KNOWLEDGE, ATTITUDE AND UPTAKE OF ANTIRETROVIRAL THERAPY FOR HIV PREVENTION AMONG DISCORDANT COUPLES: PUMWANI MATERNITY HOSPITAL COHORT

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Project proposal submitted in partial fulfillment of the requirement for the degree of Master of Science in Tropical and Infectious Diseases, University of Nairobi, Institute of Tropical and Infectious Diseases (UNITID).
DECLARATION
No portion of this work has been submitted in support of an application for a degree or qualification to this or any other University or institution of learning.

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DEDICATION
This work is dedicated to my dear husband Dr. Tonny K. Omwansa and our two sons Joshua and Paul. For your patience, love and prayers that carried me through the entire study period.

God bless you!
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I would like to thank God for His constant love and provision that has enabled me to complete the course.

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ABBREVIATIONS

AIDS - Acquired Immunodeficiency Syndrome
ARV - Antiretroviral drugs
ART - Antiretroviral therapy
CD4 - Cluster of differentiation 4 (Helper T cells)
FGD - Focus Group Discussion
HAART - Highly Active Antiretroviral Treatment
HIV - Human immunodeficiency virus
HPTN 052 - HIV Prevention Trials Network 052 study
KACP - Kenya AIDS Control Project
KAP - Knowledge, Attitudes and Practice
KAIS - Kenya AIDS Indicator Survey
PMTCT - Prevention of Mother To Child Transmission
PEP - Post Exposure Prophylaxis
PreP - Pre-Exposure Prophylaxis
TaSP - Treatment as Prevention
SMS - Short Message Services
UNITID - University of Nairobi (Institute of Tropical and Infectious Diseases)
UON - University of Nairobi
VCT - Voluntary Counselling and Testing
WHO - World Health Organisation
ABSTRACT

**Background:** The consistent use of a combination of antiretroviral drugs referred to as Highly Active Antiretroviral Therapy (HAART) has been shown to reduce the viral load in body fluids especially in blood and genital secretions. This has great implications as the HIV virus is spread mainly through sexual contacts. In discordant couples where one partner is HIV seropositive, the HIV negative partner is constantly exposed through sex and hence at a high risk of HIV acquisition. However, early initiation of HAART on the HIV infected partner could be beneficial to the HIV negative individual in the discordant relationship. This could be achieved through the adoption of Treatment as prevention (TaSP), a strategy whose aim is to initiate use of antiretroviral drugs as early as possible regardless of the CD4+ count. This concept aims at treating the HIV positive partner at the point of diagnosis regardless of the disease stage.

**Objectives:** The objective of this study was to assess the knowledge, attitudes and practices regarding the uptake of treatment as prevention in a cohort of discordant couples. The study sought to examine the participants knowledge in terms of HIV transmission methods and HIV preventive measures. We also assessed the couples attitudes towards high risk behaviours, determined their sexual practices and finally the reasons for/ or against the use of antiretrovirals for HIV prevention.

**Methodology:** This was a cross sectional study that focussed on the knowledge, attitudes and practices among the discordant couples enrolled at the Pumwani cohort, Nairobi. Standardized questionnaires were used to collect data from the Pumwani discordant couples cohort until the sample size for the study was reached. Focus group discussions were also utilized to gather qualitative information on use of HAART for treatment as prevention from randomly selected discordant couples.

Collected data was then entered into a secured database, cleaned and then exported into SPSS Version 2.0 for analysis.

**Results:** A total of 338 participants who were in a discordant relationship were enrolled into the study. Most of the participants, 320 (95.2%) knew about the availability of antiretroviral drugs while 16 (4.8%) had not heard of them. However, only 94(27.7%) could correctly name an antiretroviral drug. Majority of them, about 245(72.27%) could not name any drug. About 119 (40.9%) of them reported 350 CD4+ cells/ml as the best level to initiate
Most of the respondents 291 (87.4%) reported antiretroviral drugs as being safe for use but 136 (40.2%) of the participants noted that the drugs had intolerable side effects. Majority 289 (87%) of them affirmed that they would be able to use the drugs regularly and consistently. More than half of the respondents, 192 (56.8%) had not heard of the treatment as prevention therapy while 178 (54.4%) had not heard of the pre-exposure prophylaxis. Interestingly, 175 (53.2%) knew about Post Exposure Prophylaxis therapy. Majority of the respondents, 289 (85.5%) reported that they would use the drugs for Treatment as Prevention if initiated on treatment.

Conclusion: Majority of discordant couples in this study knew about the existence of antiretrovirals though only a few of them were able to name the specific drugs. However, less than half knew about Treatment as Prevention concept and this could explain the poor uptake of this HIV prevention strategy at the Pumwani and Baba Dogo health facilities. Besides, majority of those in discordant relationship did not perceive themselves at high risk of HIV acquisition. Greater efforts should therefore be put into education on HIV risk perception in addition to demand creation for treatment as prevention as a novel strategy and a priority among discordant couples.
1.0 BACKGROUND

Human immunodeficiency virus (HIV) is the virus that causes Acquired Immunodeficiency Syndrome (AIDS). Very little information was known about the virus regarding transmission, presentation, prevention and treatment in the early 80s, but this has changed over the years. The various transmission methods were later defined as sexual, vertical, and through contaminated body fluids and possibly surgical instruments before the beginning of the 90s. The main transmission method has been sexual and the interactions could either be heterosexual, homosexual or bisexual contacts. Heterosexual transmission among couples within a union has been noted to account for 44.1% of new HIV infections in Kenya.\(^1\)

The HIV is known to strip the body of the immune defences leaving the patient exposed to opportunistic infections. This is because the virus attacks the body's immune system, especially targeting the Cluster of differentiation 4 (CD4+) cells. As the viral load increases in number, the CD4+ cells decreases over time. This compromises the body's ability to fight simple infections and the body becomes prone to organisms that would otherwise not cause disease. During the early periods after the discovery of the HIV, morbidity and mortality rates were high. Opportunistic infections were rampant due to the depleted immune system that would leave the body further weakened hence the high mortality rates. The HIV positive patient also had reduced quality of life due to the increased morbidity.

Globally, there are about 35 million people currently living with HIV.\(^2\) The disease is widespread and is found mainly among the heterosexual, homosexuals and bisexual populations. Sexual transmission of HIV-1 from infected persons to their partners is strongly correlated with concentrations of HIV-1 in blood and genital tract.\(^3\) Studies have shown that high rates of HIV-1 transmission occur between HIV-discordant partners who are often in unstable relationships but unaware of both partner's HIV-1 serostatus due to the constant exposure.\(^4\) According to the Kenya AIDS Indicator survey 2012, 6% of all married or cohabiting couples in Kenya are considered to be discordant. This corresponds to about 260,000 couples nationwide.\(^5\) The HIV prevention options currently available to this vulnerable group include voluntary testing and counseling, advocacy for correct and consistent condom use, reduction in number of sexual partners, male circumcision, use of post exposure prophylaxis (PEP), reduction of alcohol intake, early treatment of sexually transmitted diseases, the choice to be faithful to one HIV free partner and use of HAART as treatment for prevention.
The use of combination Antiretroviral therapy has improved the survival rate of HIV-1 infected persons by reducing the replication of the human immunodeficiency virus.\(^\text{(6)}\) Combination antiretroviral therapy has also been shown to reduce the level of HIV-1 in genital secretions.\(^\text{(7)}\) This means that the infected persons on ART are increasingly able to lead normal lives, including having safer intimate relations with their partners. However, higher viral loads in the infected partner essentially means higher risk of transmission. Therefore maintaining viral loads at undetectable levels in the HIV positive partner is an important management goal besides being protective to the seronegative partner. This is especially true in discordant couples where this protective result has been confirmed in several recent studies.

Highly Active Antiretroviral therapy (HAART) utilizes multiple drugs that act on different viral targets that act maximally to stop the multiplication, progression of HIV disease and/or transmission. The synergistic effect decreases the patients total burden of HIV, maintaining the patients immune system function and prevent opportunistic infections that lead to death. Therefore, CD4+ cell count is an important immunological marker on when to start the beneficial HAART. The WHO standard guidelines now recommend initiation of HAART at CD4+ levels of 500c/ml but the adoption of this new cut off point has been slow in many countries.\(^\text{(8)}\) In addition, treatment as prevention concept has also been demonstrated in recent studies to have major benefits among HIV infected patients when Antiretroviral drugs are initiated as soon as the virus is detected despite the CD4 counts.

A clinical study, the HIV Prevention Trials Network 052 (HPTN 052) study was carried out in various countries among discordant couples. The couples were divided into two groups, one that had early initiation of Antiretroviral Therapy and the other that had delayed initiation of treatment. In the end, the HPTN 052 study showed a relative reduction of 96% in the total number of HIV-1 transmissions resulting from the early initiation of antiretroviral therapy.\(^\text{(9)}\) The clinical study also showed a marked reduction in the HIV transmission rates to the uninfected partner and proved the benefits of early antiretroviral therapy initiation among the discordant couples. Hence, this new intervention combined with all the other available preventive measures if widely availed as part of the prevention package could significantly reduce the transmission dynamics of the HIV disease among the discordant couples.
2.0 LITERATURE REVIEW

2.1 Introduction

2.1.1 The HIV and AIDS virus
The AIDS virus was discovered in the early 1980, among the homosexual community. These men presented to the medical facilities with similar symptoms of immunosuppression in a backdrop of opportunistic infections. The HIV virus was later discovered as the causative agent of the immunosuppressive condition. To this day, HIV/AIDS continues to be a significant global health problem. A lot of studies have been conducted in the treatment and management of the disease but the ability of the HIV to mutate makes the search for a cure elusive.

HIV infection in the sub-Saharan region is shadowed by a background of poverty and lack of resources. Patients in this developing areas are faced with higher rates of opportunistic infections. The general environment is characterized by exposure to opportunistic infections due to overcrowding, poor disposal of waste products, inadequate access to healthcare and high poverty rates. Thus, individuals infected with the HIV virus in our settings have higher rates of infection with tuberculosis, bacterial infections and diarrheal diseases as compared to those from the west. In developed countries, these diseases are increasingly classified as non-severe events even when they are AIDS defining illnesses. There are studies that show that HIV progression is more rapid in the developing areas due to the high rates of endemic diseases that generate immune activation and activate rapid progression of the disease. This difference could also be related to the late presentation of the patients to the medical facilities in addition to the inadequate health facilities that compromises the quality of care. These facilities may have poor diagnostic equipments and inadequate drug stocks. Trained health workers may also be lacking due to poor remuneration. This factors all work together to increase the mortality rates in the patients who are HIV infected. The introduction of Antiretroviral therapy coupled with proper patient education in programmes that have adequate follow up and surveillance mechanisms have greatly reduced the mortality and morbidity levels.

2.1.2 Prevention strategies
Various intervention combinations have been initiated to prevent disease transmission among the discordant couples. The most important is the creation of awareness and knowledge on the disease status. This portal, commonly referred to as Voluntary Counselling and Testing (VCT) in Kenya encourages individuals to go for HIV testing voluntarily. Voluntary counseling and testing centers provide basic information on the HIV disease, transmission, role of viral load,
CD4+ counts and the available treatment options. These centers also offer knowledge on HIV transmission and prevention. Counsellors also discuss the advantages of using condoms (both the male and female condoms). Safer sexual practices and mutual masturbation methods are also explored. Living positively with the HIV/AIDS virus is addressed and couples are usually encouraged to go for counselling and testing together. If the results are found to be discordant, the couple is then offered additional support services. When assessing the effectiveness of HIV prevention interventions in the developing countries, Voluntary Counselling and Testing (VCT) was found to be the most effective tool when directed at the discordant couples. For example, less than 30% of couples reported current condom use during intercourse prior to VCT exposure. In the year after, the rate of condom use had risen to over 80%. This wholesome approach to the HIV/AIDS testing and follow up techniques give the discordant couples the strength and will to stay together as a couple despite the challenges faced.

Other preventive methods include the proper and consistent use of condoms, circumcision and being faithful to one partner. Prompt treatment of sexually transmitted diseases also serves to reduce HIV transmission rates. Drug and alcohol abuse is also addressed as it causes disinhibition that can lead to harmful behaviour that increases transmission. The use of Antiretrovirals irrespective of the CD4+ cell counts among the discordant couples is also being promoted since has been shown to be beneficial in the control and reduction of morbidity and mortality rates among the infected.

The use of some microbicides, PreExposure Prophylaxis (PrEP), the Prevention of Mother to Child Transmission (PMTCT) and Treatment as Prevention (TaSP) are all programmes that lower rates of transmission through the use of the antiretroviral drugs. The observed reduction of HIV transmission is multifactorial and the idea is to continue tackling prevention from several fronts. The use of HAART has been found to be advantageous especially when used together with the other prevention methods and is currently being aggressively promoted by all HIV prevention stakeholders.

2.1.3 The role of Highly Active Antiretroviral Therapy (HAART) in stemming the tide cannot be underestimated.

The introduction of potent combination antiretroviral therapy in 1996 and the public health approach to HIV treatment in resource-limited settings in 2002 have changed the course of the epidemic. There are assorted programmes that have now been designed that use the Antiretroviral drugs in order to reduce the chances of HIV transmission. Post Exposure
Prophylaxis (PEP) uses short term Antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure. This could be occupational or sexual exposure. On the other hand Pre Exposure Prophylaxis (PreP) programs supports the daily use of antiretrovirals in HIV uninfected people who engage themselves in high risk sexual behaviors to block acquisition of HIV infection. This is especially true among discordant couples who may include men who have sex with men, transgender women and those amongst them who have sex with men. Treatment as Prevention (TasP) on the other hand is HIV prevention method that uses ART in the HIV positive persons living in a discordant relationship to decrease the chances of HIV transmission independent of CD4+ cell count. All this are various ways in which the use of antiretroviral therapy is helping to curb the spread of HIV and AIDS. A study carried out in 2011 showed a relative reduction of 41% of clinical events in HIV-1 infected persons if initiated early on antiretroviral therapy. This suggests that clinical benefit exists for initiation of antiretroviral therapy when a person has a CD4+ count of 350-550 cells per cubic millimetre as compared with therapy that is delayed until the CD4+ counts fall to the range of 200-250 cells per cubic millimetre. Also viral load is now confirmed to be the greatest risk factor for HIV transmission. Lowering of viral loads is critical in interrupting transmission and has also significant effects on morbidity and mortality. Antiretroviral drugs have basically changed the perception of HIV disease especially in the West from a fatal condition to one that can be managed effectively.

2.1.4 HAART uptake and compliance
The goal of HAART is to achieve maximal and durable suppression of viral replication. Adherence plays a very important role in the success of these drugs and there is a significant association between adherence and virologic suppression in the treatment of HIV infection. Once initiated, ART should never be stopped. The selection pressure of incomplete suppression of viral replication in the presence of drug therapy causes the drug sensitive strains to be selectively inhibited. This allows the drug resistant strains to become dominant and hence the importance of adherence to the prescribed regimen. Early drug initiation is known to expose the patient to adverse drug reactions and side effects and therefore a high risk of poor adherence. In resource limited areas like India, Sub-Saharan Africa etc, failure in HIV treatment is due to either drug intolerance or adverse drug reactions. About 84% of HIV patients discontinue their initial HAART within the first 8 months of therapy due to adverse drug reactions that lead to non-compliance. In addition, the patient’s status is revealed to the health workers and to family members. This may act as a barrier to compliance due to the stigma
associated with the disease. Despite these challenges, there are potential benefits with the adoption and scaling up of TaSP programme.

2.1.5 Discordant couples and their challenges
The fight against the HIV disease initially focused on the HIV negative population. Research later showed that interventions focused on the HIV positive individuals reduced high risk behaviors. A substantial proportion of HIV-1 infected individuals in Sub-Saharan Africa are in stable relationships with HIV-1 uninfected partners, and HIV-1 serodiscordant couples thus represent an important target population for HIV-1 prevention. Having unprotected sex has been identified as one of the most important risk factors for transmission in the population.

The risk of transmission through unprotected sex differs depending on which partner is infected, because receptive intercourse carries a higher risk per exposure than does insertive intercourse. It has been estimated that the female partner of an HIV-positive man has a 0.1 to 0.2% risk of becoming infected with HIV as a consequence of a single act of unprotected intercourse. The discordant couples therefore need a lot of follow up as one of the partners is constantly exposed.

It has been found that most new infections in Sub-Saharan Africa now occur in married and cohabiting couples, many of whom do not realize that one of them is infected with HIV.

The discordant couples are a special group that have normal needs and wants. They desire frequent intimate contacts and have a need for children despite one of the partners being HIV seropositive. The latter coupled with the fear that disclosure of HIV positive status to an HIV negative spouse could result in abandonment, divorce or violence against the woman whether she was positive or negative complicates issues. However, pregnancy rates similar to those of the general population continue to be recorded among HIV discordant couples.

Consequently, contraceptive services that are socially and more economically accessible to couples should also target the discordant couples who face challenges of achieving fertility desires while also managing the risk for infection. This puts the seronegative partner at a high risk of acquiring the disease due to the constant exposure. It is estimated that the HIV negative individuals living in stable HIV discordant partnerships are twice as likely to get infected with HIV as those living in concordant HIV negative relationships.

2.1.6 Antiretroviral therapy for HIV prevention
Antiretroviral drugs are used universally in the management of HIV/AIDS and are used to decrease the viral load of the patient. The use of Antiretroviral drugs for HIV patients has shifted the perception of HIV/AIDS from a fatal condition to a chronic yet manageable
infection. It is also an accepted fact that integrated programs could work better to reduce HIV transmission rates in Africa (27). A study was carried out in Nairobi that assessed the barriers to ARV initiation. The study showed that despite the access to regular healthcare, referrals to treatment centres and free access to ART, over 30% of participants with CD4 counts levels that had surpassed the cutoff point had not started ART within one year (28). This study also showed that only about 60% of eligible discordant couples in Nairobi are on ART, thus missing the benefits of the intervention. ART work best if used together with counselling, reduction of high risk behaviours, condom use and other preventive measures. ART acts by reducing the viral loads, reducing mortality, opportunistic infections and maintaining immune function (29). In order to maintain the quality of life in the HIV positive patient, the viral loads should be undetectable at 400 copies/ml (30). Consensus statement on behalf of Swiss Federation Commission for HIV and AIDS suggests that people receiving effective Antiretroviral therapy and have undetectable plasma HIV RNA of below 40 copies/ml are sexually non infectious (31).

However, antiretroviral therapy use has introduced the risk of disinhibition and risk compesation. This theory states that with the reduction of transmission rates, the general population will engage in risky behaviour that supports the spread of the virus (8). Use of ART and poor adherence also introduces an aspect of drug resistance that could affects the patients quality of life in the long term (32). The possibility of adverse side effects may affect the actual uptake of the ART regimen and selection of combinations that are easy to administer and less toxic are important aspects in persons who are asymptomatic.

Monitoring of the ART drug resistance patterns should be scaled up as this has the potential of reducing the efficacy of standard treatment regimes that are used in large populations. The drug resistance patterns are very important due to the limited availability of alternative ART regimens. Human rights and the ethical implication of treating persons who may not be a priority could also arise. Of the 34 million people living with the HIV virus in Sub-Saharan Africa, only 47% are on treatment. About 7.5 million still need treatment (8). The resource rich settings have the high risk groups such as discordant couples on treatment at CD4 levels of above 350 cells/mm3. Hence, denying access to the TaSP programme for all those who qualify in resource poor settings could raise several ethical concerns. Despite all noted challenges, TaSP programme has benefits that far outweigh all potential disadvantages.
2.2 Justification and Rationale
Finding a cure for the HIV/AIDS virus has been an elusive chase as the virus mutates rapidly. The fight against the disease has now shifted from curative to preventive measures. There is more emphasis on abstinence, condom use, prompt treatment of sexually transmitted diseases, being faithful when in a relationship and avoiding risky behaviours. Discordant couples however face quite a unique scenario as one partner is seropositive and the other is negative. The negative partner is therefore constantly exposed to the infection if no condoms are used. Various programmes have been initiated that target this special group. These programmes counsel on use of condoms, risk reduction, advantages of circumcision, importance of HIV management, antenatal and postnatal programmes and safe delivery options for HIV infected women but these options are not easy to follow. Also, those affected are also advised to avoid risky behaviour such as having multiple partners, alcohol use and injection drug use. Most importantly, they are advised on the advantages of the antiretroviral treatment regime that boosts their immunity and keeps away opportunistic infections.

Despite the availability of all these prevention options, discordant couples live in the real world and do not always use the recommended preventive measures such as condoms every time they have intimate contact. Hence, the risk of the HIV negative partner being infected if the positive partner has a high viral load is real. Thus, treatment as prevention, a strategy that aims at initiating antiretroviral treatment on the infected partner as soon as one is found to be positive would be a game changer. Interestingly, as community mobilization to encourage couples to be tested for HIV-1 are being scaled up, the uptake of the ART as a prevention strategy will unfortunately depend on several individual and environmental factors. The individuals knowledge, perception of the ARTs and the prevailing stigma to those taking the drugs within the community will have a great impact on acceptability of the program. This cross-sectional study attempted to gather the required evidence that could help better prepare the prioritization of prevention of HIV-1 among discordant couples in the country. We believe that programmes that are tailor made to meet the needs of the discordant couples are likely to have a better chance of success and ultimately a greater impact.
2.3 Significance of the Research

We believe that the proposed research study addressed an extremely important area in HIV prevention research that is not currently well understood. Our findings have the potential to contribute substantially to the scientific understanding of HIV risks and vulnerability among discordant couples. A better understanding of their knowledge, risk taking behaviors and challenges in adopting HIV treatment as prevention is key. We trust that the results of this study have a broad local and regional application.

2.4 Study Objectives

2.4.1 Broad objective
To determine the knowledge, attitude and uptake of Antiretroviral therapy for HIV prevention among discordant couples enrolled in a HIV prevention program

2.4.2 Specific objectives
1. To determine the knowledge of HIV infection, transmission, prevention strategies, management issues and antiretroviral therapy in general among the discordant couples enrolled in the program.

2. To evaluate their attitudes towards the use of Antiretroviral therapy for HIV prevention.

3. To assess the uptake and/or barriers of Antiretroviral therapy among the discordant couples for HIV prevention.
3.0 METHODOLOGY

3.1 Study Design
The study was a cross sectional survey and respondents were identified from an existing database and invited to participate in the study after informed consent. Recruitment of eligible participants remained open until the required sample size was reached. In addition no follow up visits were required. Research assistants were recruited and trained with regards to the background, rationale, research protocol and data collection tools (participant information sheet, informed consent and questionnaire). Data was then collected during working hours. Targetted discordant couples were sensitized through health information sessions at the facilities, phone calls and written methods in order to enhance their rates of participation.

Two sets of data were collected. The first database comprised of the quantitative variables obtained through a standardized questionnaire while qualitative data was obtained through focus group discussions.

3.2 Study Area
The Pumwani Maternity Hospital has a HIV comprehensive care center managed by the University of Manitoba program and actively identifies discordant couples as part of the borader HIV prevention strategy. The discordant couples cohort was established in 2009 under the prevention with positives (PWP) initiative supported by NASCOP- MOH. These couples are recruited from the Pumwani and Baba dogo comprehensive care centres where index clients enrolled in the HIV care program are encouraged to bring their spouses for HIV counseling and testing under the prevention with the positive (PWP) platform. The cohort had 468 registered discordant couples by Sept 30th 2013 who attend facilitated support groups meetings at least once a month. These couples also receive ongoing prevention and medical care, free medical supplies, counselling opportunities and could access ART for treatment and prevention.

3.3 Study population
The study involved serodiscordant couples, where one partner is HIV positive, have disclosed HIV status to each other and registered at the Pumwani hospital comprehensive care center for services and follow-up.
The Pumwani discordant couples cohort have regular support group meetings every (third Saturday) month and any opportunity to sensitize them about the study was utilized. During these support groups all present were invited to participate in the study after their questions and concerns were addressed. After eligibility was determined, study participants were all required to provide written informed consent before questionnaire administration and/or participation in the focus group discussions. No biological samples were collected.

*Inclusion criteria*

The respondents who participated in the study met the following criteria:

- Over 18 years old
- Heterosexual
- In a discordant relationship
- Had disclosed their HIV status
- Gave informed consent.

*Exclusion criteria*

Those excluded from the study were:

- Under 18 years of age.
- Not in a HIV discordant relationship
- Those who had not disclosed their HIV status
- Not willing to give informed consent.

**3.4 Sample size**

The required sample size was calculated using the following formula:

\[ n = z^2 p (1 - p) / e^2 \]

Where:

\[ p = 60\% \]
Expected prevalence or proportion of discordant couples on ART treatment in Kenya. About 60% of discordant couples in Kenya who had met cut off CD4 levels for initiation had started treatment as per KAIS 2012.

\[ e = 5\% \]

Degree of precision or a tolerance error margin or width of the confidence interval (a measure precision of the estimate).

To obtain a narrower CI, we need to design a study with a smaller \( e \) (good precision or smaller error of estimate).

\[ z = Z \text{ statistic for a level of confidence or is the normal distribution critical value for a probability of } \alpha \text{/2 in each tail.} \]

For a 95% CI, \( z = 1.96 \).

The formula above assumes purposive sampling and that the sample size is small relative to the population size.

Using \( p \) as the prevalence of ART use among discordant couples at 60%.

\[ z = 1.96 \text{ using 95\% confidence interval} \]

\[ e = 5\% \]

The sample size required for this study is:

\[ 1.96^2 \times 0.66(1 - 0.66) / 0.05^2 \approx 345 \]

\[ n \approx 345 \]

Therefore, at least 345 discordant couples were to be interviewed for this study.

3.5 Sampling

The study targeted all discordant couples enrolled at the Pumwani hospital based cohort willing to give informed consent. There are about 468 registered discordant couples who are currently on follow up who access services at both the Baba Dogo ART clinic and the Pumwani Hospital HIV comprehensive care center. Simple random sampling of the discordant couples using the
existing cohort list was done, where each couple was assigned a random number. These numbers were then pooled and selection conducted randomly until required sample size was reached. All discordant couples whose numbers were picked were invited to participate in the study. The couples who confirmed their interest in the study were allocated interview dates. Short text messages were then sent out to these couples as reminders to avail themselves for the interviews. On the interview date, each couple got two questionnaires, one for each partner. They were then separated and directed to different rooms where each responded to the questions privately. Each couples' questionnaires were then matched/linked after collection and, every tenth discordant couple were invited to participate in the focus group discussions at a later date. A total of three focus group discussions were conducted.

3.6 Study instrument
A standardized questionnaire was administered to each of the clients after informed consent and then linked. Three Focus group discussion targeting about 10% of the interviewed couples were then carried out to assess the group dynamics on their knowledge of HIV, ART and prevention issues, uptake of ART, practices and attitude towards HIV prevention issues and treatment as prevention (TasP) strategy.

3.7 Recruitment and consent procedures
Study participants were recruited from the Pumwani hospital discordant couples cohort. Eligible patients visiting the centre during working hours were informed and/or reminded of the study through short text messages by the research assistants who were nurses working at both Pumwani and Baba Dogo ART clinics. Discordant couples who were interested in participating in the study were then led into a private consultation room for more information. Study participants were also taken through the consent documents and only asked to join when they had fully understood details of the study. Study participation was voluntary and only those meeting the selection criteria signed the consent forms for enrollment into the study. The research assistants then proceeded to administer the questionnaire. Each participant was assisted to complete their own questionnaire that was assigned a unique number. However, couples had numbers that assisted in linking the two. Every 10th discordant couple was then requested to sign up for one of the three planned focus group discussions. These discussions were conducted by a trained facilitator and helped to gain a deeper understanding of the issues that face the discordant couples as they deal with HIV infection, prevention, ART and management issues.
3.8 Focus group discussions

Focus group discussions were platforms that allowed for free interaction where some of the ideas and aspects that were missing from the questionnaire were picked up. After filling in the questionnaires, every tenth couple was requested to join the focus group discussions. This represented about 10% of all the couples interviewed. There were about 10-12 participants in each FGD. About three FGD sessions were carried out and facilitators used the FGD guide that is appended to this document. The sessions were recorded by an audio recorder and were carried out in the afternoon and took about 1-2 hours each.

3.9 Data Management

The following are the elements of the data management process for the study.

Data Entry/Analysis

Data from the questionnaires was entered by the principal investigator and one data clerk into Microsoft Access Office Database. In addition, key themes from the focus group discussions were summarized by the research team. After completion of the data collection, the data was cleaned before being exported into SPSS for analysis.

Data analysis

The study generated quantitative and qualitative data. Proportions were determined as regards discordant couple’s knowledge, attitudes and practices towards the treatment as prevention programme. The quantitative data was collected mainly through questionnaires. It was entered and themes, relationships and correlations sought. SPSS version 20 (SPSS Chicago Illinois, USA) was used to analyse the qualitative data derived from the study. This was summarized and presented as mean, mode and median figures. The qualitative data was analyzed for relationships, themes as well as contradictions. This was summarised and presented in tabular or pictorial forms.

3.10 Ethical Consideration

Ethical approval for the study was obtained from the Kenyatta National Hospital/University Of Nairobi Ethics and Research Committee. Consent forms were signed individually after the eligible partners had fully understood the study, their rights and roles within the study. Confidentiality of patients was assured through the use of study unique numbers. Patients who
declined to join the study were assured of their right to continued care with no penalties. Their decision to decline to participation was also maintained as confidential information.

There was minimal risks for those participating in the study as confidentiality was maintained. However, there was minimal risk of disclosure to the other clients using the comprehensive care center as discordant couples.

Those participating in the study were given Ksh 200 each as transport reimbursement.
4.0 RESULTS

4.1 Socio-demographic characteristics of the participants

A total of 338 participants who were in a discordant relationship were enrolled into the study. They were recruited from Baba Dogo health clinic and the Pumwani Hospital site that contribute members to the Pumwani discordant couple cohort. Fewer men 145 (42.9%) were interviewed as compared to 193 (57.1%) of the women. The median age of the respondents was 35 years. The men were on average older than the women as the median age for the men was 39 years and for the females was 32 years. About 262 (77.5%) of them had the husband being older than the wife while 21(6.2%) had the wife being older. 13(3.8%) couples had the same age. 42(12.4%) of the respondents did not respond to the question

Of the participants interviewed, 140(41.5%) were earning less than 1,000 shillings in a month, 144(42.7%) between 1,000 to 10,000 shillings. About 32(9.5%) earned 10,000 to 20,000 shillings while 12(3.6%) earned about 20,000 to 30,000 shillings in a month. Less than 10(2.7%) of the population had an income of more than 30,000 shillings in a month.

Figure 4.1 shows the income distribution of the participants enrolled in the study.

**Figure 4.1 Income distribution of the participants enrolled in the study in Kenya Shillings**
Majority of those who participated were literate. About half of them 160 (47.5%) had received primary education, 116 (34.4%) had studied up to secondary school level, 49 (14.5%) had reached college and only 2 (0.6%) attained university education. About 10 (3%) did not receive any formal education.

Most of the respondents, 139 (41.2%) were living as married. Out of the sampled population, 123 (36.5%) had done a traditional wedding. Those who did a formal church based wedding were 51 (15.1%) while 20 (5.9%) were single but committed to the relationship. About 4(1.2%) of the participants were either bereaved or separated. Among those who were interviewed, 100 (29.9%) had been married for 6 to 10 years. There were 99 (29.6%) who had been married for 1 to 5 years, 57 (17.1%) for 11 to 15 years and another 17.1% for over 15 years. Those who had been married for less than a year were 21 (6.3%). Most of the respondents, 133 (39.7%) were self-employed, while 86 (25.7%) were in salaried employment. A total of 76 (22.7%) earned a living as casual laborers and 40 (11.9%) were involved in other forms of sustenance.

4.2 The most common HIV/AIDS transmission methods according to the discordant couples.

As regards the most common method of HIV transmission, 332 (98.8%) participants chose sexual contact as the most common method. A total of 269 (80.1%) chose needles and sharps, 227 (67.6%) chose blood transfusion, 174(51.8%) chose 'Mother to Child Transmission' while 19(5.7%) chose utensils as a method of transmission.

4.2.1 The period of time the positive partners had known their HIV/AIDS status and the time it took to disclose the status to the spouse

About half of the respondents (52.3%) had known their status for more than 4 years, 32.2% for the past 1 to 4 years, while 7.9% for the past 6 months to 1 year. A further 25 (7.6%) had known their status for less than 6 months. Most of the participants, 143(46.3%) had known their partners status for the past 4 years, 103(33.3%) for the past 1 to 4 years while 34 (11%) for the past 6 months to 1 year. Only 27 (8.7%) had known their partners status for less than 6 months. In terms of disclosure, majority 280(89.2%) disclosed in under 6 months. 21(6.7%) took 6 months to a year to disclose. Those who took 3 to 4 years to disclose were 6(1.9%) while 4(1.3%) had taken more than 4 years to disclose their status to their partner. Figure 4.2.1 below highlights the time taken to disclose the HIV/AIDS status to a spouse.
Those who took more than 6 months to disclose their status to their spouses described fear of abandonment as the most significant factor. About 11(3.3%) thought that they would be abandoned by their spouses after the disclosure, 9(2.7%) simply feared the disclosure process while 42(17.7%) had various reasons such as being in denial, ailing health and wanting their child to test negative before disclosing the status to the partner. Of those who took more than 6 months to disclose, 26(7.5%) had their fears confirmed as they faced some challenges after the disclosure. 41(11.9%) did not go through their fears and hence had a good outcome while 261(77.2%) did not respond to the question.

As regards factors that can help people to disclose their status easily 81(23.9%) reported counseling as the most important factor, others reported self-confidence and positive living as being a factor at 34(9.2%). Transparency levels between the couple 27(7.9%), caring for the partner 24(7.1%), having the correct knowledge on HIV/AIDS 12(3.5%) and waiting for the sickness to show before disclosure 7(2%) were other reasons noted. Other variables that serve to increase disclosure rates included factors such as knowing they will get help once they disclose etc.

More than half of the participants 205(61.2%) felt that they were at a high risk for HIV/AIDS transmission due to their discordant status, while 115(34.3%) did not think they were at a high risk for transmission but 15 (4.5%) of the participants did not know whether they were in a high risk relationship. Majority of the respondents 288(87.5%) claimed it would be easy to reduce
HIV/AIDS transmission in the relationship while 41(12.5%) thought it was hard to reduce transmission rates in the relationship.

4.2.2 Factors that increase the chances of HIV/AIDS transmission in a discordant relationship

Factors that were thought to increase chances of HIV/AIDS transmission in a discordant relationship were quite many. More than half of the participants 233(68.9%), noted poor condom use as the most important factor in increasing the chances of HIV/AIDS transmission. Other factors were poor antiretroviral use at 3.8%, increased sexual interaction at 3.5%, ignorance or being in denial at 3.5%, sharing of sharps at 3%, poor education and mentorship at 1.3%, unfaithfulness at 1.3% and 1.6% gave no response. Other factors like stress or being drunk accounted for 10.3%. The table 4.2.1 below describes the various factors that the participants thought would increase the rate of HIV/AIDS transmission in a discordant relationship.

Table 4.2.2 The factors that increase the rate of HIV/AIDS transmission in a discordant relationship.
4.2.3 Factors that reduce the HIV/AIDS transmission rate in a discordant relationship

Factors that reduce the rate of HIV/AIDS transmission were condom use at 43.2%. This was highlighted as the most important factor in reducing the transmission rates. Only 45(13.31%) considered faithfulness as being important. Of the respondents, 10(2.9%) believe that being clean and avoiding sharing of sharps could reduce the transmission rates, 28(8.3%) thought education and increased awareness about the infection would reduce the rates, openness and trust were at 5.32%, antiretroviral use 14.49% and other factors at 8.82%. Table 4.2.2 below summarizes factors that reduce HIV/AIDS transmission in a discordant relationship.

Table 4.2.3 The factors that aid the reduction of HIV/AIDS transmission among discordant couples.

![Bar chart showing factors reducing HIV/AIDS transmission]

4.3 The rate of correct and consistent condom use among the discordant couples.

The participants understood the importance of condom use as a means of preventing HIV/AIDS infection. Most of the participants (95.5%) believe that condoms use can prevent transmissions while 4.5% thought otherwise. About 293 respondents (86.7%) were consistently using condoms during coitus while 45(13.3%) admit to having sex without using condoms. Figure 4.3.1 shows the percentage of discordant couples who believe that correct and consistent condom use can reduce the transmission of rates of HIV/AIDS.
Figure 4.3 The percentage of discordant couples who believe that the use of condoms can reduce the transmission rates of HIV/AIDS infection in a discordant relationship.

Through the support groups, all the participants had been taught the importance of condom use in the reduction of HIV transmission. Those who used the condom 100% of the time were 180 (60.4%), those who used it 75% of the time were 53 (17.8%), 50% usage were 46 (15.4%), 25% usage was 19 (5.7%) and those who never used condoms at all were 32 (9.1%).

Of those who had other partners outside the home, 33 of them (68.8%) admitted to using condoms every time they had sex while 15 (31.2%) reported not using any protection. Figure 4.3.3 shows the percentage use of condoms among those who had other partners outside the home.

4.3.1 The rate of usage of family planning methods among the discordant couples

Less than half 152 (45.5%) of the participants were on some method of family planning while 182 (54.5%) were not. About 22.4% of the respondents believed that contraceptives aid the spread of the disease while 204 (60.9%) did not think so. About 56 respondents (16.7%) did not know the answer to the question. Majority of the respondents (72.2%) thought that contraceptives prevent the transmission of HIV/AIDS while 61 (18.8%) thought that the contraceptive usage does reduce the transmission rates. As many as 29 respondents (9%) did not know the answer to the above question.

4.4 The rate at which the HIV positive status has affected the quality of the relationship between the discordant couples
The positive HIV/AIDS status had not affected many of the respondent's relationships. Most of them 218 (64.9%) said that the status had not changed their relationship in any way while 118(35.1%) said their relationship had changed.

4.4.1 The rate of alcohol use among the discordant couples

Of the total study participants, 263(77.8%) reported not taking alcohol while 75(22.2%) said they took alcohol.

4.4.2 The frequency of sexual contact among the discordant relationship

When asked about the frequency of sexual relations in their relationship, 260(77.7%) said they had engaged in sex in the past 3 months. 156(46.7%) reported that they had not had any sex in the past one week, 88(26.3%) at least once in the week, 85(25.4) reported at least 2 to 3 episodes and 5(1.5%) reported more than 3 episodes. Few of the respondents 23(6.8%) reported to having sex during the monthly period while majority 313 (93.2%) abstained during that time of the month.

4.4.3 Love in the discordant relationship and the rate of violence amongst the spouses.

About 324(96.4%) of the respondents said they loved their spouses while 12(3.6%) felt that there was no love in their relationship. As regards violence in the relationship, 67(20.2%) of the participants experienced some form of violence due to the HIV status while 264(79.8%) had not faced any violence. Figure 4.4.1 below shows the percentage of participants who had experienced violence in their relationship due to their HIV status.

**Figure 4.4.3 The percentage of participants who had experienced violence in their relationships due to their HIV status.**
4.4.4 Discordant couples who desired more children within their relationship.

In the past 5 years, 188 (55.6%) of the participants had given birth to a child while 150 (44.4%) had not. Majority of them (71.2%) reported the partner as being the father to all the children in the family while 92 (28.8%) had children who did not belong to the current husband.

The respondents who were planning to have more children were 106 (31.5%) of them, while 231 (68.5%) had achieved the desired family size. Those who knew the HIV status of the children were 266 (82.1%) while 41 (12.5%) had not had their children tested for the virus.

4.5 The level of knowledge about antiretroviral treatment among the discordant couples

Most of the participants, 320 (95.2%) knew about the antiretroviral drugs while 16 (4.8%) had not heard of the drugs. Only 94 (27.7%) could correctly name an antiretroviral drug. Majority of them, about 245 (72.27%) could not name any drug. They said that the names were hard to remember and others had never bothered to read the names.

4.5.1 The level of CD4 cell counts for antiretroviral therapy initiation among the discordant couples

119 (40.9%) participants reported 350 CD4+ cells/ml as the best level to initiate antiretroviral treatment. About 114 (39.2%) reported it as 250 CD4+ cells/ml while 32 (11%) thought the treatment should be initiated at 500 CD4+ cells/ml. Only 7 (2.4%) knew that the treatment could be initiated at all CD4 levels while 19 (6.5%) did not know the answer. This showed that most of the participants were not aware of Treatment as Prevention option that seeks to initiate treatment as soon as possible. Figure 4.5.1 shows the CD4 levels at which the antiretroviral drugs should be initiated as suggested by the participants.

4.5.2 The safety profile of antiretroviral drugs among the discordant couples

Most of the respondents 291 (87.4%) reported antiretroviral drugs as being safe for use. Only 19 (5.7%) said the drugs were not safe to use and 23 (6.9%) did not know whether they were safe or not. About 158 (49.1%) reported the availability and accessibility as excellent, 138 (42.9%) thought it was good, 15 (4.7%) termed the availability as fair, 5 (1.6%) as poor and 6 (1.9%) could not gauge the availability of the drugs. Less than half of the participants, about 136 (40.2%) noted that the drugs had intolerable side effects, 157 (46.4%) did not think that the side effects were that significant while 45 (13.3%) did not know the extent of the side effects. Majority 289 (87%) of the participants affirmed that they would be able to use the drugs
regularly and consistently while 25(7.5%) did not think they would be able to take them regularly. A few of the respondents, 9(2.7%) reported that maybe they would not be adherent while an equal number did not know whether they would handle the drug usage.

Majority of the participants, 327 (97.3%) reported that they would support a spouse if they were to be initiated on the ARV medications, 8(2.4%) reported that they would not support the spouse while 1(0.3%) did not know whether the support would be available.

4.5.3 Knowledge levels on the Treatment as Prevention concept

More than half of the participants, 192(56.8%) had not heard of treatment as prevention therapy while 146(43.2%) were familiar with the treatment concept. Figure 4.5.2 shows the percentage of the participants who had heard of the Treatment as Prevention concept.

Figure 4.5.3 Percentage of the participants who had heard of the Treatment as Prevention concept.

4.5.4 Knowledge levels ART prophylaxis usage among the couples

More than half of the respondents 178(54.4%) had not heard of the pre-exposure prophylaxis concept while 149(45.6%) were familiar with the concept. About half of the participants 175 (53.2%) knew about Post Exposure Prophylaxis therapy while 154(46.8%) were not aware of the treatment therapy. Most of the participants, 289(85.5%) reported that they would use the drugs for the Treatment as Prevention therapy if initiated on treatment. Only 11(3.3%) reported that they would consider using the drugs while 37(11%) would not use the drugs at all.

4.6 The role of support groups for the discordant couples
As regards advantages of attending the discordant support group meetings, gaining knowledge and education was the most important at 191(38%), for communal support at 114(22%), counseling at 72(14%), exchanging ideas at 25(5%), free medication at 9(2%) and others such as stress management and socialization at 57(11%). 42(8%) did not respond to the question.

Many of those who were interviewed, about 201(60%), did not think attending the discordant support group had any disadvantages. Some disadvantages that were highlighted were the time consuming nature of the support groups at 20(6%), 26(8%) thought there was some stigma attached to the attendance while 70(21%) had no response to the question. Other factors such as inadequate financial compensation, gossip within the group members accounted for 19(5%) of the participants.

One of the key barriers that keep participants away from the support group was reported as stigma and fear at 151(35%). About 70(16%) cited lack of time as a barrier, 45(10%) had ignorance as a factor, work related constraints accounted for 38(9%) of the responses. Only 52(12%) did not respond and 78(18%) had other factors such as ignorance and embarrassment that acted as barriers to the support group attendance.
5.0 DISCUSSION

The study was carried out at the Pumwani Maternity Hospital and at the Baba Dogo Clinic. A total of 338 participants were interviewed over a four month period. Interestingly, more than half of all the participants were women. The Kenya AIDS Indicator survey reports a higher proportion of women aged 15-64 (6.9%) than men (4.4%) are infected with the virus(5). This may explain why there were more women than men who participated in the study. As regards the median ages of both the males and the females, the men were on average older than the women. A few of the couples had the woman being older than the men. Majority of the couples had been together for at least 5 to 10 years. Only about 5% had been married for less than a year. This either means that the younger couples were generally fewer in number, or they separated after the disclosure or that they were not attending the support group as often.

During the Focus Group Discussion sessions, it was noted that the older couples had lived together for longer periods as they understand each other. They choose to stay together for the sake of the children and because the thought of starting another relationship was unappealing. Hence, counseling and mentorship programs should be initiated so as to target the group that has been together for less than a year to empower them to maintain the relationship.

As regards income levels, more than 80% of the participants were earning less than 10,000 Kenya shillings in a month. Most of them were casual laborers and an equal number were self-employed. Most of the participants were literate as most of them had attained either a primary or secondary level education. Less than 1% of the respondents had obtained tertiary education. This is important as it means that the training and education that they receive at the health facility should be made as simple and as straight forward as possible to ensure understanding of the concepts being shared.

About half of the participants had known their status for more than four years. Majority of them had disclosed their status in less than six months. A few of them had taken more than four years to disclose their status to their significant others. In terms of disclosure, majority of them disclosed their status in less than 6 months. Nevertheless, most of them feared abandonment by their spouses hence the delay. Counseling was highlighted as the most important factor in hastening the disclosure process. This means that more effort should be put into counseling and education as early disclosure means early initiation of medication and better adherence of the
same. The health seeking behaviors improve significantly when they have been counseled on how to live positively with the disease and on benefits of the treatment modalities. The presence of family support serves to improve compliance to the various supportive modalities that are available. Counseling of both the positive partner and of the family members was also highlighted as the most important factor during the focus discussion group sessions. About 82% of the respondents knew the HIV/AIDS status of the children while 12% had not had their children tested for the virus. The ones who did not know the status of the children cited fear as greatest deterrent. During the Focus Group Discussion, they reported that it would kill them to know that their children are HIV positive. In the cases where the parents knew the status of the children the children were on treatment without them knowing the type of illness being treated. This raises the important issue of disclosure as regards children. The age at which disclosure should be done and the method of disclosure were issues of contention during the Focus Group Discussion. The couples should be empowered so that they know when and how to disclose this information to their young ones in a way that the message would be received positively.

As regards the most common method of HIV transmission, almost all the respondents chose sexual contact as the most common method. They understood and could appreciate the other transmission modalities but they still acknowledged sexual transmission as the most important method. They are in a discordant relationship so the need for safer sex practices should be emphasized. The need for correct and consistent use of condoms should also be re-affirmed. Unfortunately, only about half of them felt they were in a high risk relationship due to their discordant status. A majority of them also reported that they found it easy to reduce the risks of transmission while in a discordant relationship.

Factors that were thought to increase the chances of HIV/AIDS transmission were many but incorrect and inconsistent condom use was cited as the most important factor. This means that the couples realize the importance of condoms use in reducing the rate of transmission hence the need to keep evaluating whether this is actually happening when they are in the domestic setting. Other factors that were thought to increase the chances of transmission of the disease were poor antiretroviral use, and increased sexual interaction in the home. The focus group discussion sessions actually revealed that the frequency of coitus within the relationship had reduced since the positive HIV/AIDS diagnosis was made. Factors that reduced transmission rates in the relationship were cited as correct and consistent condom use. Other factors that were mentioned included faithfulness, education and antiretroviral use as other protective measures used to reduce the transmission rates.
About 98% of the participants reported sexual contact as the most common method of HIV/AIDS transmission. Over 95% of them understood the importance of correct and consistent condom use in decreasing the rates of HIV/AIDS infection. However, only 87% of them were using the condoms consistently with slightly more than half using the condoms 100% of the time. Of those who had other partners outside the home, slightly more than half admitted to using condoms every time they had coitus outside the home. Despite the knowledge on the importance of correct and consistent condom use, only half of them were using condoms every time they were having coitus. The Focus Group Discussion revealed that the number may even be lower than reported as they said using the condoms 100% of the time was unrealistic. The partner, especially the husband may demand for sex without protection, they may just want to have unprotected sex as it is more enjoyable and that in the heat of the moment, it is not practical to start looking for protection. Even those who were having extra-marital affairs were not using the condoms as consistently as they should. The importance of correct and consistent condom use should be re-emphasized in order to reduce the transmission rates.

Less than half of them were using some form of contraception with more than half of them having given birth in the past 5 years. According to the Kenya Health Demographic survey, about a third of all married women use some form of contraception (32). About 75% of the participants believed that contraceptive use prevents the transmission of the disease while 22% believed that contraceptives aid the spread of the disease. Throughout the interview process, majority of them kept re-evaluating their responses to the above questions. This shows that there is a gap in the knowledge on the use and on the various functions of contraceptives. The education programs at the health facilities should include contraceptives and family planning sessions in order to empower the decisions of the couples. In the last 5 years, almost half of the couples had delivered a child. In about 70% of the cases, the current partner was the father of all the children in the family. This means that approximately 30% of them had children from other partners. Only 68% had attained their desired family size and about 31% were willing to get more children. This means that the discordant couples are still conceiving in spite of the discordant state. They should be assisted to make proper reproductive choices that will not increase the chances of transmission.

As regards the quality of their relationships, most of them reported that the positive diagnosis had not affected the quality of their relationship. Majority of the couples had engaged in coitus over the past 3 months with more than half reporting that they had not had any sex over the past week. The Focus Group Discussion sessions also revealed that the number of times they
engaged in coitus had reduced after the positive HIV/AIDS diagnosis. Majority of them still loved their spouses and this means that improved counseling and mentorship would really improve the quality of their relationships. Only 22% reported to the use of alcohol. This is important as alcohol use may inhibit the ability to make decisions that would reduce the rates of transmission. About a quarter of all the participants had experienced some form of violence in the relationship due to their discordant status. The Kenya Demographic and Health survey states that 47% of all women have experienced some form of violence with the partner or husband at some point in time (32). The violence forms were physical, psychological or sexual in nature. The most common form of violence that was reported was the psychological one. The violence that was reported was regardless of the HIV/AIDS status. If the partner was positive, there may be resentment directed to the negative one. The negative partner may also resent the positive partner due to the distrust and doubt brought about by the positive status. Either way, one of the partners may feel aggrieved and this may lead to some form of violence in the home. The couples need a lot counseling and support so as to ensure that the quality of life in the home is improved despite their discordant state.

As regards the use of antiretroviral therapy, 95% knew about the drugs and were knowledgeable about the uses of the drugs. Only 27% were able to name an antiretroviral agent. They cited ignorance as a reason and others said that the names were too hard to read and memorize. This means that they hardly know what drugs regimes they are on hence reporting on compliance and side effects of the drugs to the health workers would be wanting. About 40% of them reported levels of 350 CD4+ cells/ml as ideal for antiretroviral drug initiation. Almost an equal number reported the levels as 250 CD4+ cells/ml. This means that the discordant couples are yet to understand the latest guidelines for antiretroviral initiation in discordant couples. About 87% thought they had a good safety profile hence were safe to use. Almost half of them reported the availability and accessibility as excellent. About half of the discordant couples noted that the drugs had intolerable side effects and this was a key finding as it would act a barrier as regards initiation of the drugs. Concerns that have been raised by discordant couples as regards the use of TaSP include the risk of side effects, adherence to lifelong treatment and the stigma associated with the use of the drugs(32).

Majority 87% of the participants affirmed that they would be able to use the drugs regularly and consistently. Almost all the participants reported that they would support the spouse if they
were to be initiated on antiretrovirals. This means that the domestic support is available and should be harnessed in order to improve compliance to medication. Slightly more than half of the respondents had not heard of the treatment as prevention concept. However, if initiated on the treatment, about 85% of them would use the drugs. A study carried out in Muhoroni, Kenya among discordant couples also found that they preferred using TaSP as compared to PreP. Majority of the participants, irrespective of gender and HIV status, found TaSP more preferable than PreP. This was likely due to the fact that TaSP offers medication to the HIV positive partner unlike the rest that offer treatment to HIV negative partners. This because the ones who are sick are more likely to comply with the medication.

Less than half of the respondents were aware of the Pre-Exposure Prophylaxis (PreP) concept and 53% knew about the post Exposure Prophylaxis (PEP) concept. They also need to be taught on the various treatment modalities available with antiretroviral drug usage. PreP and PEP are important modalities especially due to their discordant state. They need to be educated and empowered so as to facilitate early diagnosis and initiation of the antiretrovirals.

The most important advantage as regards the attendance of the support group was the knowledge, education and mentorship gained. This means that the staff members should be empowered so as to counsel and educate them on the latest and most recent information. During the Focus Group Discussion, the men highlighted the need of having male mentors who would educate and mentor them. The women have their own group called mentor mothers who go to the community to counsel and support the women in discordant relationships. The men requested for an equivalent forum and cited this as one of the factors that would improve male participation in the clinic activities. They would be more comfortable sharing their issues with a man than the existing female mentors.

The most common disadvantage that was highlighted was the stigma they faced after the disclosure. The support groups are attended by many people and they fear meeting people that they know and the retribution that may follow as a result of that disclosure. Barriers that kept them away from the support group still had stigma and fear as the most significant factor. Counseling and greater public awareness should be done in order to reduce the stigma associated with a positive HIV/AIDS diagnosis. Self-acceptance and positive living will go a long way in improving the health status and the health seeking behaviors of the discordant couples and this would lead to better outcomes and reduction of HIV/AIDS transmission rates.
Study limitations

1. Assessment of discordant couples who belong to an existing support group presents a challenge as the couples are knowledgeable on transmission and prevention methods. This may not be a true reflection of the discordant couples from Kenya especially those enrolled in other programs.

2. Self reports was used for the analysis with their inherent challenges.
6.0 CONCLUSION AND RECOMMENDATIONS

Conclusion
The discordant couples group at Baba Dogo and Pumwani benefit from the discordant support groups that they attend. They learn how to live positively and most importantly are counseled on how to keep the family together. Most have disclosed their status to their partners though they felt they needed to be empowered so as to tackle the situation better. Majority of the discordant couples know the importance of correct and consistent condom use. However, not all of them use them consistently, even with the other partners outside the home. The importance of proper condom use should be re-emphasized to ensure reduction of the transmission rates. During the focus group discussion session, the couples disclosed that they hardly use the condoms as often as they should.

Although majority of the respondents have heard about the use of antiretrovirals, many are not aware of treatment as prevention concept. Disclosure of HIV status to family and friends and the use of the antiretroviral drugs in addition to being in a discordant relationship as stigmatizing was noted. Stigma was also noted to be a major reason for those who fail to attend the discordant couple support group. Therefore counseling targeting discordant couples and health education to the community members should be provided to reduce the stigma associated with a positive HIV/AIDS diagnosis.

Recommendations
This study recommends that

- All discordant couples should be counseled and advised on how to live positively with the condition. Acceptance will impact positively on the health seeking behaviors of the participants.
- All discordant couples should be educated on treatment as prevention and those willing to initiate ART supported immediately
- Issues of disclosure should also be addressed, whether it is targeting a spouse to spouse or a parent to child relationship. The couples should be empowered on how to disclose in a manner that will maintain the integrity of the relationship.
- Correct and consistent use of condoms as a major method in the reduction of HIV/AIDS transmission should be emphasized.
- Male mentors should be introduced who will be able to mentor and educate the men at a personal level.
- Health education on the use of family planning methods and the issues around attaining the desired family size should be addressed. Most of the couples want to get other children and they should be educated on safe methods of conception.

In order to increase attendance of the discordant couples in the health facilities, there is need for the government to

- Adopt social media to educate the society on discordant relationships. This will reduce the stigma levels that the discordant couples face on a daily basis.
- The staffs at the health facilities providing ART should be competent and qualified with good inter relational skills.
- Finally, health workers at ART clinics should attend continuing medical education sessions to sharpen their skills regularly especially on the latest treatment trends.
REFERENCES


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APPENDICES

Questionnaire

KNOWLEDGE, ATTITUDE AND UPTAKE OF ANTIRETROVIRAL THERAPY FOR HIV PREVENTION AMONG DISCORDANT COUPLES: PUMWANI MATERNITY HOSPITAL COHORT.

Study number: é é é é é é é é é é é é

A. Demographics

1. Date of Birth ________________ Couples age difference é é é é é é

2. Gender
   Male □ Female □

3. Level of education
   Primary □ Secondary □ College □

4. Marital status
   Married(civil/traditional) □
   Unmarried but committed □
   Living as married □

5. How long have you been married?
   1-5 yrs □ 5-10 yrs □ 10-15 yrs □ Over 15 years □

6. Occupation of the respondent
   Farmer □ Employed □ Businessman □ Others □

7. How much does the family earn every month
   Husband: é é é é é
   Wife: é é é é é
c   Combined incomes: é é é é é é

B. Knowledge on HIV/AIDS transmission

1. Have you ever heard of HIV/AIDS?
   Yes □ No □
2. What was your source of information about HIV/AIDS?

Hospital [ ] Media [ ] Community leaders [ ] Friends [ ]

3. How is the disease transmitted?

Sexual interaction [ ]
Sharing injection needles [ ]
Mother to child transmission [ ]
Sharing utensils [ ]
Blood transfusion [ ]
Others: Specify [ ]

4. Does the presence of sexually transmitted diseases increase the risk of HIV/AIDS transmission?

Yes [ ] No [ ]

5. Have you had a Sexually Transmitted Disease in the past 6 months?

Yes [ ] No [ ]

C. Awareness on methods of preventing HIV/AIDS infection

1. Do condoms prevent the spread of the disease?

Yes [ ] No [ ]

2. Have you ever used condoms?

Yes [ ] No [ ]

3. Did you use a condom last time you had sex with your spouse?

Yes [ ] No [ ]

4. Ever heard of PMTCT (Prevention of Mother to Child Transmission)?

Yes [ ] No [ ]

5. Ever heard that ARVs can be used to prevent HIV infections?

Yes [ ] No [ ]

6. Ever heard of the following HIV prevention methods:

PEP (Post Exposure Prophylaxis)
PrEP (Pre Exposure Prophylaxis)
Yes ☐ No ☐

TaSP (Treatment as Prevention)
Yes ☐ No ☐

**Attitudes and behaviours related to HIV/AIDS**

1. Do you think HIV/AIDS infection is a threat to your family’s well being?
   Yes ☐ No ☐

2. List the key threats you think of constantly:
   
   1. 
   2. 
   3. 
   4. 
   5. 
   6. 

3. Do you think HIV infection is a curse:
   Yes ☐ No ☐

4. Do you believe HIV infection can be managed?
   Yes ☐ No ☐

5. In your opinion do those living with HIV deserve it?
   Yes ☐ No ☐

6. What do you think of stigma to those living with HIV?
   
   1. 
   2. 
   3. 
   4. 
   5. 
   6. 
   7. 
   8. 
   9. 
   10. 

7. Is discrimination to those HIV infected justifiable?
   Yes ☐ No ☐

8. Do you take alcohol?
   One of us ☐
   Both of us ☐
   None ☐
9. When did you last have sexual contact with your partner?

10. On average how many times do you have sex in a week?

   None
   Once a week
   2-3 times a week
   More than 3 times a week

11. How many other sex partners do you have?

   1
   2
   More than 3

12. When did you last have sex with your other partner(s)

13. Do you use condoms with them? Yes No

14. Do you love your spouse? Yes No

15. Do you trust your Spouse? Yes No

16. Do you have sex when you are in your monthly periods?

   Yes No

17. Have you ever experienced violence from your spouse?

   Yes No

   If yes, do you think the violence was in any way linked to your HIV/AIDS status?

   Yes No

18. What personal methods do you use to reduce the HIV transmission rates in the home?

19. Have you had any children in the past one year?

   Yes No
20. Are you planning to have any children in the near future?
   Yes [ ] No [ ]

21. How do you protect yourself from getting HIV infected or reinfection?
   (Enter your own response)

22. Have you disclosed your HIV status to other people other than your spouse?
   Yes [ ] No [ ]

23. Are there benefits to disclosing HIV status?
   Yes [ ] No [ ]

24. What are the challenges of disclosing HIV status?
   (Enter your own response)

**Antiretroviral therapy**

1. Have you heard of Antiretroviral drugs (ARVs)?
   Yes [ ] No [ ]

2. What is the role of the ARV treatment?
   - To eradicate the virus [ ]
   - To boost the immune system [ ]
   - To fight opportunistic infections [ ]
   - I don't know [ ]

3. At what CD4 level should ARVs treatment be initiated?
   - 250 cells/ml [ ]
   - 350 cells/ml [ ]
   - 500 cells/ml [ ]
   - As soon as possible [ ]

4. Do you consider antiretroviral drugs expensive?
   Yes [ ] No [ ] I don't know [ ]
5. In your opinion, do you believe ARVs can help manage HIV?

   Yes [ ] No [ ]

6. How would you grade the availability and accessibility of the ARV drugs?

   Excellent [ ]
   Good [ ]
   Fair [ ]
   Poor [ ]

7. Do the drugs have side effects?

   Yes [ ] No [ ] I don't know [ ]

8. Would you take your medications regularly and consistently?

   Yes [ ] No [ ] Maybe [ ] I don't know [ ]

9. Have you ever heard of the Treatment as Prevention therapy concept that targets discordant couples?

   Yes [ ] No [ ]

10. If Treatment as Prevention therapy was proven to be safe and effective, would you consider using the drugs?

   Yes [ ] No [ ] Maybe [ ]

11. What would help you use ARVs?

   [ ]

12. What would stop you from using ARVs?

   [ ]

13. In your opinion what do you see as key barriers towards using this HIV prevention approach?

   [ ]

**Discordant Couples Support Group**

1. Are you a member of any discordant couples support group?

   Yes [ ] No [ ]

2. Where?
3. Do you think these groups help in any way?
   Yes [ ] No [ ]

4. What are some of the barriers that prevent many infected people from joining such groups?
   [made up text]

5. What are some of the disadvantages of joining support groups?
   [made up text]
Focus Group Discussion Guide

Subject Information Sheet/ Verbal Consent

For Focus Group Discussion Participants: To be read before starting the focus group discussion.

Hallo, My name is Lydia Atambo. I am a master of science student at the University of Nairobi/UNITID centre. I am conducting a study to find out why discordant couples are not taking up treatment as prevention program. This is despite their awareness of the benefits of early initiation of antiretroviral treatment. I would like to invite you to participate in this study. The study aims to gather information on issues around the knowledge of the HIV and AIDS disease, attitudes towards the condition and the actual practices on the ground. We will also assess the barriers that work to reduce the uptake of the available discordant couple support services. We are looking forward to hearing your experiences and learn from you and your peers. The study will focus on challenges and gaps that prevent the uptake of the early onset ART initiation.

We are carrying out focus group discussions to gather this information. We asking if you will be willing to participate in one of these group discussions and share your views. Focus discussion groups have about 8-12 people who get together and discuss their ideas and thoughts about important issues. The discussions are led by a member of our research staff and an independent facilitator. Your responses, opinions and ideas are very important to this project. You do not have to talk about your personal experiences. You will be asked to speak generally about your and others opinions and experiences. Please do not use any names when you share what others have told you. We will not use any names when writing our reports.

We would like to invite you to participate in one of the planned focus group discussion this week. This session will be tape-recorded and a transcript of the discussion will be made. By consenting to participate in the study, you are agreeing to the tape recording of the session. The session will take about 2 hours to complete.

If you agree to take part in the study, you will be given a soda during the session and provided with 150 Shillings to help pay for your transportation fee to your Nairobi home.
You may not feel comfortable answering some questions in front of your peers. You have the right to refuse to answer any question that you do not wish to answer. Also, you can choose to leave the discussion at any time. You do not have to participate if you do not want to but this will not affect your chances of ever joining or using the services provided through the program.

The benefit to you is that you will be sharing your opinions and experiences that will help improve the service provided to you especially those related to uptake of the antiretroviral treatment.

By agreeing to participate you are agreeing not to share information provided by this group outside this focus group discussion. However, we cannot guarantee that information discussed in the group will not be shared, so please consider this before discussing personal matters. We will protect information about you and your taking part in this research to the best of our ability. Your name will not appear on the interview records or transcripts. We will keep all sensitive files, notes, and interview tapes password protected or in locked cabinets and we will destroy all interview tapes at the end of the study. If the results of the research are published, neither your name nor personal identifying characteristics or those of anyone else in the study groups will be revealed.

- Do you have any questions?
- Do you agree to participate in the focus group discussion? If you do not want to participate, you may leave the room at this time.

**FOCUS GROUP FACILITATOR**: You must sign below before proceeding. Your signature certifies that the objectives and procedures of this study have been read to the focus group participants. It also certifies that you have answered all the questions that the respondents had about the study and that each participant remaining in the room has voluntarily agreed to take part in the research.

__________________________________________
Date                                                Signature of Focus Group Facilitator
Facilitator Instructions:

- The first step is to explain to participants that this focus group discussion will be recorded. Explain why you need to record the session and give them time to express questions or concerns.
- Once you have all people agree to the recording, start the tape recorder and begin with the informed consent process.
- As a warm up, you as the moderator need to introduce yourself (a bit of information about your job, your family, and what participants can call you) and give some information about the number of discordant couples and the actual number of those who have taken up the TaSP program.
- The discussion will assess the couples knowledge, awareness and attitudes to the HIV/AIDS disease. The facilitator will assess the general information about ART services, especially the treatment as prevention programme that provides ARVs to discordant couples.
- Then find out about participant’s children if any, other occupation, and what they want to be called during the tape recording.

Facilitator: I am going to describe for you the situation faced by a discordant couple that have been married for about 10 years. As I read, think about whether you know any one like them and think about what their life must be like. Then I will ask you some questions on how they might act in a certain situation.

(Mary and John:) We have been married for about 10 years. They have two children who attend the nearby primary school. John works as a Security officer and has to be away from home for extended periods of time. Mary is a housewife who also runs a local greengrocers shop. During a recent visit to the medical facility, they had a HIV test done that showed John as HIV positive. Mary on the other hand is HIV negative. John has fallen sick.
many times in the recent past and have been advised to have his CD4 levels and viral load determined. The medical staff who are helpful and supportive would want him to begin his Antiretroviral treatment as soon as possible. However, to date, John is yet to begin his ART treatment. However, they both agreed to join the discordant couples support group where they are given free counselling, treatment and even preventive measures such as condoms and other contraceptive measures.

1. Should Mary and John seek medical care from the medical centre regularly?
2. Is it advisable for them to attend the support group together?
3. Do you think they are likely to face social stigma due to their discordant state?
4. What is the main role of the antiretroviral drugs?
5. Should John start taking the Antiretroviral therapy as advised by the medical personnel?
6. At what stage should John start taking the medication? (At diagnosis or when he starts getting opportunistic infections?)
7. Are the medications cheap and accessible?
8. Why would he not take the beneficial ART treatment? (Discuss side effects, stigma associated with taking of the drugs, lifelong treatment regimes)
9. What incentives or additives should be included in order to improve the uptake of the drugs?
10. Has the discordant status affected the quality of their relationship? Does Mary trust John?
11. Does John have a casual sexual partner around the workplace?
12. Does the partner know about John’s HIV status?
13. Should Mary get another sex partner or boyfriend?

The medical staff at the support facility advocate for various prevention methods to reduce the transmission rates. The most common is correct and consistent use of condoms known to reduce the transmission rates.

14. How often are condoms generally used especially with spouses at most homes?
15. Is it easy to use condoms correctly and consistently?
16. If not how can we improve use of this prevention method among discordant couples??
17. In your opinion should testing HIV positive in one partner affect the number of times they have sex? 

18. What other internal mechanisms can they adopt to reduce the transmission rates among them? 
   (Discuss coitus interruptus, complete abstinence etc) 

**Due to the problems posed by the HIV status, both Mary and John have other sex partners**

19. How often do you think they use condoms with these partners? 
20. If they don’t use condoms all the time, is it because they love them or that they trust them? 

**Despite the challenges posed by the discordant HIV results, Mary and John want another baby. Should they get another baby?**

21. In your opinion is this acceptable? 
22. How can they avoid infecting each other 
23. How can they protect the unborn child? 

**John finally accepts to start ARVs early for prevention. His CD4 levels are still high and the viral load is low. He begins collecting drugs at the nearby medical facility. In your opinion, do you think this is a wise move?**

24. Do you think collecting the drugs from the clinic would pose any problems for them at the community level? 
25. What would you do if you were in John’s shoes? 
26. What side effects is John likely to experience? 
27. Other than the spouse, who else should John inform about his taking of ARVs 

**John and Mary continue attending the discordant couples support group meeting every Sunday and they think the meetings are beneficial and have improved their quality of life.**

28. In your opinion, do you think support groups help? 
29. Since John is taking ARVs, should they continue attending the support group meetings anyway? 
30. When should John stop taking ARVs?
Knowledge, Attitudes and Uptake of Antiretroviral therapy for HIV prevention among Discordant couples : Pumwani Maternity hospital cohort

PATIENT INFORMATION FORM

Introduction

The Human Immune Virus (HIV) was discovered in the early 1980s. This virus is mainly transmitted through contact with infected body fluids. The most common method of infection is through sexual contact. Antiretroviral treatment was introduced in the late 1980s and the drugs reduce the viral load as well as increasing the body’s CD4+ cell counts. This serves to enhance the body’s immune status hence reducing the morbidity and mortality rates that were initially witnessed with HIV infection. These drugs have a few disadvantages such as adverse reactions that are experienced after intake, inconvenience of taking multiple pills daily for life, the possibility of development of resistance and the stigma associated with taking of the drugs. However, the benefits to an infected individual outweighs the observed side effects.

Discordant couples involves one HIV positive partner and the other negative. Majority continue to have unprotected sexual contacts and even have children. This is a unique group as it means that the HIV negative partner is constantly exposed to the virus. Use of antiretroviral therapy on the HIV infected partner as soon as the diagnosis is made would therefore help improve quality of life and to significantly reduce the risk of HIV transmission to the negative partner. This has great benefits to the family unit.

Why is the study being done?

The study seeks to understand the knowledge and awareness among discordant couples of benefits that may accrue from early initiation of the antiretroviral treatment especially targeting the HIV positive individual in the discordant relationship. The study also seeks to assess the awareness of risk factors in the spread of HIV, attitudes and actual practices as regards to HIV transmission, prevention, management and use of ART for care and prevention.

Why are you being requested to join the study?
The study involves HIV/AIDS discordant couples only. The study seeks to assess the awareness, knowledge and opinions of discordant couples regarding several issues on HIV prevention, management and use of antiretroviral treatment.

*What will the study involve if you agree?*

Answering questions about your life such as HIV treatment, opportunistic infections, HIV prevention measures. The study will be carried out at the Pumwani hospital during regular hours. The clients will be expected to take about 60 minutes to respond to issues raised using a standardized questionnaire. Some couples will also be selected and requested to participate in focus discussion groups at a later date.

The questionnaires will be administered by the project nurse.

*Are there risks involved?*

There will be a slight inconvenience due to the time taken to answer the questions.

*Are there any benefits in participating in the study?*

There are no major benefits to the individual or discordant couple. However, the information will help the medical personnel take better care of you. Findings from the study may help us provide better care to discordant couples by informing the appropriate changes required to the program.

*Confidentiality of the information*

The information provided will be confidential.

You will be assigned a study number that will be known by yourself and by the research team.

Your name or the data number will not be used in any computer database or book records.

We intend to publish the research results but your identity will not be revealed.

Your clinical records may be used by other organizations or individuals for quality control and data analysis. Your identity will remain a secret.

*What happens if a refuse to participate?*

Participation in this study is voluntary.
You have the freedom to make the choice as to whether to participate or not.

If you choose to participate, you are free to withdraw from the study at anytime.

If you decline to participate or if you choose to leave the study, this will not affect your care now or in the future.

What if I have questions clarifications or problems?

In case of any questions, concerns or comments about the study, please call Dr Lydia Atambo. She is the principal researcher at the University Of Nairobi, Institute of Tropical and Infectious diseases on 0723 276820.

Feel free to also contact my supervisor, Dr Kimani, Kenya AIDS Control Project, Nairobi on 020 234 1108.

As regards participants rights, please contact Prof A.N. Guantai, the Chair to the Kenyatta National Hospital/University Of Nairobi Ethics and Research Committee at the department of pharmacology and pharmacognosy, School Of Pharmacy, University Of Nairobi on 2725452 ext 44102.

You can also make an appointment to see her at the University Of Nairobi
Kiambatisho: Habari na ridhaa ya kidato

Maarifa, mitazamo na Matumizi ya kurefusha maisha kwa ajili ya tiba ya kuzuia Virusi Vya Ukimwi miongoni mwa wanandoa ambao mmoja ndiye aliyeambukizwa, Kikundi cha hospitali cha uzazi, Pumwani.

Fomu itakayotumiwa na mgonjwa


Wanandoa ambao mmoja wao ameathirika yanayohusu VVU mpenzi mmoja chanya na hasi nyingine. Watu wengi wakiendelea kuwa na mawasiliano zembe na hata kuwa na watoto. Hii ni kundi kipekee kama maana yake ni kwamba mpenzi HIV ni daima wazi kwa virusi. Matumizi ya tiba ya kurefusha maisha juu ya mpenzi aliye na virusi haraka kama utambuzi ni kufanywa ingekuwa hivyo kusaidia kubora ubora wa maisha na kwa kiasi kikubwa kupunguza katari ya maambukizi ya VVU kwa mpenzi hasi. Hii ina faida kubwa kwa familia.

Ni kwa nini utafiti huu unafanyika?

Utajibu maswali kuhusu maisha yako, kama vile habari juu ya tiba ya VVU, magonjwa nyemelezi, hatua zinazokulia kuzuia VVU. Utafiti huu utafanywa katika hospitali ya Pumwani Inatarajiwa kuwa utachukua kama dakika kumi kujibu masuala yaliyomo katika dodoso sanifu. maswali utasimamia na muuguzi mradi huo.

Je, kuna hatari ya kushiriki?

Kutakuwa na usumbufu kidogo kutokana na muda utakaotumika kuyajibu maswali.

Je, kuna faida yoyote katika kushiriki katika utafiti?

Hakuna faida kubwa kwa mtu binafsi. Hata hivyo, habari hii itasaidia wafanyakazi wa afya ili kuweza kuwahudumia kwa njia bora. Usiri wa taarifa Taarifa zote zitazotolewa zitakuwa za siri.

Utakuwa na nambari ya utafiti ambayo itakuwa inajulikana na wewe mwenyewe na timu ya utafiti pekee.

Jina lako au habari yeyote itakayokuhusu haitatumiwa katika komyuta au kurekodiwa katika kitabu chochote.

Tuna nia ya kuchapisha matokeo ya utafiti huu lakini hakuna matokeo yeyote yatakayo husishwa na mtu binafsi.a.

Rekodi zako za kliniki zinaweza kutumika na mashirika mengine au watu binafsi kwa ajili ya kudhibiti ubora na uchambuzi wa ripoti hii. Utambulisho wako utabaki siri.

Nini kitatokea kama utakatasa kushiriki?

Kushiriki katika utafiti huu ni kwa hiari yako.

Una uhuru wa kufanya uchaguzi kama iwapoutsahiriki au la.

Kama utachagua kujishirikisha, unaweza pia kujiondoa kutoka utafiti huu wakati wowote. Kama utaamua kushiriki au kama wewe kuchagua kujiondoa kutoka utafiti huu, huduma unayoipata kutoka hospitali hii haita athirikakwa njia yoyote.


Jisikie huru kuwasiliana na msimamizi wangu, Dk Kimani, Kenya AIDS control Project, Nairobi 020 234 1108.

Kwa upande wa haki za washiriki, tafadhali wasiliana na Prof AN Guantai, Yeye ni mwenyekiti wa Hospitali ya Taifa ya Kenyatta / Chuo Kikuu cha Nairobi anayehusika na Maadili na Kamati ya Utafiti. Anafunza katika idara ya pharmacology na pharmacognosy, Shule ya Pharmacy, Chuo Kikuu cha Nairobi 2,725,452 ext 44,102.
**Consent form**

I have had the research explained to me. I have understood all that has been read and my questions have been answered satisfactorily.

I agree to take part in this research for the collection of clinical data.

I understand that enrolment is completely voluntary and I can withdraw at any time. I understand that withdrawal will not affect the quality of care given to me in any way.

Name 

Date 

Signature/thumb print

For research staff

I have explained the nature and purpose of this study to and that I have followed all the study specific procedures and standard operating procedures for obtaining consent.

Name of staff 

Signature 

Date
Fomu Ya Ridhaa

Mimi...........................(jina la mshiriki) nimeelezewa juu ya utafiti utakaofanyika. Nimeelewa yote ambayo nimeyasoma na maswali yangu yote yamejibiwa kwa njia ya kuridhisha.

Ninakubali kuhusika katika utafiti huu kwa ajili ya ukusanyaji wa maoni.

Naelewa kwamba kujihusisha ni kwa hiari na naweza kutoka wakati wowote. Ninaelewa kwamba kujiondoa kutoka utafiti huu hautaadhiri ubora wa huduma ninayopata au nitakayopata kwa njia yoyote.

Mshiriki....................................................

Sahihi........................................................

Tarehe......................................................

Kwa wafanyikazi wa utafiti

Mimi,..............................................................nimemuelezea ............................................asili na kusudi la somo hili. Nimefuata utaratibu wote unaohusiana na utafiti huu kwa ajili ya kupata idhini.

Mfanyikazi..............................................

Sahihi........................................................

Tarehe......................................................