responsibility to seek family planning services from the clinic, however they may often lack the control to make decisions regarding their own fertility. Men often control sexual and familial economic decision-making [19-21], and many women rely on their spouses for income [22, 23] complicating access to these

services. A study in Zimbabwe documented that among the majority of families (64%), men made the decisions regarding family planning use and family size [24].

In Malawi, although modern contraceptive use is improving, similar barriers to family planning exist. For example, there remain many misconceptions perpetuated in the community concerning contraception. One study in rural Malawi found awareness of family planning methods to be high. However misinformation leading to fear of side effects, prolonged menstruation, genital sores, impotence and infertility, was among the many reasons for contraceptive non-use [25]. In rural Malawi, one study found that one of the main factors that discouraged women from use of modern contraceptive methods was partner's disapproval [25]. Additionally, a study evaluating 6 African countries including Malawi, found that contextual factors play a role in modern contraceptive use, where approval of family planning by the community has a large effect on contraceptive use[26].

Specific barriers to IUD and implant use include client misconceptions about their safety, lack of understanding about their mechanism of action, inadequate training of providers to administer these methods, and lack of culturally-sensitive marketing to increase knowledge and allay concerns related to LARC methods [27, 28]. Overcoming misconceptions and knowledge gaps among patients and providers is critical to increasing LARC use [29]. Few nurses in sub-Saharan Africa have the training to provide these contraceptive methods to their patients, leading to poor knowledge of the methods among patients because nurses are not inclined to discuss what they are not

comfortable providing [13]. As a consequence, US funded contraceptive procurement projections for 2009-2015 assume 2.5% of modern contraceptive method users will use the IUD or implant [30]. This cycle can be overcome by addressing supply-and-demand aspects concurrently by giving providers didactic training to improve knowledge and practical skills to ensure their comfort with insertions and removals, along with improving medical education for clients [31, 32].

Importance of integration of family planning and HIV care

Governments and funding agencies agree that HIV/STI and family planning services should be integrated [33, 34]. In areas such as sub-Saharan Africa, which has a high prevalence of HIV/STI in heterosexual populations, target audiences for HIV/STI and family planning services overlap broadly and can benefit from, and in fact prefer, joint services [35-40]. Preventing maternal-to-child transmission of HIV is less costly by preventing unwanted pregnancies with contraception than with antiretroviral treatment (ART) of pregnant women [41-44]. Considerations of contraceptive choice among HIV-positive women are complicated by the dual need to both prevent pregnancy and to prevent HIV transmission; for all HIV-infected women, condoms are always recommended for prevention of HIV transmission regardless of primary contraceptive method chosen. Studies among discordant couples in two African countries found that despite high knowledge of contraceptive methods, use of contraception remains low [13]. Furthermore, there is strong evidence supporting poor utilization of dual protection with condoms [14].Common factors influencing non-use of contraception are: lack of female decision-making power [13], poor economic resources [15], low quality care at family planning services, and desire for large families. The influence of having HIV and

receiving ART on these factors is unclear. Fear of side effects of contraception may be particularly exaggerated among HIV+ individuals who are particularly sensitive to their health status [13].

Barriers to integration have roots in historical, philosophical, and structural differences in the areas of family planning and HIV prevention [34], which results in disjointed services. Clinic staff often view family planning and HIV prevention as mutually independent services and are not trained to administer them together [45]. Service delivery in family planning clinics tends to be an instructive and fact-giving approach, while HIV-testing service delivery is often a client-centered, counseling approach [46]. Dual method use is not widely promoted; family planning programs often emphasize condom use rather than dual method use despite the high failure rate of condoms for prevention of pregnancy [34]. Given the importance of dual method use, it is therefore critical that HIV prevention and family planning programs provide integrated services mutually reinforcing HIV prevention and family planning goals [34, 37, 47].

Furthermore, initiatives often focus on how to integrate a specific HIV service into a specific reproductive health service (e.g., introducing HIV testing into antenatal care services) or vice versa (e.g., introducing family planning services into posttest HIV counseling), with minimal attempt to understand and respond to the experiences of individuals over time [48, 49]. The most recent HIV practice guidelines in Malawi encourage provider-

initiated provision of Depo-Provera and condoms in pre-ARTand ART clinics[50]. This

strategy represents a strong effort by the government to encourage family planning as an essential part of HIV care. However, DMPA may not be ideal or desirable by many clients and so the fertility and reproductive health needs of these individuals may remain unaddressed. In developing programs, it is imperative to involve the HIV-infected community in order to align the correct needs and intentions of this community[49].

Family Planning for women with HIV:

Prevention of unintended pregnancy among women with HIV infection is dually critical: to prevent the unnecessary morbidity and mortality associated with pregnancy and to prevent the transmission of HIV infection to infants of HIV-infected mothers. Given the high pregnancy rate among those using condoms alone for a contraceptive method, we must promote dual protection with additional forms of effective reversible contraceptives. Despite its widespread use, there are concerns regarding the potential for hormonal contraceptive methods to impact HIV acquisition, transmission and disease progression. Changes in hormonal levels are known to alter immune function, chemokines and cytokines in the genital tract [51], mucosal cellular composition, and epithelia cell receptor expression. Also altered are vaginal wall thickness, vaginal pH, cervical ectopia, and cervical mucous production,[52] as well as susceptibility to sexually transmitted infections. The impact of a hormonally-altered environment on HIV transmissibility has been studied in relation to hormonal fluctuations with the menstrual cycle, menopause, and hormonal contraception with conflicting conclusions [53, 54]. Increased HIV acquisition and transmission has been reported during pregnancy and among hormonal contraceptive users [55-57]. Several cross sectional and prospective studies have indicated an association with hormonal contraceptive use and increased shedding of HIV-

1 DNA in the genital tract [54, 58-60]. A recent study reported a 2-fold increase in HIV acquisition, transmission and viral shedding among DMPA users compared to non-hormonal contraceptive users [61]. There are no prospective randomized trials that address the concern for increased transmission.

A study in Zambia of 599 postpartum, HIV-infected women not on antiretroviral therapy found clinical disease progression (death or CD4+ lymphocyte count dropping below 200 cells/microliters) was more common in women who were allocated to hormonal contraception (13.2/100 woman-years) than in women who were allocated to the non-hormonal copper IUD (8.6/100 woman-years; hazard ratio, 1.5; 95% CI, 1.04-2.1) [62, 63]. An interesting aspect of this study's findings is that the IUD had a higher discontinuation rate than hormonal contraception; 49% of the IUD group discontinued compared to 13% of the hormonal contraception group. These findings contrast with those typically found in healthy populations where DMPA is discontinued more often than IUD. In healthy populations, the continuation rate for DMPA is 26-59% and for IUDs is 78-90% at one year. This finding may have been specific to the randomized study design and this population, however, it requires further investigation to determine if IUD acceptability is different among HIV+ clients.

Although ART use is increasing with recent data supporting earlier initiation of ART, there is a paucity of data that evaluates the impact of hormonal contraception among women with HIV who are on ART. Currently, the World Health Organization (WHO) only cautions against use of combined hormonal contraceptive use with specific

Ritonovir (RTV)-containing ART regimens[64]. Theoretical concern exists regarding drug-drug interactions with hormonal contraceptive use among women taking other ART regimens. Such interactions could be mediated by effects on intestinal or liver CYP3A4, glucuronyl transferases, P-glycoprotein (P-gp), and cellular drug transporters, and could reduce efficacy of antiretroviral medications or alter efficacy or safety of the hormonal contraceptive. As the potential for interactions between ART and hormonal contraception exists, the impact of hormonal contraception on genital viral shedding and thus HIV transmission may be potentiated. Tissue and compartmental drug concentrations, which could effect genital viral replication and shedding, may be influenced by a number of factors including protein binding capacity of the drug and the pH of the compartment. It is unclear if these factors are influenced by hormonal contraceptives.

As there are potential limitations with the use of hormonal contraception, the copper IUD may be ideal for use for HIV-infected women. The World Health Organization Medical Eligibility Criteria [64] assigns a category "2" (i.e. can use) for insertion of both the copper IUD (CuT380A-IUD) in women with HIV positive status and/or AIDS if stable on antiretroviral medication. Studies looking at one model of the copper IUD, the CuT380A-IUD, have found no increased risk of infection-related or overall complications in HIV-positive women compared with HIV-negative women users [65, 66]. Studies of the same model have demonstrated no increase in genital shedding of HIV with its use[67, 68].

Fertility, family planning and sexual behavior among individuals with HIV

Few studies have explored the impact of HIV on fertility decisions [69-75]. Evidence suggests that socio-cultural factors play a large role in fertility decision-making and that there is a rich and complex range of factors, including HIV status and ART use, which influence reproductive decisions [75, 76]. One study in Malawi suggested that fertility intentions alter with time after diagnosis, and although the desire for children was reduced among HIV infected women, those with no children still desired future fertility[77]. A study in rural Uganda showed that the desire to stop childbearing was 6.25 times greater for HIV-positive individuals compared to HIV-negative individuals [14]. Although studies have noted changes in fertility intentions among those with HIV on ART [14], it is unclear as to what influences these fertility decisions and specifically whether the diagnosis of HIV or the use of ART plays a primary role.

Many of the same factors influencing family planning use in a community will likely influence contraceptive use for individuals with HIV. The influence of having HIV and receiving ART on these factors is unclear. Previous studies have shown that among HIV+ women in Rwanda, despite high initial contraceptive uptake after counseling, contraceptive use declined over time [18, 78]. There are many barriers that influence low contraceptive use in sub-Saharan Africa and the influence of having HIV and receiving ART on these factors is unclear. As mentioned, the fear of side effects of contraception may be particularly exaggerated among HIV+ individuals who are particularly sensitive to their health status [13]. Among HIV-infected women in Côte d'Ivoire and Kenya, better education[79] and marriage[80] were associated with increased contraceptive use. In Uganda among HIV-infected women, higher parity, higher sexual frequency, previous

discussions of family planning with a partner, and a current married or a non-marital relationship were found to be associated with higher contraceptive use, while no current relationship, current condom use, breast feeding, older age, and symptoms of an opportunistic infection were associated with reduced contraceptive use.[81]

Menstrual irregularity may influence sexual behavior and perception of contraceptive need. Although HIV-infected women frequently report menstrual disorders[82], the role of HIV and ART in menstrual abnormalities is unclear. Some studies have shown that amenorrhea and irregular cycles are more common among HIV-infected women [83, 84]. In the setting of HIV infection, confounding variables such as weight loss, chronic disease, substance abuse, or use of psychotherapeutic medications, may be related to menstrual disorders[83, 85]. HIV status was not associated with menstrual abnormalities when data were controlled for age, ethnicity, body mass index, smoking status, alcohol use, drug use, and parity. Among more immunosuppressed women (with CD4 counts of less than 200 cells per cubic millimeter), there was a suggestion of increased prevalence of long (greater than 90 days) or short (less than 18 days) cycles[86]. However, those using ART and with higher CD4 counts were less likely to have menstrual abnormalities [82].

Among women with HIV, there are few studies evaluating how their fertility desires, family planning use, or sexual behavior is influenced by their HIV diagnosis or by ART use. Furthermore, as research is supporting the role of ART as a preventive method in

reducing HIV infectivity, there is little information available from urban settings on sexual practices and fertility intentions among women with HIV on ART.

To increase the use of both condoms and effective birth control methods (particularly the IUD), we need to further understand what methods are safe for use, what methods are being chosen, and some of the factors associated with safe sexual practices with condom usage. Previous studies have considered pregnancy intention, marital status, education, self-efficacy, and history of unplanned pregnancy among the potential factors associated with contraceptive choice and condom usage, however no studies have evaluated this in this setting. By understanding these factors, we can target our interventions to higher risk groups and toward challenging the obstacles that reduce condom usage.

Hypothesis and Objectives:

We hypothesize that most individuals are medically eligible for most available contraceptive methods and desire modern effective contraceptive methods after counseling. We hypothesize that condoms are not being used consistently in this population.

Objective 1: Determine the proportion of women who meet WHO medical eligibility for the modern contraceptive methods (IUD, Implant, DMPA, COCs) in a population of HIV positive women on ART.

Objective 2: Evaluate modern contraceptive preferences among this population after receiving counseling on contraceptive options.

Objective 3: Evaluate factors associated with contraceptive method choice

Objective 4: Determine the proportion of individuals who always use condoms during sexual intercourse and those who report using a condom the last time they had intercourse.

Objective 5: Evaluate factors associated with condom use.

Methods

Study Design:

We performed a cross sectional data analysis from data collected during screening and enrollment for a randomized trial comparing the copperT380A IUD to depo medroxyprogesterone acetate (DMPA). The study population consisted of HIV-infected women in Lilongwe, Malawi who attended the Lighthouse clinic and desired family planning. The data used for this analysis was collected between August 2nd 2010 and December 2nd 2010. The initial screening questionnaire collected cross-sectional information regarding contraceptive medical eligibility and desirability among women at an HIV clinic. If eligible and enrolled in the randomized controlled trial, the enrollment questionnaire was administered to collect data on fertility intentions, family planning use history, and condom use.

Education regarding family planning methods was integrated into clinical care at the Lighthouse clinic at the study initiation, both to the clinical staff and to patients. Prior to the screening and enrollment phases, several staff sessions were held to specifically address the misconceptions regarding contraception, and the IUD in particular. Staff was trained on contraception initiation and IUD placement according to the Malawi

reproductive health guidelines. Clinic rooms were built to provide a private space for gynecologic evaluation and instruments needed for IUD placement were procured. Patient education information, including flipbooks, was developed for the clients and these were integrated into morning education sessions and one-on-one client counseling sessions. All screening therefore occurred after routine education had been integrated into the clinic and the family planning capacity was built at Lighthouse. This structured survey design allowed us to gain insight from a larger number of individuals than we would have received from focus groups as well as provide the critical information needed for recruitment into the randomized trial. The number screened and enrolled was determined based on the randomized trial to reach a total of 200 women enrolled.

Criteria for the selection of subjects

The study was conducted in Lilongwe at The Lighthouse Clinic at Kamuzu Central Hospital campus. The Lighthouse staff identified women when they presented for routine antiretroviral therapy visits. If interested in family planning, these women were then referred to the family planning area of the clinic. Interested clients interacted with study staff that were fluent in Chichewa and who were available during all hours of clinic operation. All women who presented to the family planning area were eligible for the initial screening phase of the study. Inclusion and exclusion criteria for study enrollment were narrower, as listed below.

Study Inclusion Criteria for enrollment in Randomized Controlled Trial

- Can provide informed consent

- Women ages 18-45
- Known HIV + status on antiretroviral therapy for at least 6 months
- Willing to initiate either DMPA or CuT380A-IUD.
- Intend to stay in Lilongwe region for the duration of the study
- Greater than or equal to 4 weeks post partum

Study Exclusion Criteria for enrollment in Randomized Controlled Trial

- Currently known to be pregnant
- Desire to become pregnant within next 12 months
- Known uterine anomalies based upon history
- Known or suspected genital tract cancer
- Evidence of current pelvic inflammatory disease or cervicitis. (Women with cervicitis at the time of examination were treated with antibiotics and eligibility reassessed at a follow-up visit at least 7 days after treatment.)
- Pelvic inflammatory disease within prior 3 months
- Contraindications to DMPA or the CuT380A-IUD per the WHO medical eligibility criteria or Malawi National Reproductive Health Service Delivery Guidelines, 2007
- Condition that would preclude start of study intervention based on clinical judgement

Those who did not meet study eligibility or declined study participation could still access services either at the Lighthouse clinic or by referral to a nearby family planning clinic.

Study Population:

Lilongwe, Malawi

The research was conducted in Lilongwe, Malawi. Lilongwe is the capital city of Malawi and is an urban area with a population estimated at approximately 700,000 inhabitants. Malawi has an estimated population of 14 million with estimated HIV prevalence at 12%.

The Lighthouse Clinic

The subjects for this study were recruited from the population of HIV+ women attending the Lighthouse clinic in Lilongwe, Malawi. The Lighthouse is a Centre of Excellence for integrated HIV Management based at Kamuzu Central Hospital and Bwaila Maternity Hospital in Lilongwe, Malawi. Lighthouse provides HIV testing and counseling, clinical care including provision of antiretroviral drugs using a family centered approach, and community home based care. These operations are supported by a training center and operational research activities. Overall, The Lighthouse Clinic has over 12,000 patients on ART and over 2,000 patients who are pre-ART. The Lighthouse has several support programs including Back to Care that follows patients who miss appointments, in order to improve program retention and treatment adherence. The Lighthouse Clinic has 190 professional and support staff. As family planning services were unavailable at this clinic prior to study initiation, services were introduced at the same time as study initiation. Prior to beginning the study, health care providers at the Lighthouse clinic were trained about study procedures and participated in sensitization activities designed to improve their knowledge and skills regarding contraception in general, and IUD use in particular. Provider education was based on standardized Ministry of Health training modules.

Permissions/Approvals

This study is a collaborative effort between the Emory University Fellowship in Family Planning, the Department of Obstetrics and Gynecology at Bwaila/KCH, the Reproductive Health Unit in the Malawi Ministry of Health, and the UNC –Project in Lilongwe, Malawi, the University of North Carolina at Chapel Hill. We received support and formal permission to conduct the study in Malawi from all sites involved including the Ministry of Health, National Health Services Research Committee in Malawi, the institution review board at Emory University, and the institutional review board at University of North Carolina.

Admission procedure

Recruitment

Women who presented for routine HIV care were educated about all available methods by Lighthouse clinic staff and then referred to the family planning area of the clinic where they received additional educational material. They were invited to participate in this study if they were 18-45 years of age. Interested clients interacted with study staff fluent in Chichewa and available during all hours of clinic operation.

Screening Consent

Upon referral to study staff, potential study participants were given further information about the study. Women who wished to learn more about the study were asked a few questions to confirm that they were within the desired study population and then

consented for screening using the study screening consent form.

Screening Questionnaire

Women who consented to participation were administered a structured screening questionnaire which assessed eligibility for DMPA or CuT380A-IUD based upon the WHO medical eligibility criteria [64] as well as their willingness to use the IUD. Those who did not desire IUD placement were asked several questions to assess the reasoning for declining. This study did not attempt to change or interfere with routine HIV care for clinic patients.

Enrollment consent

Women who were eligible and amenable for participation in the randomized trial completed informed consent for the randomized controlled trial (RCT), including careful review of the risks and benefits, and addressing all questions relevant to participation in the RCT. Subjects were provided counseling about the copper IUD and DMPA describing typical benefits and side effects. Subjects had to be willing to be randomized to either the IUD or DMPA and followed for 12 months. A urine pregnancy test was done at that time to confirm that individuals were not pregnant. Those who met all eligibility requirements and consented to participate in the randomized trial, were consented for enrollment. This included consent for limited access to their medical records for 12 months after study enrollment.

Enrollment questionnaire

After informed consent was obtained and randomization occurred, women were administered an additional questionnaire, received a pelvic examination, and had blood and urine testing to collect the following information:

- Contact information and method by which participants desire to be contacted
- Medical and gynecologic history not previously assessed
- HIV and antiretroviral history, other medication use (both traditional and formula)
- Physical data including weight, height, and age
- CD4 count
- Hemoglobin
- Pelvic exam to exclude any active infections or potential contraindications to IUD placement

Following completion of this evaluation, the participant received either a DMPA injection or underwent IUD placement based on allocation from randomization. Sequentially numbered sealed envelopes contained the subject allocation and were made prior to study initiation. Randomization allocation was determined in blocks of 4 and 6 using an online randomizer program (http://www.randomizer.org).

Dual Method Use Counseling

All study participants were provided comprehensive counseling regarding available family planning methods at The Lighthouse Clinic, specifically focusing on the study methods. Although these methods were effective for family planning, it was emphasized

that they are not effective for STI prevention, including HIV transmission. These methods were discussed as options to reduce unintended pregnancy. Usage of condoms for STI prevention was encouraged for all participants, per clinic standard of care. Both Male and Female condoms were available at the clinic free of charge.

Statistical Considerations

Sample size justification

Sample size was determined based upon the primary outcome for the randomized trial, contraceptive method adherence at 1 year. The screening data was to be collected on all individuals until the enrollment goal of 200 individuals was met. At 1 year, assuming a continuation rate for the DMPA of 60% (consistent with findings of recent study in Lilongwe by Stuart et al.) we needed 83 individuals in each group to have an 80% power of detecting a 20% difference in adherence to the IUD with a 2-sided 95% CI. Given an assumed 20% loss to follow-up, we needed 100 patients in each group.

Alternatively, for the purpose of this analysis, collecting enrollment data on 200 subjects (190 based upon Kelsey calculation) gives adequate power (80% power of detecting with a 2-sided 95% CI) to detect a 20% difference in condom usage (always used a condom in the past 12 months) among individuals in a monogamous relationship compared to those not in a monogamous relationship (assuming that approximately 50% of the individuals will be in a monogamous relationship and of these approximately 50% will always use condoms).

Variables evaluated and coding

Two clinical research forms (CRF) were used to collect data, one for screening and one for enrollment (see appendix). Questionnaires included information on: basic demographic information, medical history, HIV history, medication history, sexual history, contraceptive history, pregnancy history, sexually transmitted infection history, future fertility intentions, contraceptive beliefs and preferences, and condom usage during intercourse. Questions were a compilation of previously validated questions use in prior research studies and the questions used in the DHS survey [87]. Questions were piloted in Chichewa prior to study initiation to ensure question clarity in the population. The semi-structured interview data were collected in paper forms by study staff in Chichewa. Physical examination data and laboratory data were entered onto paper forms. Urine pregnancy tests were done during screening and data entered into the CRF, as well as hemoglobin values, which were collected during enrollment with a point-of-care Hemacue machine. Blood collected for CD4 count was sent during enrollment with reported results entered into the CRF upon receipt from the lab.

Laboratory testing:

Point of care hemoglobin testing and urine pregnancy tests were conducted at Lighthouse clinic during their study visits. Blood was drawn at Lighthouse clinic and tested at laboratories at UNC Project for CD4 count.

Pelvic exam

A study staff clinician performed a pelvic exam on all participants receiving a

contraceptive method and at each follow-up visit to assess for infection or other complications. The clinician documented on the study forms the findings, including evaluation of the vulva, vagina, cervix, uterus and adnexa. Presence of purulent cervicitis or pelvic inflammatory disease (PID), determined by the guidelines described below, was identified and treated accordingly at any time during the study.

Examination for Pelvic Inflammatory Disease (PID) and Management

The PID diagnosis criteria for the purpose of determining medical eligibility for IUD initiation and for the provision of antibiotic treatment at enrollment was very sensitive (to minimize false negatives) and based on the CDC's *Sexually Transmitted Diseases Treatment Guidelines 2006* and the *Malawi STI Guidelines, the Management of Sexually Transmitted Infections Using the Syndromatic Management Approach[88]* If the clinician determined that the woman had PID based on the diagnosis criteria, the clinician explained the diagnosis to the woman who was infected, explained the treatment regimen, and provided the regimen to the woman.

Statistical Analysis:

SPSS Statistical software version 17.0 was used for the statistical analysis. Descriptive statistics were used to determine the proportion of patients who met medical eligibility for the contraceptive methods out of all those screened, to describe the contraceptive method preference of individuals after counseling, and to report patterns of self-reported condom utilization. Univariate associations between dichotomous and categorical variables and outcomes were determined using Chi-square or Fisher exact tests (for cases

where fewer than 5 individuals were in any cell of a 2*2 table). Logistic regression was used to determine odds ratios for potential factors associated with outcome variables. Multivariate logistic regression models contained all variables in the univariate analyses. No interaction terms were evaluated in the models. Associations are reported as odds ratios (ORs) with 95% confidence intervals (CIs).

Potential factors included in the model:

- Age
- Education
- Marital status
- Relationship status
- Length of time on ART (months)
- Gravidity (Number of times pregnant)
- History of 1 or more abortion
- HIV Status of partner
- History of STIs
- Desire for more children
- Partner desire for more children
- Partner desire for her to use birth control

Outcomes

- Condom utilization:
    - Used a condom the last time she had intercourse

  - Always used a condom during intercourse in the past 12 months
- Current contraceptive use (including the reported use of a condom for birth control)

Data Management:

Database entry and management

Structured questionnaires, examinations, and blood sampling were the primary data collection methods for this study. A study database in Microsoft Access was created for the data entry and management. The purpose of this database was to support investigation of the clinical trials undertaken in Lilongwe. Trained data management personnel were responsible for data entry on site in Malawi. All data were entered using double entry and validated using predetermined queries.

Data Quality Assurance

Prior to beginning data collection at Lighthouse, staff participated in training that included modules on research ethics, maintaining confidentiality, interviewing, data management, and codebook development.

Data Confidentiality Assurances:

The participants' personal privacy and the confidentiality of the data remain protected by the following procedures:

- Information linking the participant with their study identification number are kept in a secure password protected file
- All evaluation forms, reports, and other records are identified by coded number to

maintain participant confidentiality

- All hard copy records are kept locked. Clinical information is not to be released without written permission of the participant, except as necessary for monitoring by IRB, NHSRC, or their designees
- All data is maintained by Lighthouse clinic
- Only Investigator-approved study staff has access to study data
- After completion of the study and after all the data has been entered into the database, the study folders are maintained in a locked location until destroyed by shredding or burning
- The database is maintained in a secure database for possible future analyses

Results

Screening and Enrollment

A total of 281 women were screened in order for200 women to be eligible and enroll in the longitudinal study (Figure 2). Table 1 shows the characteristics of all screened women enrolled versus those not enrolled. There is no difference between mean age, gravidity, or parity between enrolled women and those not enrolled in the study. Women enrolled have been on ART significantly longer than those not enrolled (enrolled duration 32.6 months, not-enrolled duration 20.6 months, p=0.00). Table 2 describes the reasons for study ineligibility among the 81 women who do not enroll in the study. Of those not enrolled, 11 (13.6%) do not meet medical eligibility for various reasons, 21 (25.9%) are on ART for less than 6 months, and 48(59.3%) desire a specific contraceptive method and decline

randomization. Of those eligible for enrollment, 80.6% are willing to be randomized and accept study enrollment.

Medical Eligibility

Among all women screened, contraceptive medical eligibility is high for all methods evaluated, including combined hormonal contraceptives, progestin-only pills, copper IUD, DMPA, and progestin-only implants (Table 3a-c). Over 97% of the women are eligible to receive the copper IUD, DMPA or the contraceptive implant. Breastfeeding children under 6 months of age is the most common reason for ineligibility for combined hormonal contraception. Among the 276 non-pregnant women, all women are eligible for at least 3 methods, with 242 (87.7%) eligible for all 5 methods.

Contraceptive choice and acceptance of the IUD

Among the 281 women screened, 58% select DMPA as their 1st choice contraceptive method, 34.9% choose the IUD, and 5.7% choose oral contraceptive pills (Table 4a). Of the 281 women screened, 222 (79%) are willing to have an IUD placed that day. Among those with a different contraceptive method as their first choice, 122 of 170 (68.2%) are still willing to receive an IUD at that visit; among the 59 who decline an IUD at that visit, 22 (37.3%) would be willing to have an IUD placed in the future (Table 4b). Table 5 shows the distribution of the reasons individuals endorsed for declining an IUD. 39% of the women desire a different method, however many women either fear IUD placement (25.4%) or have heard negative things about the IUD (25.4%).

Characteristics of women enrolled

Characteristics of the women enrolled are described in table 6. Most women are between 26 and 35 years of age and married. Most women are poorly educated with 13.6% of the women having at least completed secondary school. Most of the women have had prior pregnancies (98.5%) with over half (51%) having had 4 or more pregnancies. Most pregnancies have resulted in vaginal deliveries, however 12% of the women have had 1 or more prior cesarean section. 19% of the women report 1 prior abortion and 8.5% report 2 or more prior abortions. We do not differentiate between spontaneous or induced abortions. The number of pregnancies and births are much greater than the number of living children with 52% having 2 or 3 children and 24% having 4 or more children.

Table 7 describes the characteristics of their partners. Most of the women (90%) have had only one partner in the past year. 88.5% of the women report currently being in a relationship, 78% living with their partner and 54.5% report being in a monogamous relationship. Most women believe their partner does not desire any more children (82.5%) and that their partner wants them to use a contraceptive method (85.3%). Almost 60% of the women have a partner with known HIV-positive status, 10.7% have HIV negative partners and almost 30% do not know their partner's HIV status. Most (96%) of the women state that their partner knows they are HIV positive.

Fertility intentions, unintended pregnancy and family planning use

There is a high reported incidence of unintended pregnancy among the women enrolled in the study (Table 8) where 69.9% of the women report that their last pregnancy was unplanned and 61% are unhappy with the timing of the pregnancy. Approximately 16% of the women report using birth control at the time of their last conception, with

approximately half of those individuals reporting condom use and the other half reporting either DMPA or pill usage. Only 10 (5%) of the 200 women state that they desire more children in the future, only desiring 1 or 2 more children. Despite the high desire to limit future fertility, few (5%) women report any current use of modern family planning methods (Table 9) other than condoms. Condom use is reported as a method of birth control for 131 of the women (65.8%). Although current contraceptive use is low, 64% of the women have at some point used DMPA, 19.5% have used pills, 2.5% have used the IUD, and 2.5% have used the contraceptive implant.

Table 10 reports the findings from univariate and multivariate analyses for covariates associated with current contraceptive use, including the use of condoms. In the univariate analysis, women who have a known monogamous relationship and women who have a partner known to support use of family planning are significantly more likely to use contraception compared to women in which monogamy or support is unknown, respectively. In the multivariate analyses, only having a known monogamous relationship remain significant. In addition, women with HIV positive partners are significantly more likely to use contraception (OR 6.15 in multivariate analyses).

Condom usage

Condom use based on self-report is documented (figures 3 and 4) for condom use at last coitus and use of condom within the past 12 months. Overall, 35.9% of the women report consistent condom usage, defined as always using a condom in the past 12 months. Inconsistent use (defined as never or sometimes using a condom in the past 12 months) is

reported by 64.1%. In addition, 37.9% of the women report not using a condom during their last coital act.

Table 12a and 12b describe the reasons women report for inconsistent condom use. Among the 127 women who report inconsistent condom usage, the most prevalent reason for reported non-use is their partner (77.2%), with either the partner having difficulty (51.2%) or the partner's discomfort (16.3%) being the 2 most common reasons condoms are not worn. Lack of availability is the third most common reason reported, accounting for 12.2% of the reasons for non-use. Factors related to the woman (such as female discomfort) or related to the couple (such as trusting each other) are uncommon reasons for condom non-use.

Evaluating factors associated with consistent condom use (Table 13), we find that in the univariate analysis higher education (completion of primary school or more) (OR 2.61), unknown status of partner's monogamy (OR 2.14), 2 or fewer pregnancies, no history of abortion, a known HIV-negative partner, and a partner not supportive of family planning use are significantly associated with consistent condom use. In multivariate analysis, higher education (completion of primary school or more) (OR 2.61), unknown status of partner's monogamy (OR 3.68), no history of abortion, a known HIV-negative partner, and a partner not supportive of family planning remain significantly associated factors. In addition, women with no current partner or on ART for 24 months or less are more likely to use condoms consistently. Among the strongest associations with consistent condom use was having an HIV negative partner. Although more likely to use condoms in discordant relationships, 31.6% of these couples do not use condoms consistently.

Examining factors associated with condom use at last coitus (Table 14), in the univariate analysis, similarly higher education remains strongly associated with condom use, being in a known monogamous relationship, 2 or fewer pregnancies, and no history of abortion is significantly associated with condom usage at last coitus. In multivariate analysis, higher education and being in a known monogamous relationship remained significant factors. In addition, having no current partner (OR 0.08) or having partner support of family planning (OR 0.04) is significantly associated with lower condom use.

Discussion

We demonstrate that family planning integration can be successful in an urban ART clinic setting in Malawi. We found high unmet need for contraception, as rates of unintended pregnancy as well as non-use of effective contraception were high. We also found high rates of eligibility for all available modern contraceptive methods; all women were eligible to be offered a minimum of 3 methods at their visit. These findings are similar to those reported by Whiteman in 2009 [89] among a 435 HIV+ women in Russia where most women were eligible to use COCs (89%) and DMPA (94%), and 87% of non-postpartum women were eligible to use the IUD. The higher rates of medical eligibility in our study may be due to slight differences in the cohorts, as only 18% of the Russian cohort were on ART and women were about 5 years younger on average. As contraceptive eligibility remains high among HIV-infected women, all contraceptive methods can and should be offered in comprehensive integrated family planning care.

Among all women screened, there is a high desire for modern contraceptive methods, mostly DMPA and the IUD. Most of the enrolled women were in monogamous

relationships with concordant (i.e. HIV-positive) partners, which were the factors we found to be significantly associated with contraceptive use, suggesting a potentially high uptake of modern contraceptive methods with integrated family planning services. In particular, there is a high rate of acceptance for the copper IUD among this cohort. Although more women chose DMPA as a first choice, almost 35% of women select an IUD as their first choice contraceptive method, with 79% of the women willing to have an IUD placed. When combined with other study findings such as high patient and partner desire for limited future fertility, and high discontinuation of methods used in the past, this suggests that this population desires effective, long-acting methods that are easier to adhere to over time. This is in stark contrast to the low IUD usage rate in Malawi. It is unclear the role that provider motivation, method availability and patient education has in this community and how it might compare to a different setting with HIV negative women, though rates of past and current contraceptive use in this study are higher than overall rates seen in Malawi DHS data (Table 15a and 15b). It does highlight the opportunities available for increasing IUD use in this high-risk group where pregnancy prevention is important and the health impact of hormonal contraception may be unclear.

Successful integration of family planning with HIV care must begin with a comprehensive education plan for all clinic staff and clients, with a goal to dispel common contraceptive misconceptions and increase provider and patient comfort with long-acting contraceptive methods. We initiated Lighthouse staff education and training prior to method availability as a precursor to the development of services. We believe

that staff training and patient education did not compromise our study findings, as all available contraceptive methods were presented, and thus is considered part of routine care that any clinic initiating services should perform. Although IUD utilization in this community is low overall, this was particularly true at this clinic prior to the study in part because the IUD had not been available and providers were not trained. Prior studies in regions with low IUD utilization have shown that after education, individuals will be willing to have an IUD placed. This is supported by the fact that 51% of our screened subjects reported fear or misinformation as their reasons for declining an IUD. Furthermore, similar to the enrolled women in our study, a feasibility study in South Africa and Jamaica [32] showed that 70% of women were willing to be randomized to the IUD or a hormonal contraceptive method.

Randomization in contraceptive studies is a topic of much debate in the family planning community. A randomized controlled trial provides the highest level of evidence in clinical studies removing selection and other unknown biases. However, contraceptive method choice has been noted to be a strong predictor of contraceptive adherence and patient satisfaction. Furthermore, if many individuals are not eligible candidates or they desire only one contraceptive method it is arguable that the sample willing to be randomized may not be representative of the population. Our findings note that almost all women screened were eligible for more than one method and that women enrolled were similar to those not enrolled, with the exception of ART duration. We similarly find a high willingness to accept randomization and study enrollment following education with over 80% of all women who are eligible willing to be randomized, and 71% of all women

screened enrolling into the study. The high acceptance of randomization may be influenced by provider motivation and the eagerness for clients to receive any contraceptive method, as prior to study initiation, only condoms were available at this clinic. This is supported by the fact that 68% of women who did not select an IUD as their first choice were still willing to have an IUD placed that day if possible. Our findings show that randomization is feasible in this setting and can assist future research aimed at exploring the impact of IUD or hormonal contraception on HIV disease acquisition, transmission and progression. Randomized trials will be more valid for investigating effectiveness and continuation of theses methods in an HIV-positive population on ART. Assessing first choice contraceptive method at time of study enrollment can allow for separate analyses to investigate if receiving the first choice method impacts the findings of the randomized trial.

The findings on poor condom use is not surprising given the multiple other studies which document ineffective condom usage, however it is particularly disheartening. These high-risk couples, despite education, fail to consistently use condoms. Factors associated with inconsistent condom use, such as lower education, higher number of pregnancies and history of abortion, may reflect both the consequences of condom non-use as well as underlying factors that may limit female empowerment. Our finding that longer duration on ART is associated with lower condom utilization may reflect a concerning trend that requires further investigation to better elucidate the potential case for this decline. The most common reason reported for non-use was the male partner. This finding is consistent with other studies in the literature that have found partners play a critical role

in condom use. Our finding may be somewhat influenced by a reporting bias by these women where it may be easier to blame the partner than take primary responsibility. Furthermore, self-reported condom use is likely even higher than true condom usage. This highlights the importance for supplemental measures to approach reducing HIV transmission, and potentially more female controlled modalities that can be used without partner knowledge or required approval. Microbicide studies and recent studies suggesting antiretroviral treatment as prevention are needed advances to allow a complimentary approach to condoms for HIV transmission prevention.

Our finding that partners who support the use of family planning are less likely to use condoms consistently seems to be inconsistent with what has been demonstrated previously where partner support seems to increase contraceptive use. As this is a cross-sectional study, it is unclear if one factor leads to another. Furthermore, interpreting this question, condoms may or may not be included as a family planning method. For example, potentially men who want to avoid pregnancy and do not want to use condoms, support their partner's use of family planning and therefore have encouraged them to seek family planning services.

These findings may not be representative of all HIV infected women at this clinic, but rather reflect the cohort targeting in this study who are highly motivated to receive contraception, a cohort seeking family planning who meet inclusion for this study who are willing to be randomized to a contraceptive method. There results are specific to this community of women on most of who are on ART and all of whom are seeking family planning, therefore external validity of these findings may be limited.

One limitation of our findings is that we rely on subjective reporting for condom usage. Self reported condom usage has been shown in some studies to be an unreliable indicator for true condom usage [90, 91]. Future studies should aim to supplement self-reported condom use with biomarkers, such as PSA, as objective measures for semen exposure. Similarly, reported partner's fertility intensions, HIV knowledge and support of family planning is limited to the woman's perception of her partner, which may be shaped by cultural expectations, partner communication and relationship factors. Another limitation in our estimation of current contraceptive use is how individuals interpreted the question. Some women may have been using several methods of birth control concurrently and only selected one therefore this may be an underestimate of true method use.

Contraceptive choice is influenced by multiple cultural and environmental factors, as well as the education message and methods available on site. Although the implant was mentioned in the discussion of family planning methods during counseling, the implant was not available on site during this study screening. No clients chose an implant as their first choice option. It is unclear how the lack of availability might have influenced why individuals did not chose this as a first choice method. Future studies will need to see how having implants available may influence contraceptive choice and if those who select implants would be coming from the pool who had selected an IUD or those who selected another hormonal contraceptive method.

As most of the women who presented were healthy on ART, the eligibility for IUD placement was high. Eligibility is based on what the individual reports and what is noted on exam and may miss unknown medical issues. Furthermore, medical eligibility criteria are known to change over time, as additional studies evaluate contraceptive safety with

health conditions we may find more individuals becoming eligible or ineligible for different contraceptive methods. Despite this limitation, we can conclude that based on current recommendations most methods of contraception are safe for use by HIV+ women who present for family planning services. As most family planning methods are safe in this population, our results highlight that efforts must be made to increase access to and uptake of long-acting reversible methods, such as IUDs.

Future Directions

The results presented today are from the baseline data collected from a prospective study of contraceptive use in HIV infected women on ART. Follow-up is underway to evaluate contraceptive method acceptability and continuation over 1 year. Furthermore, we hope to be able to evaluate the impact of contraceptive method on self-reported condom use, side effects and disease progression. We are now initiating a second study at the same clinic that will hopefully elucidate some of the sexual behavior and fertility questions that have been raised by this study. The upcoming study will be a mixed method study combining qualitative evaluation (focus groups) and quantitative evaluation (surveys) to explore knowledge, attitudes and practices for both male and female clients with HIV on ART focusing on sexual behavior, family planning and fertility intensions. We hope this study will help us to understand how HIV and ART influence knowledge, sexual behavior and practice.

As for our integrated services, this is also ongoing. We have added implants and will be able to evaluate this method over time to determine how the availability may impact

alternative method use. We will also be adding a program for cervical cancer screening. Two women in this study during screening were found to have cervical cancer. HPV is prevalent in this region and HPV is known to more frequently progress to cervical cancer among individuals immunosuppressed. The early detection and treatment of precancerous changes on the cervix can be lifesaving for these women.

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Tables& Figures

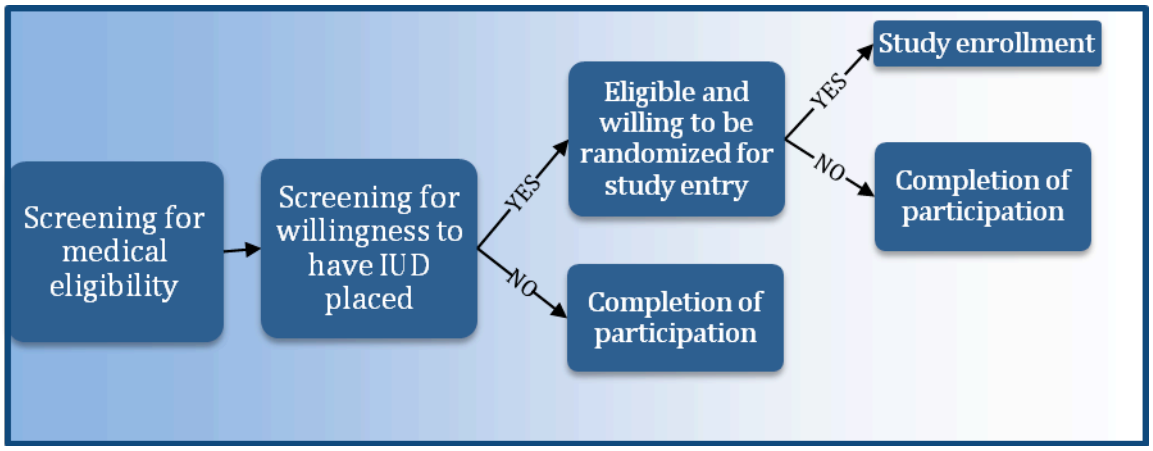

Figure 1 –Diagram for flow of Screening and Enrollment

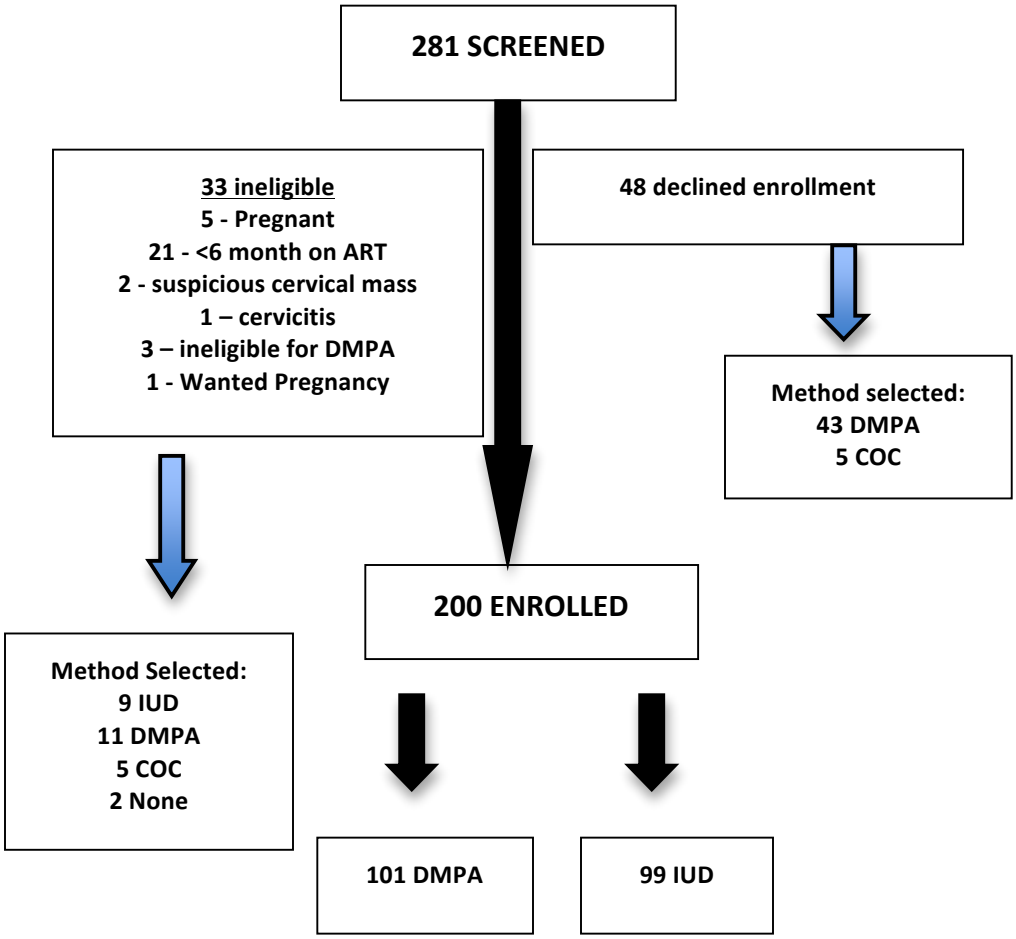

Figure 2: Summary of clients enrolled in study

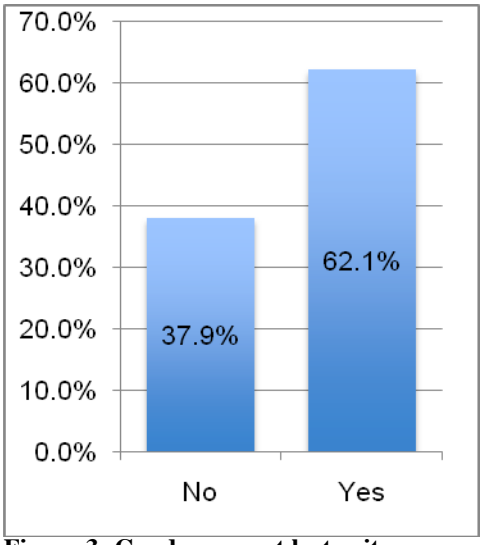

Figure 3: Condom use at last coitus among women enrolled
Missing = 2

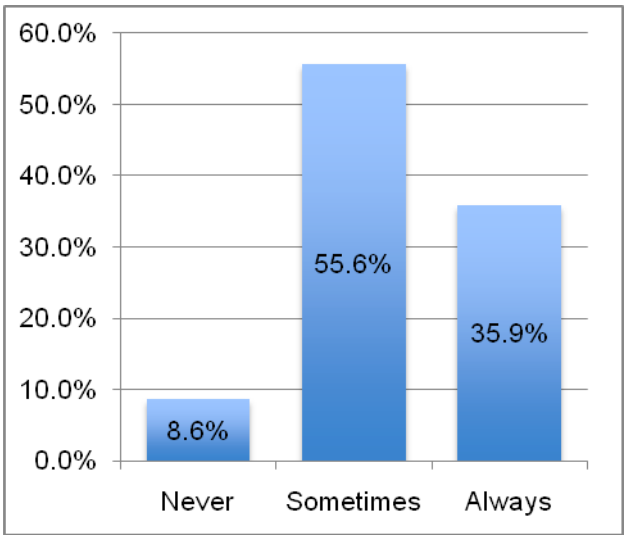

Figure 4: Condom use in past 12 months among women enrolled
Missing = 2

Table 1: Differences between individuals screened who did enroll compared to those who did not enroll

	Enrolled (n=200)	Not enrolled (n=81)	p-value
Age mean (SD)	32.3 (5.6)	31.07 (5.1)	0.08
ART duration mean (SD)	32.6 (22.3)	20.6 (21.1)	0.00
Gravidity mean (SD)	3.9 (2.8)	3.5 (1.8)	0.33
Parity mean (SD)	3.3 (1.8)	3.1 (1.7)	0.40

Table 2: Distribution of reasons for ineligibility among those not enrolled in the study

Reason for ineligibility	n=81	%
Pregnant	5	6.2
On ART for less than 6 months	21	25.9
Active cervicitis	1	1.2
Wanted a specific method	43	53.1
Suspicion for cervical cancer	2	2.5
Other medical history	3	3.7
Desired a child	1	1.2

Table 3a. Incidence of Health/Medical issues that restrict (category 3 or 4) any contraceptive method initiation according to World Health Organization medical eligibility criteria for contraceptive use 2010.

Health/Medical Issue	Method	n=281	%
Breastfeeding > 6 weeks and < 6 months	CHC	20	7.1
Ritonovir (Alluvia) Use	CHC, POP	6	2.1
Pregnant	All	5	1.8
Hypertension*	CHC	2	0.7
Migraines + aura or >35yo	CHC	2	0.7
Cervical Mass	IUD	2	0.7
Rifampicin Use	CHC	1	0.4
Stroke	CHC, DMPA	1	0.4
Active Cervicitis	IUD	1	0.4

*History of hypertension where blood pressure cannot be evaluated or blood pressure systolic 140-159 or diastolic 90-99

Table 3b. Proportion of clients who are eligible for contraceptive initiation (category 1 or 2) according to World Health Organization medical eligibility criteria for contraceptive use 2010

Method	n=281	%
CHC	245	87.2
POP	269	95.7
Cu IUD	273	97.2
DMPA	275	97.9
Implant	276	98.2

CHC = combined hormonal contraception
POP = progestin only pill
Cu IUD = copper IUD
DMPA = depo medroxyprogesterone acetate
Implant = progestin implant

Table 3c. Number of methods that can be offered to clients for initiation based on eligibility for contraceptive initiation (category 1 or 2) according to world health organization medical eligibility criteria for contraceptive use 2010

Number of methods	n=281	%
0	5	1.8
1	0	0
2	0	0
3	8	2.8
4	26	9.3
5	242	86.1

Table 4a. First choice contraceptive method among 281 women screened with HIV presenting for family planning

Method	n=281	%
DMPA	163	58.0
IUD	98	34.9
Oral contraceptives (CHC or POP)	16	5.7
Do not know or Missing	4	1.4

Table 4b. Willingness for IUD placement among HIV positive clients presenting for family planning in clinic

Group	Group (n)	Accepting (n)	%
On that clinic day:			
All clients	281	222	79.0
Eligible for IUD	275	217	78.9
IUD not 1st choice	179	122	68.2
In the future:			
Clients declining on clinic day	59	22	37.3

Table 5. Reasons for declining IUD among women who would not consider IUD placement on that clinic day

REASON DECLINING IUD PLACEMENT	n = 59	%
I prefer a different method	23	39.0
Fear of placement, pain, bleeding, infertility or infection	15	25.4
I have heard negative things about the IUD	15	25.4
I have previously used the IUD and did not like the IUD	4	6.8
I do not feel comfortable having something inside my body	3	5.1
I need to ask or discuss with my partner first	2	3.4
I want to get pregnant soon	2	3.4
My partner does not want me to use any contraception	1	1.7
I have a friend who was unhappy with the IUD	1	1.7

Table 6. Demographic characteristics of 200 women enrolled in study:

Characteristic	N	%
Age mean (SD)	32.3 (5.6)	
<=25	20	10.0
26-35 years old	126	63.0
>36	54	27.0
Marital status		
Single	4	2.0
Married monogamous	128	64.0
Married polygamous	15	7.5
Living with partner	4	2.0
Divorced/widowed	31	15.5
Do not know/decline	18	9.0
Educational status		
None	27	13.6
Some primary	67	33.7
Completed primary	28	14.1
Some secondary	50	25.1
Completed secondary	23	11.6
Any tertiary	4	2.0
Missing	1	
Number of pregnancies		
None	3	1.5
One	14	7.0
Two	31	15.5
Three	50	25.0
Four	45	22.5
Five or more	57	28.5
Number of vaginal deliveries		
None	27	13.6
One	67	33.7
Two	28	14.1
Three	50	25.1
Four	23	11.6
Five or more	4	2.0
Number of cesarean sections		
None	176	88.0
One	17	8.5
Two or more	7	3.5
Number of abortions		
None	145	72.5
One	38	19.0
Two or more	17	8.5
Number of living children		
None	17	8.5
One	31	15.5
Two	51	25.5
Three	53	26.5
Four	28	14.0
Five or more	20	10.0

Table 7: Partner related characteristics among women 200 enrolled in the study

	n	%
Number of partners in past year		
None	9	4.5
One	180	90.0
Two	7	3.5
Three	4	2.0
Current partner		
No	23	11.5
Yes	177	88.5
Relationship status		
Mutually monogamous	109	54.5
Not monogamous	26	13.0
Do not know	42	21.0
NA/No current partner	23	8.2
Does partner want more children		
No	146	82.5
Yes	13	7.3
Do not know	18	10.2
NA	23	
Do you live with your partner		
No	39	22.0
Yes	138	78.0
NA	23	
Does your partner want you to use family planning		
No	9	5.1
Yes	151	85.3
Do not know	17	9.6
NA	23	
Is your partner HIV+		
No	19	10.7
Yes	106	59.9
Do not know	52	29.4
NA	23	
Does your partner know you are HIV+		
No	3	1.7
Yes	170	96.0
Do not know	4	2.3
NA	23	

Table 8. Fertility intentions and unplanned pregnancy among HIV+ clients enrolled in study

	n=200	%
Last pregnancy		
Planned	59	30.1
Unplanned	137	69.9
Missing/NA	4	
Happy with timing of last pregnancy		
Yes, happy with timing	75	37.5
No, unhappy with timing	122	61.0
Missing/NA	3	
Using birth control when most recently became pregnant		
No	166	84.3
Yes	31	15.7
N/A	3	
Method used when got pregnant		
OCP (CHC or POP)	5	16.1
DMPA	12	38.7
Male condoms	14	45.2
N/A	169	
Do you want more children in the future		
No	190	95.0
Yes	10	5.0
Number of children you want in the future		
0	190	95.0
1	7	3.5
2	3	1.5

Table 9. Family planning use among HIV+ clients enrolled in study

	n=200	%
Contraceptive methods previously ever used		
OCP	39	19.5
Implant	5	2.5
Male Condom	184	92.0
Female Condom	17	8.5
DMPA	128	64
IUD	5	2.5
Emergency contraception	0	0
Rhythm method	4	2
Withdrawal	2	1
Abstinence	27	13.5
Any modern contraceptive method ever used other than condoms		
No	61	30.5
Yes	139	69.5
Contraceptive method currently using		
None	53	26.6
OCP	1	0.5
DMPA	9	4.5
Male Condom	131	65.8
Female Condom	1	0.5
Rhythm method	1	0.5
Abstinence	3	1.5
Missing	1	

Table 10. Factors associated with current contraceptive use (including condoms for intention of family planning), crude and adjusted odds ratios with all variables in model:

Factor	UNADJUSTED OR (95% CI)	ADJUSTED OR (95% CI)
Age (mean (SD))	1.03 (0.97, 1.09)	1.108 (1.02, 1.21)*
Education		
None or some primary school	1 (Ref)	1 (Ref)
Completion of primary school or more	1.07 (0.58, 1.99)	1.80 (0.72, 4.51)
Marital status		
Single	1 (Ref)	1 (Ref)
Married	1.3 (0.13, 12.95)	0.53 (0.01, 56.18)
Divorced/Widowed	0.19 (0.02, 2.09)	0.50 (0.01, 45.54)
Relationship status		
Monogamous	1 (Ref)	1 (Ref)
Non monogamous	0.39 (0.14, 1.04)	0.24 (0.05, 1.16)
Do not know	0.37(0.16, 0.86)*	0.16 (0.05, 0.49)*
No current partner	0.03 (0.01, 0.10)*	0.30 (0.01, 7.78)
ART duration		
0-24 months	1 (Ref)	1 (Ref)
>24 months	1.23 (0.67, 2.36)	1.71 (0.678, 4.31)
History of STI		
No	1 (Ref)	1 (Ref)
Yes	1.12 (0.52, 2.42)	1.92 (0.59, 6.21)
Pregnancy number		
0-2	1 (Ref)	1 (Ref)
3 or more	0.79 (0.37, 1.65)	0.35 (0.10, 1.18)
History of an abortion		
No	1 (Ref)	1 (Ref)
Yes	1.63 (0.79, 3.38)	2.28 (0.74, 7.03)
Partner's HIV status		
Negative	1 (Ref)	1 (Ref)
Positive	2.81 (0.92, 8.58)	6.15 (1.42, 26.73)*
Do not know	1.23 (0.39, 3.89)	3.41(0.69, 16.89)
Desire more children		
No	1 (Ref)	1 (Ref)
Yes	0.79 (0.19, 3.29)	1.18 (0.09, 15.90)
Partner supports FP use		
No	1 (Ref)	1 (Ref)
Yes	7.32 (1.65, 32.45)*	5.77 (0.43, 78.24)
Do not know	5.42 (0.88, 33.36)	4.52 (0.18, 114.68)

* Statistically significant

Table 11. Condom use reported by 200 women enrolled in study

Condom use		n	%
At last intercourse	No	75	37.9
	Yes	123	62.1
	Missing	2	
In the past 12 months	Never	17	8.6
	Sometimes	110	55.6
	Always	71	35.9
	Missing	2	

Table 12a. Primary reason reported for inconsistent condom use (n=127)

REASON FOR NOT ALWAYS USING A CONDOM	N	%
Partner has difficulty	63	51.2
Partner objected	7	5.7
Uncomfortable for partner	20	16.3
Partner was drunk	5	4.1
I did not want to use	2	1.6
Uncomfortable for me	1	0.8
Did not have a condom	15	12.2
We were caught up in the moment	2	1.6
Trust each other	1	0.8
Other	7	5.7

n=123 (4 missing)

Table 12b. Primary reason reported for inconsistent condom use

(n=127), categorized into factors for non-use

REASON FOR NOT ALWAYS USING A CONDOM	N	%
Availability	15	12.2
Partner factor (objected, drunk, discomfort, difficulty)	95	77.2
Female factor (discomfort, chose not to use)	3	2.4
Couple factors (caught up in moment, trust each other)	3	2.4
Other	7	5.7

n=123 (4 missing)

Table 13. Factors associated with consistent condoms, unadjusted and adjusted odds ratios with all variables included in the model

Factor	UNADJUSTED OR (95% CI)	ADJUSTED OR (95% CI)
Age (mean (SD))	1.02 (.96, 1.07)	1.03 (0.95, 1.10)
Education		
None or some primary school	1 (Ref)	1 (Ref)
Completion of primary school or more	2.61 (1.42, 4.80)*	3.68 (1.66, 8.14)*
Marital status		
Single	1 (Ref)	1 (Ref)
Married	0.19 (0.02, 1.91)	0.29 (0.02, 4.66)
Divorced/Widowed	0.10 (0.01, 1.14)	0.06 (0.01, 1.02)
Relationship status		
Monogamous	1 (Ref)	1 (Ref)
Non monogamous	1.03 (0.42, 2.53)	0.90 (0.24, 3.38)
Do not know	2.14 (1.04, 4.41)*	2.72 (0.98, 7.55)
No current partner	0.32 (0.09, 1.17)	0.04 (0.00, 0.10)*
ART duration		
0-24 months	1 (Ref)	1 (Ref)
>24 months	0.71 (0.39, 1.28)	0.45 (0.21, 0.99)*
History of STI		
No	1 (Ref)	1 (Ref)
Yes	0.59 (0.28, 1.27)	0.71 (0.27, 1.89)
Pregnancy number		
0-2	1 (Ref)	1 (Ref)
3 or more	0.43 (0.22, 0.84)*	0.43 (0.18, 1.06)
History of an abortion		
No	1 (Ref)	1 (Ref)
Yes	0.45 (0.22, 0.92)*	0.34 (0.14, 0.87)*
Partner's HIV status		
Negative	1 (Ref)	1 (Ref)
Positive	0.26 (0.09, 0.73)*	0.20 (0.06, 0.74)*
Do not know	0.22 (0.07, 0.69)*	0.16 (0.04, 0.68)*
Desire more children		
No	1 (Ref)	1 (Ref)
Yes	2.84 (0.77, 10.42)	0.46 (0.03, 7.29)
Partner desires more children		
No	1 (Ref)	1 9 (Ref)
Yes	2.65 (0.83, 8.50)	1.42 (0.15, 13.9)
Do not know	0.64 (0.22, 1.88)	0.70 (0.09, 5.25)
Partner supports FP use		
No	1 (Ref)	1 (Ref)
Yes	0.07 (0.01, 0.59)*	0.03 (0.01, 0.44)*
Do not know	0.05 (0.01, 0.53)*	0.04 (0.01, 0.91)*

*Statistically significant

Table 14. Factors associated with using a condom during last coitus, unadjusted and adjusted odds ratios will all variables in model

Factor	UNADJUSTED OR (95% CI)	ADJUSTED OR (95% CI)
Age (mean (SD))	1.00 (0.95, 1.05)	1.02 (0.95, 1.09)
Education		
None or some primary school	1 (Ref)	1 (Ref)
Completion of primary school or more	2.66 (1.46, 4.81)*	5.99 (2.55, 14.05)*
Marital status		
Single	1(Ref)	1 (Ref)
Married	0.61(0.06, 6.00)	1.71 (0.10, 29.02)
Divorced/Widowed	0.29 (0.03, 3.13)	1.14 (0.07, 19.17)
Relationship status		
Monogamous	1 (Ref)	1 (Ref)
Non monogamous	0.32 (0.13, 0.77)*	0.11 (0.03 0.44)*
Do not know	0.71 (0.34, 1.49)	0.50 (0.18, 1.42)
No current partner	0.40 (0.15, 1.02)	0.08 (0.00, 0.18)*
ART duration		
0-24 months	1 (Ref)	1 (Ref)
>24 months	0.75 (0.42, 1.36)	0.49 (0.23, 1.05)
History of STI		
No	1 (Ref)	1 (Ref)
Yes	0.64 (0.32, 1.29)	0.76 (0.32, 1.82)
Pregnancy number		
0-2	1 (Ref)	1 (Ref)
3 or more	0.40 (0.19, 0.84)*	0.44 (0.16, 1.23)
History of an abortion		
No	1 (Ref)	1 (Ref)
Yes	0.48 (0.25, 0.90)*	0.46 (0.20, 1.08)
Partner's HIV status		
Negative	1 (Ref)	1 (Ref)
Positive	0.79 (0.26, 2.38)	1.02 (0.27, 3.87)
Do not know	0.36 (0.11, 1.14)	0.31 (0.07, 1.31)
Desire more children		
No	1 (Ref)	1 (Ref)
Yes	1.45 (0.36, 5.78)	0.32 (0.02, 4.53)
Partner desires more children		
No	1 (Ref)	1 (Ref)
Yes	1.17 (0.34, 4.00)	1.64 (0.18, 15.06)
Do not know	0.42 (0.16, 1.12)	0.38 (0.07, 2.14)
Partner supports FP use		
No	1 (Ref)	1 (Ref)
Yes	0.24 (0.03, 1.96)	0.04 (0.01, 0.63)*
Do not know	0.07 (0.01, 0.68)	0.06 (0.01, 1.32)

* Statistically significant

APPENDICES

Table 15a: Ever use of contraception among women interviewed and in Malawi DHS

	HIV+ women	2010 DHS All women	2010 DHS Married	2010 DHS Unmarried sexually active
Any method	93.5%	65.8%	78.7	71.8
DMPA	64.0%	48.8%	61.3	42.5
OCP	19.5%	12.6%	15.1	14.4
Implant	2.5%	1.7%	2.2	1.3
IUD	2.5%	0.8%	0.9	1.1
Male condom	92.0%	18.6%	19.6	49.8
Female condom	8.5%	1.2%	1.3	3.2

Table 15b: Current use of contraception among women interviewed and in Malawi DHS

	HIV+ women	2010 DHS All women	2010 DHS Married	2010 DHS Unmarried sexually active
Any method	73.4%	32.6	42.2	46.3
DMPA	4.5%	19.2	25.8	15.4
OCP	0.5%	1.9	2.5	2.4
Implant	0%	1.1	1.3	0.9
IUD	0%	0.2	0.3	0.0
Male condom	65.8%	2.7	2.4	23.0
Female condom	0.5%	0.1	0.1	0.2

Appendix

LIGHTHOUSE

FORM 1- SCREENING	HIV IUCD/DMPA STUDY **Screening Eligibility Assessment**	Version 1
ADD PATIENT EDS BAR CODE LABEL HERE	ADD STUDY ID LABEL HERE	
Form filling date	(dd / mm / yy)	
Time filled:	(24 hour clock hh : mm)	:
Filled by (use staff code whenever possible)		

BEFORE SCREENING ASSESSMENT: ALL CLIENTS MUST RECEIVE COMPREHENSIVE FAMILY PLANNING EDUCATION WITH EITHER THE CLINIC NURSE, CLINICIAN OR FAMILY PLANNING EDUCATOR.

Interviewer: Please read the question below and circle appropriate answer – base answer on patients response, the medical passport and computerized medical record				
1	**What is your age in years?** *Muli ndi zaka zingati?*	|___|___|		DO NOT KNOW (99)
E1	Age 18-45 *Zaka 18-45*	NO (0)	YES (1)	DO NOT KNOW (99)
2	How long have you been on ART (months) Mwakhala pa mankhwala kwa nthawi yaitali bwanji?	|___|___|		DO NOT KNOW (99)
E2	Has been stable for 6 months or more on antiretroviral therapy *Mwakhazikika pa mankhwala a ma ARV kwa miyezi khumi ndi umodzi.*	NO (0)	YES (1)	DO NOT KNOW (99)
3	Are you currently pregnant? Kodi muli ndi mimba?	NO (0)	YES (1)	DO NOT KNOW (99)
4	**Do you want to avoid getting pregnant for at least 12 months (1 year)** *Mukufuna pathe chaka musanatenge pakati?*	NO (0)	YES (1)	DO NOT KNOW (99)
5	Have **you ever** had a hysterectomy **OR** a tubal ligation Kodi munachotsedwapo chiberekero kapena kutseketsapo?	NO (0)	YES (1)	DO NOT KNOW (99)
6a	**Have you had a baby within the past 4 weeks?** *Kwa milungu inayi yapitayi mwaberakako mwana?*	NO (0) →7a	YES (1)	DO NOT KNOW (99)
6b	**Was this delivery in the last 2 days**? *Mwanayo wabadwa m'masiku awiri apitawa?*	NO (0) →7a	YES (1)	DO NOT KNOW (99)
6c	**Did you lose a lot of blood?** *Munataya magazi ambiri?*	NO (0)	YES (1)	DO NOT KNOW (99)
7a	**Have you had a stillbirth abortion or miscarriage within the past 4 weeks** *Mwanayu anabadwa wakufa, munachotsa mimba kapena munapita pa dera pa milungu inayi tapitayo?*	NO (0) →8a	YES (1)	DO NOT KNOW (99)
7b	**Was this stillbirth, abortion or miscarriage after 5 months (or 24 weeks) of pregnancy?** *Mwana wakufayu, kuchotsa mimbaku kapena kupita paderaku kwachitika miyezi isanu chitengereni mimba?*	NO (0) →8a	YES (1)	DO NOT KNOW (99)

	7c	**Was this stillbirth, abortion or miscarriage in the last 48 hours?** *Kodi zimenezi zachitika m'masiku awiri apitawa?*	NO (0) →8a	YES (1)	DO NOT KNOW (99)
	7d	**Did you lose a lot of blood?** *Munataya magazi ambiri?*	NO (0)	YES (1)	DO NOT KNOW (99)
8a		**Are you currently breastfeeding a baby?** *Kodi panopa mukuyamwitsa?*	NO (0) →9a	YES (1)	DO NOT KNOW (99)
	8b	**Is the baby less than 6 months old?** *Mwanayo sanadutse miyezi isanu ndi umodzi?*	NO (0) →9a	YES (1)	DO NOT KNOW (99)
	8c	**Is the baby less than 6 weeks old?** *Mwanayo sanadutse masabata asanu ndi imodzi?*	NO (0)	YES (1)	DO NOT KNOW (99)
9a		**Have you been told that you have or ever had tuberculosis (TB)?** *Munauzidwapo kuti muli kapena munadwalapo chifuwa chachikulu (TB)?*	NO (0) → 10	YES (1)	DO NOT KNOW (99)
	9b	**When you had tuberculosis (TB) was it ever in your abdomen or female organs?** *Chifuwachi chinali (TB) m'mimba kapena mziwalo zanu zachizimayi?*	NO (0)	YES (1)	DO NOT KNOW (99)
	9c	**Do you currently take Rifampicin for tuberculosis (TB)** *Pano mukumwa (Rifampicin) mankhwala a TB?*	NO (0)	YES (1)	DO NOT KNOW (99)
10		***Do you have irregular vaginal bleeding between your menstrual periods or after intercourse?*** *Kodi m'mataya magazi mosayenera pamene muli mu nsambo kapena mutangogonana ndi mwamuna?*	NO (0)	YES (1)	DO NOT KNOW (99)
11		***Have you been told that you have a uterine abnormality or fibroids?*** *Munauzidwapo kuti muli ndi zotupa m'chiberekero?*	NO (0)	YES (1)	DO NOT KNOW (99)
12		**Have you been told that you have any type of cancer in your genital (female) organs or reproductive tract** (such as endometrial, cervical, or ovarian cancer)? *Munakhalapo ndi cancer ya ziwalo zanu zoberekera (mkati mwa chiberekero/njira ya chiberekero)*	NO (0)	YES (1)	DO NOT KNOW (99)
13		**Have you ever been told that you have a rheumatic disease such as lupus?** *Kodi munadwalapo nyamakazi ya m'mafupa?*	NO (0)	YES (1)	DO NOT KNOW (99)

14	**Do you currently have gall bladder disease, a serious liver disease (active hepatitis or tumors) or jaundice (yellow skin or eyes)?** *Kodi munadwalpo matenda/zotupa mu chiwindi (Kapena chikasu)?*	NO (0)	YES (1)	DO NOT KNOW (99)
15	**Have you ever been told you that you have problems with your blood vessels or veins (peripheral vascular disease)?** *Munakhalapo ndi vuto la misempha (Ya Magazi)?*	NO (0)	YES (1)	DO NOT KNOW (99)
16	**Have you ever had a blood clot in your legs OR lungs?** *Munakhalapo ndi vuto la kuundana kwa magazi m'miyendo kapena m'mapapo mwanu?*	NO (0)	YES (1)	DO NOT KNOW (99)
17	**Have you ever had a stroke, heart disease OR a heart attack?** *Munakhalapo ndi vuto la kufa kwa ziwalo kapena matenda a mtima?*	NO (0)	YES (1)	DO NOT KNOW (99)
18	**Have you ever been told you have breast cancer?** *Munadwalapo cancer ya m'mawere?*	NO (0)	YES (1)	DO NOT KNOW (99)
19	**Have you ever been told you have high blood pressure?** *Muli ndi vuto la kuthamanga kwa magazi?*	NO (0)	YES (1)	DO NOT KNOW (99)
20a	**Have you had diabetes (high sugar in your blood)** *Muli ndi vuto la matenda a shuga?*	NO (0) → 21a	YES (1)	DO NOT KNOW (99)
20b	**Have you had diabetes for more than 20 years?** *Mwadwala koposa zaka makumi awiri?*	NO (0)	YES (1)	DO NOT KNOW (99)
20c	**Do you have problems with other organs such as your eyes or kidneys because of diabetes** *Muli ndi vuto lina lililonse lokhudzana ndi maso kapena impso chifukwa cha matenda a shuga?*	NO (0)	YES (1)	DO NOT KNOW (99)
21a	**Have you ever had seizures (fits)** *Munadwalapo khunyu?*	NO (0) → 22	YES (1)	DO NOT KNOW (99)
21b	**Do you currently take medication, such as anticonvulsants, for your seizures?** *Panopa mukumwa mankhwala a khunyu?*	NO (0)	YES (1)	DO NOT KNOW (99)
22	**Do you take Alluvia for ARV therapy?** *Panopa mukumwa Alluvia ngati mankwala anu a ma ARV?*	NO (0)	YES (1)	DO NOT KNOW (99)
23a	**Do you have migraine headaches – these are repeated severe headaches, often on one side or pulsating that can cause nausea, and may be worse with bright light, noise, or movement?** *Mukudwala mutu wa chinglalanglala?*	NO (0) → 24	YES (1)	DO NOT KNOW (99)

	23b	**Do you sometimes feel a warning sensation 10-30 minutes before you get this type of headache (aura)?** *Umayamba bwanji?*	NO (0)	YES (1)	DO NOT KNOW (99)
24		**Do you smoke cigarettes?** *Mumasuta fodya?*	NO (0)	YES (1)	DO NOT KNOW (99)
25		**Have you ever been told that you have a problem with your blood where you have difficulty forming blood clots and therefore bleed more than expected** *Kodi muli ndi vuto lakuti mukapweteka magazi samasiya nsanga kutuluka?*	NO (0)	YES (1)	DO NOT KNOW (99)
26a		**Have you ever been told that you have Pelvic Inflammatory Disease (PID)?** *Munauzidwa kuti muli ndi matenda okhuza ziwalo zoberekera?*	NO (0) → 27a	YES (1)	DO NOT KNOW (99)
	26b	**Have you had PID in the past 3 months?** *Munadwala miyezi itatu yapitayi*	NO (0)	YES (1)	DO NOT KNOW (99)
27a		**Have you ever been told that you have a sexually transmitted infection (not including HIV), such abnormal vaginal discharge syndrome, gonorrhea or Chlamydia?** *Munadwalako matenda opatsilana pogonana monga chizonono**?***	NO (0) →28	YES (1)	DO NOT KNOW (99)
	27b	**Have you had a sexually transmitted infection (not including HIV) in the past 1 month** *Munatenga matendawa mwezi umodzi wapitawu.*	NO (0)	YES (1)	DO NOT KNOW (99)
	27c	**Did you receive treatment for the infection?** *Munalandila chitandizo cha mankwala?*	NO (0)	YES (1)	DO NOT KNOW (99)

28.	**What method of birth control would be your FIRST choice if available today, either to start or to continue if you are already using this method?** *Mungakonde njila yiti kukhala yoyamba lero?* ***(CIRCLE ONLY 1)***	(1) Oral Contraceptive Pills (2) Depo-Provera (DMPA, the Shot) (3) Intrauterine contraception (IUCD or Loop) (4) Contraceptive Implant (Norplant) (5) Male condoms (6) Female condoms (7) Rhythm method / Natural family planning (8) Withdrawal (9) Abstinence (10) Surgical sterilization – tubal ligation (11) Surgical sterilization – vasectomy (12) Emergency Contraception (13) Other _____ (99) Do not know/Decline

29a	**Would you consider using an IUCD today** Kodi mungakonde kuti mulandire lupu (IUCD) lero?	NO (0)	YES (1) → 30	DO NOT KNOW (99)

29b	**Why do you NOT want to have an IUCD placed?** *Mwati simunakonde njila ya lupu chifukwa chiyani?* (ASK THE QUESTION AND CHECK ALL THAT APPLY BASED ON THEIR ANSWER. DO NOT READ THROUGH ALL THE ANSWERS BELOW. CHECK THE ANSWER (S) THAT ARE MOST SIMILAR TO THEIR RESPONSE, CIRCLE ALL THAT APPLY)	(1) I want to get pregnant soon (2) I prefer a different method (3) I have heard negative things about the IUCD (4) I have previously used the IUCD and did not like the IUCD (5) I have a friend who was unhappy with the IUCD (6) I do not feel comfortable having something inside my body (7) I do not believe it is effective for birth control (8) I am afraid of having it placed (9) I am afraid that it will be cause me pain (10) My partner does not want me to use contraception (11) My partner does not want me to use this method (12) I am afraid that I will not be able to get pregnant in the future (13) I can not use because of HIV (14) I can not use because of different medical condition (15) I am afraid of changes in my bleeding (16) I am afraid of infection (17) I am interested however not today (18) I need to ask or discuss with my partner first (19) I am afraid it will travel to other parts of my body (heart, brain) (20) I want it, but not today (21) Other (specify): (99) Do not know/Decline

29c	**Would you consider getting an IUCD placed at another time in the future?** *Nanga mtsogolo muno?*	NO (0)	YES (1)	DO NOT KNOW (99)

30: CHECK PREGNANCY TEST THEN EVALUATE BELOW IF ELIGIBLE FOR STUDY ENROLMENT		
30a. SCREENING ASSESSMENT (FORM B):		**(NOT ELIGIBLE)**
IS YES/NO CIRCLED IN ANY SHADED BOX	**NO (0)**	**YES (1)**
30b. BP today is greater than 160/90	**NO (0)**	**YES (1)**
30c. URINE PREGNANCY TEST	**NEGATIVE**	**POSITIVE**

IF YES TO ANY OF THE ABOVE OR IF Urine Pregnancy Test is positive: Client is not eligible for the study. Thank the patient for their participation *Thank you for taking the time to participate. We feel that participation in the larger study is not right for you. We can assist you with where you can go if you are interested in receiving birth control at this time.*

IF NO TO ALL QUESTIONS ABOVE THEN ELIGIBLE FOR STUDY PARTICIPATION:

We would like to invite you to participate in another study. We want to better understand birth control options available to individuals who are HIV positive and taking antiretroviral therapy (ARVs). The purpose of this research study is to learn about the experience of women who use the IUCD (the Loop) compared to women who use an injection called DMPA or Depo-Provera (the Shot) for contraception. To participate in this study you MUST be willing to receive both the IUCD (The Loop) and Depo (the Shot), as you will be assigned by the staff to receive one of these method. If you would like to participate in this study we will ask you to sign an informed consent document that discusses the details of the study

Hand the woman the informed consent and read through the consent with her to ensure she understands. If she would like to be in the study please have her sign the enrollment consent.

HAS THE CONSENT BEEN SIGNED?

YES → FORM 2 -- ENROLLMENT FORM

NO → FP INTAKE PHYSICAL EXAM FORM

Form 2 - Enrollment	HIV IUCD/DMPA STUDY	LIGHTHOUSE
	Enrollment Assessment	Version 1

Form filling date (dd / mm / yy)

Time filled (24 hour clock hh : mm) :

Filled by (use staff code whenever possible)

Thank you for agreeing to participate in our study. I will be asking you some questions. Answer to the best of your ability.

1		**What is the highest grade in school that you have completed**? *Sukulu munalekezera kuti?*	(0) None, No formal education (1) Some primary school (2) Completed primary school (3) Some secondary school (4) Completed secondary school (5) Any tertiary education/post-secondary (99) Do not know/Decline		
2a		**Have you ever been pregnant?** *Munakhalapo ndi mimba?*	NO (0) →4a	YES (1)	DO NOT KNOW (99)
	2b	**How many times have you been pregnant?** *Munaberekapo kangati?*	|___|___| (0-30)		DO NOT KNOW (99)
	2c	**How many normal (vaginal) deliveries have you had?** *Kubereka kwabwinobwino, mwabereka kangati?*	|___|___| (0-30)		DO NOT KNOW (99)
	2d	**How many cesarean sections (Cesars) have you had?** *Nanga kwa mpene (cesars?)*	|___|___| (0-30)		DO NOT KNOW (99)
	2e	**How many abortions or miscarriages have you had? (That is a spontaneous or induced passage of a pregnancy before you were 28 weeks pregnant)** *Mwachotsa mimba/kupita padera kangati?*	|___|___| (0-30)		DO NOT KNOW (99)
	2f	**How many stillbirths have you had? (That is a delivery of a dead infant after 28 weeks of pregnancy)** *Munaberekapo mwana wakufa kangati?*	|___|___| (0-30)		DO NOT KNOW (99)
	2g	**How many of your children are currently alive today?** *Muli ndi ana angati amoyo?*	|___|___| (0-30)		DO NOT KNOW (99)
	3a	**Thinking back to right before your last pregnancy, had you planned or wanted to have more children at that time or at some point in the future when you got pregnant?** *Mimba yanu imene munali nayo yomaliza munachita kupanga chisankho kapena munafuna kudzakhala ndi ana*	NO (0)	YES (1)	DO NOT KNOW (99)

	mtsogolo?			
3b	**At that time, were you happy with the timing of the pregnancy or would you have been happier if there was more time or space before you had become pregnant?** *Munakhutitsidwa kapena m'mafunabe nthawi yokwanira musanatenge mimba?*	(1) I was happy to be pregnant **AT THAT TIME** (2) I would have been happier if I got pregnant **LATER** (99) Do not know/Decline		
3c	**Were you using birth control when you most recently became pregnant?** *Mumalera nthawi imene munapezeka ndi mimba?*	NO (0) → 4a	YES (1)	DO NOT KNOW (99)

	3d	**What method of birth control were you using at that time?** *Nanga ndi njira iti mumagwiritsa nchito ya kulera?*	(1) Oral Contraceptive Pill (2) Depo-Provera(The shot,Depo, DMPA) (3) IUCD (Loop) (4) Contraceptive Implant (Norplant) (5) Male condoms (6) Female condoms (7) Rhythm method / Natural family planning (Counting beads/ days) (8) Withdrawal (9) Abstinence (10) Surgical sterilization – tubal ligation (11) Surgical sterilization – vasectomy (12) Other _____ (99) Do not know/Decline		
4a	**Do you want to have (more) children in the future?** *Mukufuna mutadzakhala ndi ana ena mtogolo muno?*		NO (0) → 5	YES (1)	DO NOT KNOW (99)
	4b	**How many (more) children would you like to have?** *Angati?*	|___|___| (0-30)		DO NOT KNOW (99)
	4c	**When do you think you would like to get pregnant in the future?** *Mufuna mutadzatenga mimba liti?*	(1) In less than 1 year (2) In 1-3 years (3) In 4 years or more years (99) Do not know/Decline		
5	**What is your marital status?** *Muli pa banja?*		(1)Single, never married (2) Married (monogamous) (3)Married (polygamous) (4) Divorced/separated (5)Widowed (6) Living with partner		

			(99) Do not know/Decline		
6a	**How many sexual partners have you had in the past year?** *Mwagonanako ndi amuna angati kwa chaka chapitachi?*		|___|___| (0-90)		DO NOT KNOW (99)
6b	**How many sexual partners have you had in the past 3 months?** *Nanga kwa miyezi itatu yapitayi*		|___|___| (0-90)		DO NOT KNOW (99)
6c	**Do you have a current sexual partner?** *Panopa muli ndi wogonana naye?*		NO (0) → 13	YES (1)	DO NOT KNOW (99)
7	**Do you or your partner have other sexual partners?** *Inuyo kapena kokondedwa wanuyo alinso ndi wogonana naye wapadera?*		(1) No - **Mutually monogamous** – my partner and I have sex only with each other (2) Multiple partners – **I have sex with multiple people** (3) Multiple partners - **My partner has sex with multiple other people**, but I do not (4)Multiple partners – **Both me and my partner have sex with other people** (99)Do not know/Decline		
8a	**Is your partner planning on having more children in the future?** *Wokondedwa anuwo akuganiza zokhala ndi ana mtsogolo muno?*		NO (0) → 9	YES (1)	DO NOT KNOW (99)
	8b	**How many (more) children would your partner like to have in the future?** *Angati?*	|___|___| (0-30)		DO NOT KNOW (99)
	8c	**When do you think your partner would like to get pregnant in the future?** *Liti limene akufuna mutadzatenga mimba?*	(1) In less than 1 year (2) In 1-3 years (3) In 4 years or more years (99) Do not know/Decline		
9	**Do you currently live with your partner?** *Panopa mukukhala limodzi?*		NO (0)	YES (1)	DO NOT KNOW (99)
10	**Does your partner want you to use birth control?** *Wokondedwa anu angafune njira za kulera?*		NO (0)	YES (1)	DO NOT KNOW (99)
11	**Is your partner HIV positive?** *Ali ndi kachirombo ka HIV?*		NO (0)	YES (1)	DO NOT KNOW (99)
12	**Does your partner know that you are HIV positive?** *Nanga okondedwa anu akudziwa kuti muli ndi kachirombo?*		NO (0)	YES (1)	DO NOT KNOW (99)
13	**Have you ever used any form of birth control?** *Munagwiritsapo njira ina iliyonse ya kulera?*		NO (0) →16a	YES (1)	DO NOT KNOW (99)

Which contraceptive methods (birth control methods) have you ever used? *Ndi njira ziti za kulera zimene munagwiritsapo nchito* **(INTERVIEWER: READ EACH METHOD AND CIRCLE YES OR NO BASED ON HER ANSWER)**				
14a	**Oral Contraceptive Pills (The pill) -** *Njila ya mapilisi*	NO (0)	YES (1)	DO NOT KNOW (99)
14b	**Contraceptive Implant (Norplant) -** *Norplant*	NO (0)	YES (1)	DO NOT KNOW (99)
14c	**Male condoms-** *Makondomu a bamboo*	NO (0)	YES (1)	DO NOT KNOW (99)
14d	**Female condoms-** *Makondomu a mai*	NO (0)	YES (1)	DO NOT KNOW (99)
14e	**Surgical Sterilization with Vasectomy** *Kutseka kwa a bamboo*	NO (0)	YES (1)	DO NOT KNOW (99)
14f	**Surgical Sterilization with Tubal ligation (BTL)** *Kutseka kwa a Mai*	NO (0)	YES (1)	DO NOT KNOW (99)
14g	**Depo (DMPA or the Shot) -** *Njila yobaya*	NO (0)	YES (1)	DO NOT KNOW (99)
14h	**IUCD (the Loop) –** *Lupu*	NO (0)	YES (1)	DO NOT KNOW (99)
14i	**Emergency Contraception** *Njira yolera yoteteza mwadzidzidzi*	NO (0)	YES (1)	DO NOT KNOW (99)
14j	**Rhythm method / Natural family planning** *Kulera kwa chilengedwe*	NO (0)	YES (1)	DO NOT KNOW (99)
14k	**Withdrawal-** *Kuchotsa/pothira*	NO (0)	YES (1)	DO NOT KNOW (99)
14l	**Abstinence-** *Kudziletsa*	NO (0)	YES (1)	DO NOT KNOW (99)

15a	**Which method of birth control are you currently using or if you are not currently using birth control, what method did you LAST use?** *Mukugwiritsa nchito njira yiti yakulela? Ngati simukulera mudagwiritsako njira yanji m'mbuyomo?*	(1) Oral Contraceptive Pill (2) Depo Provera (The Shot, Depo, DMPA) (3) IUCD (Loop) (4) Contraceptive Implant (Norplant) (5) Male condoms (6) Female condoms (7) Rhythm method / Natural family planning (8) Withdrawal (9) Abstinence (10) Surgical sterilization – tubal ligation (11) Surgical sterilization – vasectomy (12) Other _____ (99) Do not know/Decline		
15b	**Are you currently using this birth control method?** *Mukugwiritsa nchito njirayi panopa?*	NO (0)	YES (1) → 16a	DO NOT KNOW (99)
15c	**What was the MAIN reason that you had stopped using your most recent form of birth control method?** *Chifukwa chiyani mudasiya kulera ndi njirayi?* **(ASK QUESTION AND CIRCLE ALL THAT APPLY BASED ON HER ANSWER)**	(1) I got pregnant (2) I wanted to get pregnant soon (3) I preferred a different method (4) I didn't like the changes in my body (5) I didn't like the changes in my period (6) It was difficult to get my method My partner did not want me to use it (7) I wasn't in a relationship/wasn't having sex (8) It was difficult to use (9) I forgot to use it (10) I was afraid that it will effect my fertility (11) I believed this method is was not safe (12) It was not convenient to use (13) My partner did not want me to use it (14) Other (specify): (99) Do not know/Decline		

INTERVIEWER: *Now I would like to ask you some questions about your periods (menses) about prior infections that you may have had in the past,* ***and*** *a couple more questions to ask you about recent sexual activity. There is no correct answer but it is important that you answer honestly.*

16a		**How frequently do you have your periods (menses)? Do you usually have one period every month?** *M'masamba kangati? Mmasamba kamodzi pa mwezi?*	NO (0)	YES (1) → 17a	DO NOT KNOW (99)
	16b	**Do you have MORE than one period every month?** *Kapena m'masamba koposa kamodzi pa mwezi?*	NO (0)	YES (1)	DO NOT KNOW (99)
	16c	**Do you have FEWER than every month, where you may have a month or several months without any periods?** *Kodi m'mapuma kapena kudumphitsa nsambo wanu?*	NO (0)	YES (1)	DO NOT KNOW (99)
17a		**Do you have normal flow during your periods (not light or heavy)** *Mumataya magazi kwambiri kapena pang'ono*	NO (0)	YES (1) →18	DO NOT KNOW (99)
	17b	**Are your periods light?** *Mumataya pang'ono?*	NO (0)	YES (1)	DO NOT KNOW (99)
	17c	**Are your periods heavy?** *Mumataya kwambiri?*	NO (0)	YES (1)	DO NOT KNOW (99)
18		**Do your periods last longer than 8 days?** *Mmasamba kopitilira masiku 8?*	NO (0)	YES (1)	DO NOT KNOW (99)
19		**Do you have bleeding between menstrual periods?** *Kodi mumasamba pakati pa mwezi?*	NO (0)	YES (1)	DO NOT KNOW (99)
20		**Do you have bleeding after intercourse (sex)?** *Kodi mumataya magazi mukamagonana ndi mwamuna?*	NO (0)	YES (1)	DO NOT KNOW (99)
21		**Do you have pain with your period?** *Mumamva kupweteka mukamasamba?*	NO (0)	YES (1)	DO NOT KNOW (99)
22		**Have you ever been treated for or been told that you had any of the following infections?** *Kodi munauzidwako kapena kudwalako matenda monga awa?*			
22a		**A sexually transmitted disease such as Gonorrhea or Chlamydia or abnormal vaginal discharge syndrome** *Chindoko / Chikhuthula / chikazi chachilendo*	NO (0)	YES (1)	DO NOT KNOW (99)
22b		**Pelvic Inflammatory disease** - *Kuphweteka m'munsi mwachinena*	NO (0)	YES (1)	DO NOT KNOW (99)
22c		**Genital Ulcers or Herpes-** *Zilonda za kumaliseche*	NO (0)	YES (1)	DO NOT KNOW (99)
22d		**Genital Warts or Condyloma** - *Njelewele za kumaliseche*	NO (0)	YES (1)	DO NOT KNOW (99)
22e		**Syphilis –** *Chinzonono*	NO (0)	YES (1)	DO NOT KNOW (99)
23		**Have you ever had a pelvic examination (this is an examination where a clinician uses a light and looks into your vagina)?** *Mudayezedwako ndi chitsulo kapena zala kunjira ya chibelekelo komanso kuunikidwa pogwiritsa ntchito tochi kapena getsi?*	NO (0)	YES (1)	DO NOT KNOW (99)

24	**During the past 12 months, approximately with how many people have you had vaginal intercourse?** *Mwagonana ndi anthu agati pa miyezi 12 yapitayi?*	|___|___|(0-30)		DO NOT KNOW (99)
25	**The last time you had vaginal intercourse did your partner use a condom?** *Kugonana kwanu komalizira munagwiritsa nchito kondomu?*	NO (0)	YES (1)	DO NOT KNOW (99)
26	**During the past 12 months how often did your partner(s) use condoms when having vaginal intercourse with you?** *Pa miyezi imeneyi munagwiritsa nchito kondomu kangati?*	(0) Never, none of the time (1) Sometimes, some of the time (2) Always, every time→ 28 (99) Do not know/Decline		
27	**There are many reasons why people may not use condoms. What was the reason or reasons your partner(s) did not use condoms every time you had vaginal intercourse since your last visit?** *Ndi chifukwa chiyani simunagwiritse ntchito kondomu kuchokera nthawi imene munabwera kuno ku chipatala?* ***(CIRCLE ALL THAT APPLY)***	(1) I did not feel comfortable asking my partner (2) I did not want to use a condom (3) I did not need protection from pregnancy (4) I did not need protection from HIV or STIs (5) I did not think condoms were effective against pregnancy (6) I did not think condom was effective against HIV or other STI (7) My partner(s) and I trust each other (8) Condoms are uncomfortable for me (9) Condom are uncomfortable for partner (10) My partner was drunk, could not use condom (11) My partner objected to condom (12) My partner has difficulty using a condom (13) I used another method instead (14) Condoms are too expensive (15) Did not have any condoms (16) We were caught up in the moment (17) Other (SPECIFY_____) (99) Do not know/Decline		
GO TO PHYSICAL EXAMINATION, RANDOMIZATION AND METHOD PLACEMENT				

PHYSICAL EXAM

VITALS/LABS			
28	Hemoglobin	_____.____g/dL	
29	Blood pressure	_____ / _____ Systolic/ Diastolic	
30	Temperature:	_____° Celsius	
31	CD4	_____	
EYES/SKIN			
32	Jaundice or Icterus	NO (0)	YES (1)
ABDOMEN			
33	Abdominal tenderness	NO (0)	YES (1)
34	Abdominal masses	NO (0)	YES (1)
35	Hepatosplenomegaly	NO (0)	YES (1)
VULVA			
36	Ulcers	NO (0)	YES (1)
37	Growths or Lesions	NO (0)	YES (1)
38	Irritation or redness	NO (0)	YES (1)
39	Swelling	NO (0)	YES (1)
40	Condyloma/Warts	NO (0)	YES (1)
VAGINA			
41	Ulcers	NO (0)	YES (1)
42	Lesions or Masses	NO (0)	YES (1)
43	Mucopurulent discharge	NO (0)	YES (1)
44	Irritation or redness	NO (0)	YES (1)
45	Condyloma/Warts	NO (0)	YES (1)
CERVIX			
46	Cervical motions tenderness	NO (0)	YES (1)
47	Erythema or petachia	NO (0)	YES (1)
48	Lesions or Masses	NO (0)	YES (1)
49	Mucopurulent discharge	NO (0)	YES (1)
50	Bleeding easily	NO (0)	YES (1)

UTERUS		
51	SIZE	____cm
52	POSITION:	(1) ANTEVERTED (2) MIDPOSITION (3) RETROVERTED

53	Fibroids	NO (0)	YES (1)
54	Uterine Tenderness	NO (0)	YES (1)
ADNEXA			
55	Adnexal Masses	NO (0)	YES (1)
56	Adnexal Tenderness	NO (0)	YES (1)
GROIN			
57	Enlarged/Tender lymph nodes >1 cm	NO (0)	YES (1)
ELIGIBLE FOR RANDOMIZATION (NO TO 58-63)			
58	Hypertension (>160/90)	NO (0)	YES (1)
59	Signs of liver disease	NO (0)	YES (1)
60	Signs of PID or cervicitis	NO (0)	YES (1)
61	Unexplained vaginal bleeding	NO (0)	YES (1)
62	Concern for cervical cancer	NO (0)	YES (1)
63	Any other medical reason to withhold DMPA or IUCD (Clinician/Nurse feels client is not suitable for participation—specify in notes)	NO (0)	YES (1)

IF ELIGIBLE: OPEN RANDOMIZATION ENVELOPE:

PLACE RANDOMIZATION STICKER HERE

GROUP: ☐**(1) IUCD** ☐**(2) DMPA**

Method placed by: _____

IUCD:

DIFFICULT IUCD PLACEMENT (0) NO (1) YES

UTERINE POSITION:

UTERINE SIZE (SOUND) _____ cm

STRING CUT TO _____ cm

IUCD LOT #: _____

DMPA

DIFFICULT INJECTION (0) NO (1) YES

LOCATION :

(RA) Right Arm (RB) Right Buttock

(LA) Left Arm (LB) Left Buttock

FOLLOW-UP VISIT: _____

English screening consent

Emory University School of Medicine Consent
Consent to be a Research Subject - SCREENING

Title: CID 0929 - Prospective Assessment of Acceptability and Adherence Associated with Use of the Copper Intrauterine Device (CuT380A-IUCD) compared to Depo-medroxyprogesterone acetate (DMPA) among HIV Positive Women in Lilongwe, Malawi

Protocol Number: CID 0929

Principal Investigators:
Dr Sam Phiri, PhD (UK), MSc (UK), Dip Clin Med (MW) (The Lighthouse Trust, Malawi)
Lisa Haddad, MD (USA; Emory University),Emory Department: Obstetrics and Gynecology

Co-Investigators: Mike Nyirenda, CO (The Lighthouse Trust; Malawi), Gift Kamanga CO, MSc (UNC project; Malawi) Chisale Mhango, MD. FRCOG (The Ministry of Health, Reproductive Health Unit; Malawi),

Funding Source and/or Sponsor: An anonymous foundation

Study Contact telephone number:
(+265) 8-88-892-523 (Malawi)
+1 (404) 778-1385 (USA)

Contact Email Address:
Sam Phiri: samphiri@lighthouse.org.mw
Lisa Haddad: lbhadda@emory.edu

Study Sponsor
This research is funded by an anonymous foundation that sponsors many studies in family planning. The researchers do not have a direct financial interest in the final results of the study.

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
Please carefully read this form or have it read to you

Please listen to the study doctor or study staff explain the study to you
Please ask questions about anything that is not clear
Feel free to take home an unsigned copy of this form and take your time to think about it and talk it over with family or friends

If you agree to join this research study, you will receive a copy of this consent form with your signature and the date, to keep. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. Nothing in this form can make you give up any legal rights. By signing this form you will not give up any legal rights.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or this health care center. If you are a patient with an illness, you do not have to be in the research study in order to get health care.

What is the purpose of this study?
We are talking to you today to see if you would like to join in a study about birth control. To be a part of this study we need to ask you some questions about your health history. If you answer all our questions and we think you would be a person to be part of our larger study we will explain the study to you. We will ask you to sign a second consent to be in the study.

How many subjects will participate in this study?
If you agree to join in the study, and we believe it is safe for you to be in the study, you will be one of more than 200 women in this research study.

How long will your participation last in this study?
This screening should take no more than 1 hour.

What will happen if you take part in the study?
You will be asked some questions about your health and your willingness to use different birth control methods. The total amount of time needed to answer these questions should not take more than 1 hour. We will also test your urine to see if you may be pregnant. After you complete these questions you may be asked to join the main study.

What are the possible risks or discomforts involved with being in this study?

You may be uncomfortable when we ask you personal questions. You do not need to answer every question. All interviews will be held in a private room. The information you share with study staff will be kept secret by study staff.

What are the possible benefits from being in this study?
You may or may not benefit personally from this screening study. By being in the screening study, you may help us learn about birth control methods that may be useful to women in Malawi.

Confidentiality
No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the Lighthouse Clinic and the UNC Project will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.
Records will be secured in locked file cabinets or in password protected files with access limited to researchers, collaborators or sponsors. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, we will take steps allowable by law to protect the privacy of personal information. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

If you agree to be in this study, a copy of this consent form will go in to your medical record.

Will you be paid for participating?
You will not be reimbursed for your participation in this study. Study visits should coincide with your routine clinic care visits. Snacks will be provided for you during your visit.

Will it cost you anything to participate?
There will be no costs to you for participating. Medications, care and examinations will be provided free of charge.

What will happen if you are injured by this research?
All types of research involve possible risk, some including the risk of personal injury. In spite of all precautions, you might develop complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment. Emory University, the UNC Project in Lilongwe, Malawi, and the University of North Carolina at Chapel Hill have not set aside funds to compensate you for any such complications or injuries, or for related medical care. However, by signing

this form, you do not waive any of your legal rights. The only exception to this policy is if it is proven that the negligence of an Emory employee directly caused your injury or illness. "Negligence" means the failure to follow a standard duty of care.
What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions, or if a research-related injury occurs, you should call Dr Sam Phiri at 08-88-892-523.

What if you have questions about your rights as a subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. This research has been reviewed and approved by the Emory Institutional Review Board, the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill and the Malawi National Health Sciences Research Committee. If you have any questions or concerns regarding your rights as a research subject, you may contact Dr. Charles Mwansambo, Chairman of National Health Sciences Research Committee at 08-88-826 946.
If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

Consent
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Name of Subject

Signature of Subject Date Time

Signature of Legally Authorized Representative (when applicable) Date Time

Authority of Legally Authorized Representative or Relationship to Subject
(when applicable)

Signature of Person Conducting Informed Consent Discussion Date Time

Consent Discussion (print)

Participant is literate ☐ illiterate ☐

Witness name, signature and date are required on this form only when the consenting participant is illiterate/not able to read.

_____
Participant name
(print)

Witness Name (print) Witness Signature Date
(As appropriate)

English Enrollment Consent

Emory University School of Medicine
Consent to be a Research Subject – ENROLLMENT

Title: CID 0929 - Prospective Assessment of Acceptability and Adherence Associated with Use of the Copper Intrauterine Device (CuT380A-IUCD) compared to Depo-medroxyprogesterone acetate (DMPA) among HIV Positive Women in Lilongwe, Malawi

Protocol Number: CID 0929

Principal Investigators:
Dr Sam Phiri, PhD (UK), MSc (UK), Dip Clin Med (MW) (The Lighthouse Trust, Malawi)
Lisa Haddad, MD (USA; Emory University),

Emory Department: Obstetrics and Gynecology

Co-Investigators: Mike Nyirenda, CO (The Lighthouse Trust; Malawi), Gift Kamanga CO, MSc (UNC project; Malawi) Chisale Mhango, MD. FRCOG (The Ministry of Health, Reproductive Health Unit; Malawi),

Funding Source and/or Sponsor: An anonymous foundation

Study Contact telephone number:
(+265) 8-88-892-523 (Malawi)
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Contact Email Address:
Sam Phiri: samphiri@lighthouse.org.mw
Lisa Haddad: lbhadda@emory.edu

Study Sponsor

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Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study

or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear
- Feel free to take home an unsigned copy of this form and take your time to think about it and talk it over with family or friends

If you agree to join this research study, you will receive a copy of this consent form with your signature and the date, to keep. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. Nothing in this form can make you give up any legal rights. By signing this form you will not give up any legal rights.

What are some general things you should know about research studies?

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or this health care center. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

What is the purpose of this study?

The purpose of this study is to better understand birth control options available to individuals who are HIV positive in Malawi. We are particularly interested in a method called the IUCD. IUCD stands for intrauterine contraceptive device. It is commonly known as a loop. The IUCD has been used throughout the world and is an effective method to prevent pregnancy. In Malawi, the IUCD is not widely used. We would like to see if the IUCD would be a good option for women at this clinic. The purpose of this research study is to learn about the experience of women who use the copper IUCD compared to women who use an injection called DMPA or Depo Provera for contraception. DMPA stands for Depot Medroxyprogestrone Acetate. We would like to see if both methods of birth control are accepted and tolerated.

If you agree to join this study, you will receive either the IUCD (Group 1) or DMPA (Group 2). This will be done by a random method (like flipping a coin). Neither you nor the study staff can choose which method you receive.

You have been invited to be in this study because you are HIV positive, do not currently want to get pregnant for at least 1 year, are safe to use the IUCD and DMPA, and agree to

IUCD placement or receiving DMPA injection. Your participation will not impact you HIV treatment or care.

What is the IUCD (the Loop) and how is it inserted?

The IUCD is a copper-releasing device that is placed in your uterus to prevent pregnancy for up to 10 years. It is made of white plastic in the shape of a 'T'. Copper is wrapped around the stem and the arms of the 'T'. Two white threads are attached to the stem of the 'T'. These threads are the only part of the IUCD that you can feel when the IUCD is in the uterus. The IUCD works by preventing sperm from reaching an egg. The IUCD is placed in your uterus during your clinic visit. A healthcare provider will first perform a pelvic exam to examine the position of your uterus. Next, he or she will cleanse your vagina and cervix, measure your uterus, and then slide a plastic tube containing the IUCD into your uterus. The tube is removed leaving the IUCD inside your uterus. Two white threads that extend into your vagina will then be trimmed. As the IUCD goes in, you may feel cramping or pinching. Some women feel nauseated or dizzy for a few minutes afterward

What is DMPA (the Shot) and how is it injected?

DMPA is a long-acting hormonal form of birth control. It contains medroxyprogesterone acetate, which is similar to the natural progesterone produced by the ovaries during the second half of the menstrual cycle. DMPA works because it prevents the release of an egg from the ovary. Because there is no egg there is nothing to be fertilized by the sperm and a pregnancy cannot occur. An injection (shot) is given in the buttock or upper arm muscle. Injections must be received on a regular basis every 12 weeks.

How many subjects will participate in this study?

If you decide to be in this study, you will be one of approximately 200 people.

How long will your participation last in this study?

Overall you will be enrolled in this study for 12 months after initiation. You will be seen today and then again in 4 weeks, 3 months, 6 months, 9 months and then one year from today. Each visit will take approximately 1 hour.

What will happen if you take part in the study?

If you agree to join this study, you will receive either the IUCD (Group 1) or DMPA (Group 2). This will be done by a random method (like flipping a coin). Neither you nor the study staff can choose which method you receive. You will then be asked several questions, have a brief physical exam including a pelvic exam, and have a blood test. The blood test will check your hemoglobin and your CD4 count. Then you will either have your IUCD placed (Group 1) or receive your injection of DMPA (Group 2). Male and female condoms will be provided to you at each visit.

This study will only follow you for 12 months, but if you receive the IUCD, you may continue to use the IUCD to protect you from pregnancy for up to 10 years. If you do not

get the IUCD placed during the study, the injection of DMPA will need to be injected every 3 months to protect you from pregnancy. After the 12-month study is complete, individuals who were receiving DMPA will have the option of having an IUD placed if desired.

When you return for each follow-up visit, you will have a pregnancy test, have a pelvic exam and complete a questionnaire about your experience using the birth control method you have been assigned. If you are in the DMPA group, you will receive a repeat injection every 3 months. You also will have a blood test today, at 6 months and at 1 year to check for low red blood cell count. This blood test will require less than 1 ml of blood, which is less than ½ a teaspoon of blood. We will also check your CD4 count today and at 1 year. This will be about 2 ml, which is less than 1 teaspoon of blood.

Additionally we may need to access your medical records at the Lighthouse Clinic for up to 1 year after you are enrolled in this study. This would be to get information such as your blood test results, if you have had any hospitalizations or complications, if you had your IUCD removed or if you become pregnant.

Are there any reasons you should not participate?

- You should not be in this study if
- You are pregnant
- You have given birth within the past 4 weeks
- You have any known abnormalities of your uterus
- You have a copper allergy
- You have had a prior reaction to Progesterone or DMPA
- You have a current gynecologic infection
- You have been on antiretroviral therapy for less than 6 months
- You have been treated for PID (pelvic inflammatory disease) in the last 6 months.
- You have a known genital cancer or pelvic tuberculosis
- You would like to be pregnant within 12 months
- You have not been stable on antiretroviral therapy for 6 months or more

What is the IUCD (the Loop) and how is it inserted?

The IUCD is a copper-releasing device that is placed in your uterus to prevent pregnancy for up to 10 years. It is made of white plastic in the shape of a ‘T’. Copper is wrapped around the stem and the arms of the ‘T’. Two white threads are attached to the stem of the ‘T’. These threads are the only part of the IUCD that you can feel when the IUCD is in the uterus. The IUCD is placed in your uterus during your clinic visit. A healthcare provider will first perform a pelvic exam to examine the position of your uterus. Next, he or she will cleanse your vagina and cervix, measure your uterus, anf then slide a plastic tube containing the IUCD into your uterus. The tube is removed leaving the IUCD inside your uterus. Two white threads that extend into your vagina will then be trimmed. As the

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What is DMPA (the Shot) and how is it injected?

DMPA is a long-acting hormonal form of birth control. It contains medroxyprogesterone acetate, which is similar to the natural progesterone produced by the ovaries during the second half of the menstrual cycle. DMPA works because it prevents the release of an egg from the ovary; thus there is nothing to be fertilized by the sperm and a pregnancy cannot occur. An injection (shot) is given in the buttock or upper arm muscle. Injections must be received on a regular basis every 12 weeks.

What are the possible risks or discomforts?

There may be side effects from the study drug that are not known at this time. Your health may or may not change as a result of your being in this study. The most common risks and discomforts expected in this study are:

General Potential Risks of study participation

- Irritation from blood tests at the collection site and a very small risk of infection exist.
- The risks associated with collection of sensitive data.
- Discomfort from physical and gynecologic examination

CuT380A-IUCD Specific Potential Risks:

- Pain during insertion: pain is typically mild and well tolerated
- Expulsion. A potential risk of participation in this study is the risk of expulsion of the IUCD and subsequent pregnancy.
- Uterine Infection after IUCD placement. The risk of infection is estimated to be less than 5/1000 and usually occurs within the first 21 days after insertion.
- Perforation of the uterus. In rare instances, a hole in the uterus may happen during IUCD insertion. This occurs in about 1/1000 insertions.
- Fainting or Lightheadedness: Occasionally, IUCD insertion can make you temporary feel lightheaded or nauseated
- Irregular Bleeding, Heavy Bleeding and/or Anemia. Occasionally IUCD use may cause heavy menstrual cramping and bleeding. It is possible that some women could develop anemia from its use.
- Failure of insertion. In rare cases, it is not possible to place the IUCD in the uterine cavity due to difficulty with insertion.
- Pregnancy. In rare cases pregnancy (6 per 1000 patients in 1 year) can occur when the IUCD is in place. In these cases there is a greater risk ectopic pregnancy (approximately 5% compared to 1%). An ectopic pregnancy can be life

threatening and must be treated immediately. In cases where there is a normal pregnancy, the IUCD should be removed.

DMPA Specific Potential Risks:

- Pain during injection
- Irregular bleeding: many women have some vaginal spotting or unpredictable bleeding after their first shot, but in most cases this decreases with each shot and eventually lots of women completely stop menstruating. (55% after one year). Most women start menstruating again 6-18 months after their last shot.
- Weight Gain: On average, 5 pound weight gain in 1st year of use, and an average of 13 lbs over 4 years.
- Allergic Reaction: Rare possibility of an allergic reaction following the injection.
- Delay in fertility: it may take up to 6-18 months to become pregnant after discontinuing injections
- Reversible bone loss – this will be a small decrease in bone mass that will return to normal after you stop the DMPA.
- Pregnancy: Risk of pregnancy for women who get their shots regularly (every 3 months or 13 weeks) is very low (3 in 1000 over 1 year).
- Mild Side effects: Mood changes, headaches, acne, hair loss, decreased sex drive, breast tenderness

What are the risks to a nursing child?

The IUCD should not affect your ability to breastfeed, or have any effect on the health, growth or development of your baby. With DMPA a very small number of women may make less milk, and some of the hormone in the IUCD may get into your milk and then be given to your baby. It is felt that this will not have any effect on the health, growth or development of your baby

If you become pregnant while being on the study:

- The intrauterine device should be taken out if pregnancy occurs with it in place.
- If you find out you are pregnant, or if you miss a period and think you may be pregnant, you should contact the study staff.

If your IUCD falls out:

- You could get pregnant right away.
- You should use another form of family planning right away (such as a condom).
- You should contact the study staff to talk about what to do for family planning.
- If you wish to have a new IUCD placed, this will be done by study staff and study participation will not be discontinued
- If you would like a different form of contraception, we will assist in helping you receive the method you choose.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it so you can decide if you

want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

What are the possible benefits?
This study is not designed to benefit you directly. This study is designed to learn more about the IUCD. The study results may be used to help other patients in the future. You will benefit from study participation by receiving effective contraception. Other possible benefits is knowing your CD4 count if not available and knowing you pregnancy status.

Will you be paid for participating?
You will not be reimbursed for your participation in this study. All study visits should coincide with your routine clinic care visits. Snacks will be provided for you during each visit.

If you choose not to participate, what other options do you have?
You do not have to participate in this research study in order to receive treatment at this clinic. You will still be seen in this clinic and receive the standard care for your illness or required service.

Confidentiality
No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC Project will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Records will be secured in locked file cabinets or in password protected files with access limited to researchers, collaborators or sponsors. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, we will take steps allowable by law to protect the privacy of personal information. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

The researchers will review the results of certain study tests and procedures only for the research. The researchers will not be looking at these results to make decisions about your personal health or treatment. Certain test results will be shared with your health care providers and included in your medical record. For this study, those things include: CD4 counts, pregnancy tests and blood test results.

To better protect the confidential nature of your research information, the other results from these study tests and questionnaires will not be included in any of your medical

record you have. These results will be placed in a research record. The researchers will take steps to make sure that these results are not placed in your medical record. The results will not be made available to any other healthcare providers who may be giving you treatment. It will be up to you to let your healthcare providers know that you are in a research study.
For safety reasons, however, some other basic information will be placed in your medical record:

- The fact that you are enrolled in a research study and you gave informed consent to join it
- Contact information for the researcher who is in charge of the study
- A description of health care that would be called for in case of medical problems you may have arising from the study; and
- A description of when and how health care providers may get research information, upon request, that they may need to give you medical care.
- We encourage you to let your health care provider know if you decide to take part in this study. That way they can have extra information that can help them to make decisions about your health care.

Will it cost you anything to participate?
There will be no costs to you for participating. Medications, care and examinations will be provided free of charge.

What will happen if you are injured by this research?
All types of research involve possible risk, some including the risk of personal injury. In spite of all precautions, you might develop complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment. Emory University, the UNC Project in Lilongwe, Malawi, and the University of North Carolina at Chapel Hill have not set aside funds to compensate you for any such complications or injuries, or for related medical care. However, by signing this form, you do not waive any of your legal rights. The only exception to this policy is if it is proven that the negligence of an Emory employee directly caused your injury or illness. "Negligence" means the failure to follow a standard duty of care.
What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions, or if a research-related injury occurs, you should call Dr Sam Phiri at 08-88-892-523.

What if you have questions about your rights as a subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. This research has been reviewed and approved by the Emory

Institutional Review Board, the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill and the Malawi National Health Sciences Research Committee. If you have any questions or concerns regarding your rights as a research subject, you may contact Dr. Charles Mwansambo, Chairman of National Health Sciences Research Committee at 08-88-826 946.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

Consent

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Name of Subject

Signature of Subject Date Time

Signature of Legally Authorized Representative (when applicable) Date Time

Authority of Legally Authorized Representative or Relationship to Subject (when applicable)

Signature of Person Conducting Informed Consent Discussion Date Time

Consent Discussion (print)

Participant is literate ☐ illiterate ☐

Witness name, signature and date are required on this form only when the consenting participant is illiterate/not able to read.

_____
Participant name
(print)

_____
_____ _____ _____
Witness Name (print) Witness Signature Date
(As appropriate)