KNOWLEDGE, ATTITUDE AND PRACTICE ON HAART ADHERENCE AMONG FEMALE SEX WORKERS IN MAJENGO AND SWOP CLINICS

BY

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DECLARATION

This project is my original work and has not been presented for a degree or other awards in any other University.

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DEDICATION

To my sister Virginiah Wangui who has taught me the value of patience and to my late mother Martha Njeri who taught me the value of honesty, discipline and hard work.

ACKNOWLEDGEMENTS

ACRONYMS

3TC	Lamivudine
AIDS	Acquired Immuno – Deficiency Syndrome
ART	Anti-retroviral Therapy
AZT	Zidovudine
CBD	Central Business District
COC	Combined oral contraceptive
DDI	Didanosine
DOT	Directly Observed Therapy
FTF	Face to Face
FSW	Female Sex Workers
HAART	Highly active anti-retroviral therapy
HIV	Human Immuno-deficiency Virus
KAIS	Kenya AIDS Indicator Survey
NASCOP	National AIDS and STI Control Program
MEMS	Medication Events Monitoring System
PCP	Pneumocytic Carinii Pneumonia
PEP	Post Exposure Prophylaxis
STIs	Sexually Transmitted Infections
SWOP	Sex Workers Outreach Programme
TCA	Tricyclic Antidepressants
WHO	World Health Organization

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ABSTRACT

Background: Current emphasis in HIV/AIDs management programs is to provide universal access to ART to all those who meet the inclusion criteria. Adherence is a critical determinant of the efficacy of prescribed HIV medications but an objective measure of compliance still remains elusive. Adherence to ART treatment is a critical factor among those on therapy and especially among high frequency transmitter core groups such as sex workers and other most at risk populations who may spread resistant viruses to their contacts.

Objective: The purpose of the study was to determine knowledge, attitudes and practices towards the required perfect ART adherence protocols among female sex workers.

Method: A cross-sectional study involving face to face exit interviews, two support/focus group discussion and abstracted data review on sex workers initiated on HAART was conducted. Face to face interviews data was collected using structured questionnaire with open and closed type questions where a total of 156 participants were interviewed. Collected data was analyzed using SPSS version 17. Descriptive statistics, univariate and multivariate analysis using logistic regression were performed.

Results: The median adherence rate among FSW was 97.4 percent. There was a significant disparity between adherence reported during the face to face interviews with adherence rates recorded on the patient charts by the clinical team on the same date ($p= 0.002$). Factors that were significantly associated with poor adherence in this study are similar to published reasons such as hard to remember to take medication ($p= 0.05$) were noted in addition to the influence of alcohol use ($p=0.032$).

Conclusion: The observed median adherence rate to ART at 97.4 percent among sex workers in Nairobi is optimal and may be higher than in other comparable groups from the general population in other African and developing countries. The study recommends that the adherence rates should be maintained at the same level or higher through increasing investments in ART support group activities, membership and frequency of these meetings. Clinicians can use this information to engage in open discussion with patients to promote adherence and identify barriers and facilitators within their own population

1.0 BACKGROUND

The World Health Organization has estimated about 33million people are living with HIV and of whom more than 30million live in low and middle income countries, as at end of 2007. It also estimates that at least 9.7million of these people are in need of HAART. Sub-Saharan Africa remains the region most heavily affected by HIV, currently hosting more than two thirds, 68 percent, of all people living with HIV and experiencing 75percent of AIDS deaths in 2007[1]. It was estimated that 1.7 million people were newly infected with HIV in 2007, bringing to 22.5 million the total number of people living with the virus in Sub-Saharan Africa. Results from the 2007 Kenya AIDS Indicator Survey (KAIS) suggest that at least 1.4 million people in Kenya could be living with HIV with an average of 7.8 percent of Kenyan adults, aged 15-49 infected with the virus. Regional variation was also noted with significant difference between Provinces with the highest HIV rates reported in Nyanza 15.3 percent, Nairobi 9.0 percent, Coast 7.9 percent, and Rift Valley 7.0 percent. The North-Eastern province had the lowest HIV prevalence at 1 percent. [2]

The rapid growth in antiretroviral therapy coverage represents one of the great success stories in recent global health history. Less than ten years ago, even as antiretroviral drugs were contributing to sharp declines in HIV related morbidity and mortality in high-income countries, it was widely assumed that these life-preserving medications would remain unaffordable and thus unavailable in most low and middle income countries. However, access to these medications has increased over the last ten years and the number of AIDS death has fallen. The annual number of AIDs deaths has declined from 2.2million in 2005 to 2.0million in 2007, partly due to increased access to HAART. (UNAIDS 2008).

More than four million people in low- and middle-income countries were accessing antiretroviral treatment at the end of 2008, up from about three million at the end of 2007. This represents an increase of 36percent in one year and a tenfold increase over five years. The greatest gains were seen in sub-Saharan Africa, where some two-thirds of global HIV infections occur. An estimated 2.9 million people in sub-Saharan Africa were receiving ART in 2008, compared to about 2.1 million in 2007—an increase of 39percent.[3] In Kenya, according to HIV service statistics, there were only about 10,000 adults on antiretroviral therapy (ART) in 2003 compared to 285, 000 by the end of August 2009 [4].

In Sub-Saharan Africa, the greatest success made with HIV/AIDS treatment is the expanded access to HAART. It has reversed what would otherwise have been a death sentence for so many patients to a manageable chronic infection[5]. However, successful HAART treatment is not without its challenges including numerous adverse drug reactions and the potential for rapid emergence and spread of resistant viral strains. The severe adverse drug reactions interfere with HAART compliance compelling a patient to take a "drug holiday" from the prescribed regimen. It has been found that patients with more than two adverse drug reactions are less likely to continue their treatment[6]. This may lead to development of resistance strains of the HIV-1 virus and the prescribed HAART may lose its potency resulting in treatment failure. On the other hand, with HIV cure still being elusive, patients on HAART are on life long treatment which has already been associated with long–term therapeutic toxicities from the medicines[1].

The complexity of the prescribed regimen is believed to strongly influence adherence. Hence, HIV management experts continue with their push for regimen simplification and fixed dose formulations to ease pill burden and frequency of intake. Over time, HIV therapy continue to evolve from the Dark Ages (1981 to 1986), when there were desperate attempts to slow disease progression, and emphasis was on management of Pneumocystis Carinii Pneumonia (PCP) to the Pre-HAART era of rational design of drugs with monotherapy like the AZT and DDI and dual therapy combination of 3TC with AZT (1987 to 1995), to the Decade of HAART (1996 to 2006) that came with the advent of Protease inhibitors[7]. The complex regimens often included three or more drugs, consisting of three or more pills each day, taken two or three times daily at strict intervals, and with their own ingestion protocol such as fasting and high-fat or high-protein meals [3]. These regimens fulfilled theoretical physiological principles but had no regards to patients concerns. Great strides have now been made towards ART regime simplification with one pill a day being a reality today and this has greatly improved adherence.

2.0 LITERATURE REVIEW

2.1 HAART adherence

Adherence to HAART can be defined as complying with the prescribed treatment plan. It's therefore highly dependent on the individual patient actions or inaction where they have more autonomy in defining and following their medical treatments compared with compliance which is a passive role that requires following the demands of the prescriber[8]. HAART's potential for long-term effectiveness is dependent upon maximum and sustained suppression of viral replication achieved by near perfect adherence. Several studies have indicated that HAART adherence levels lower than approximately 95 percent increases the chance of virological failure and promotes the development of resistant virus strains [9] [10] [11]. These required levels of adherence are much higher than what many people on therapy are achieving. The link between adherence and resistance also depends on the pharmacokinetics of HAART regimen. Studies that have been done on protease inhibitors show that an adherence rate between 90 percent and 98 percent demonstrated high rates of virological suppression [12]. Apart from evolution of HAART resistant strains, non adherence can result in the reduction of treatment options.

2.2 The association between HAART experience and adherence

Lars et al (2005) has shown that HAART adherence rates are typically higher among patients with acute conditions, as compared to those with chronic conditions with the non-adherence rates being highest for preventive regimens or patients who are asymptomatic [9]. In a study done in Kenya, only 51 percent of the cohort completed the full course of Post Exposure Prophylaxis regimen (PEP)[13]. While in Bangkok, 544 individuals who qualified for PEP, only 36.6 percent completed the full 28-day course[14]. The studies were mainly observational and the mean age was 16 years. Data describing other risky behaviours that the participants might have engaged in was also not available.

Studies by Ward et al. (1993) showed non-adherence in a third of the cancer patients monitored who had either missed or omitted prescribed doses for pain management which remains the main stay of palliative care in cancer[15]. Patient adherence may improve by helping patients have more control over their disease. There is limited research towards programs that focus on patient related barriers to management of chronic diseases. Adherence to medications among patients with chronic conditions is also disappointingly low, dropping most dramatically after the first six months of therapy[16] [17] [18]. In the United

Kingdom, a factorial randomized study indicated that among depressed patients started on tricyclic antidepressants (TCA) drugs, 40 percent of them dropped within 12weeks of starting therapy[19]. The study validated reported adherence rates with electronic however it was impossible to know whether there was selection bias.

The "white coat adherence" phenomenon has also been observed in patients with chronic conditions where the patients improve their medication-taking behavior in the 5 days before and after an appointment with the health care provider, as compared with 30 days after [17]. This gives an inaccurate picture of the actual adherence rates with self reports. Reasons for overestimation could include difficulty recalling the details of medication taking, attempting to please practitioners or to avoid confrontation, or a combination of these factors. Similarly, the patient's behaviour in cohort studies can alter when they are aware that someone is closely monitoring/observing them in what is referred to as the Hawthorne effect. These effects could greatly influence the reported and recorded adherence levels for the better especially when the information is collected by familiar care providers.

2.3 Predictors of Adherence

There are factors which are believed to be good predictors of non-adherence. These predictors of non - adherence vary greatly across populations and settings and no one factor has been consistently associated with non-adherence across all studies[20]. Simplification of therapy and the advent of the once daily dosing or twice daily but with a single pill has reduced the pill burden and eased adherence to a great extent. However, the effect of pill burden on adherence is closely associated with disease stage where the asymptomatic patients tend to take fewer pills compared to the symptomatic patients[21]. Additional predictors of adherence cited include, active substance or alcohol abuse, lack of education about HIV disease, untreated psychiatric disorders (e.g., depression, denial, anxiety, and personality disorders), side effects, poor patient-provider relationship, lifestyle, cognitive problems lack of social support and concerns about social stigma.

2.4 HAART adherence in women

Women and minorities are less likely to receive antiretroviral medications to treat HIV/AIDS. A study by Stein et al (1991) found that women, non-Whites, and injection drug users were half as likely as others to be offered antiretroviral therapy (in this case, AZT [Retrovir] monotherapy) [22]. Gender has inconsistently been associated with adherence and HIV-infected women may be an especially vulnerable population in need of improving adherence to antiretroviral therapy. Turner et al. (2003) found that women are less likely to adhere to

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HAART. However the study might have been confounded by differing socioeconomic status. A number of studies have shown, however, that women are more likely to succeed in taking and adhering to HAART when they have a longstanding patient-provider relationship and when they truly trust their provider[23]. It is helpful for care providers to identify the motivators in HIV positive women. Once their motivating factors are identified, women in treatment together with the health care worker should try to keep focused on them as women work to adhere consistently to their particular regimen. Women are more often than not impoverished and are more likely to do well on treatment when they are focused on their own health and quality of life or on relationships with important individuals in their lives such as children, partners, or other family members or friends. HIV- focused medical care in women has been found to improve adherence[24]. The study was done in developing countries and no studies that have been done in developing countries in women in focused care like the female sex worker.

2.5 HIV risk taking behaviour

HIV/AIDS still is associated with behaviors widely considered taboo, including sex work, drug abuse, and same sex orientations. Female sex workers (FSW) in many settings play a critical role as key drivers of the HIV/AIDS epidemic and also determine the course of HIV/AIDs epidemic in specific areas. In 2006 a survey done in Mali found that more than 35 percent of FSWs were living with HIV [25]. In Kenya, more than 33.5 percent of sex workers tested in Majengo clinic were found to be HIV-positive[26]. FSW are vulnerable to HIV infection because of their extensive sexual and social networking with the general public. Most FSWs have unprotected sexual contacts with multiple sexual partners who in turn have additional sex partners within the general population. A study of 64 clients of female sex workers in Nyanza province in Kenya revealed that clients were mostly married men, often with extramarital relations, who have a mobile or highly paid job or are in close contact with FSWs in their working situation[27]. Hence sex workers in Kenya have clients from all social strata, do not use condoms all the time and entertain multiple partners even on the same day. Commercial sex is therefore a complex socioeconomic transaction in the country that has been fueled by a booming tourism industry and poverty.

The FSWs however face violence, addiction, poverty, illness, disease, depression, and insecurity everyday and their lives are full of uncertainty [27]. For most FSWs, HIV and health might be of secondary importance compared with the need to earn some income for their upkeep and in turn, may infect their clients or regular sex partners. Most of them are on drugs to help escape the realities of their life circumstances, and on the other hand some drug users

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turn to sex work for financial need to support their addiction. This exchange of sex for drugs or money under the influence of drugs is a high risk encounter that can compromise judgment and ability to practice safe sex. Sometimes FSW are coerced into unsafe sex by a threatening client, or they may simply be offered more money to dispense without the condom. Condom use is thus erratic among sex workers and one study reports that condom use by FSW for all sexual liaisons was 79 percent in Kenya compared to 74 percent in Uganda[28]. In the same study, condom use with regular clients was reported as 51 percent in Uganda compared to 69 percent in Kenya. The number of sex workers reporting 100 percent condom use was 26.8 percent in Kenya and 18.9 percent in Uganda.

The potential for poor adherence to HAART by FSW could be attributed to the circumstances under which the sex workers work. Studies in women in the general population have associated adherence with alcohol use and abuse [24.] FSW may prefer to take alcohol and combined oral contraceptives (COC) at the expense of HAART. HAART has restrictions e.g. no alcohol use which may interfere with their sex work. Most sex workers operate at night for various reasons and this interferes with their ability to adhere to efavirenz based regimen that comes with alcohol as a contraindication. Other FSW take COC to avoid pregnancy or to help skip their monthly period. Conversely it's been found that there is a 29 percent decrease in levels of ethinyl estradiol and an 18 percent decrease in levels of norethindrone in women taking nevirapine while using a COC containing these hormones[29]. Cross-border mobility of sex workers also contributes to different exposure risks and FSW are likely to be non adherent to HAART as they change work locations spontaneously.

The illegal nature of sex work in Kenya forces sex workers to hide, which has the effect of cutting them off from society and keeping them from prevention and/or care services. Prohibitive legislation also affects the health, welfare, and self-esteem of sex workers. FSW are also stigmatized and their ability to form social support groups is hampered by stigmatization and legislation. These support groups play a big role in disclosure, treatment support and adherence. Poor networking hampers the formation of larger support system that FSW would use for economic protection and rights to safe work environments. It has been observed that the more control sex workers have over their lives, the more likely they are to develop self-esteem and the responsibility that comes with it. If they do not, they are more likely to be careless and thereby taking huge risks of being infected or infecting their partners with HIV and/or being non adherent to their HAART treatment.

Few studies have directly focused on adherence to highly active antiretroviral medication (HAART) in sex workers both males and females. This could be due to the fact that sex work is illegal and most studies are on preventive measures. The female sex workers may have unique barriers and facilitators to taking medication, and a deeper understanding of their adherence patterns could enhance intervention strategies.

2.6 Adherence measurement

Adherence is a critical determinant of the efficacy of medication but ideal measures of adherence still remain elusive. Many interventions to improve adherence have been tested but found to be complex and labour intensive with modest effects on clinical outcomes. Pharmacy databases can be used to check when prescriptions are initially filled, refilled over time, and prematurely discontinued. The disadvantage of this approach is that obtaining the medicine does not ensure its use. Liu et al (2001), found that while Medication Events Monitoring System (MEMS) underestimates adherence, pill count and patient self-reports both tended to overestimate adherence[30]. The study was a longitudinal cohort study in a public clinic. They found that a combined adherence score that used all three of the methods was better at predicting virological suppression but would be a logistics nightmare in our settings. However, the problem with patient self-reports is thought that it may be well rehearsed and hence patient recall still remains unreliable[31]. The standardized self-reported adherence assessment method continues to be used but the accuracy of these reports remains unknown. Intensive counseling and the involvement of people living with AIDS in community mobilization have helped overcome barriers to uptake and adherence to treatment in settings such as in Brazil and Khayelishta, Cape Town, South Africa[32].

Overestimation of adherence by patients is difficult to study and is presently poorly documented. Overestimation of HAART non-adherence could lead to unnecessary anxiety among care providers or use of HAART resistance testing. At times could lead to potentially unnecessary or harmful switches to the more expensive second line treatment. On the other hand, HAART non-adherent patients judged otherwise by their physician may receive inappropriate prescriptions and unnecessary investigations.

2.7 HAART adherence monitoring at the Majengo and SWOP clinics

Several studies regarding interventions to improve patient adherence have been performed in the general public but information on sex workers experiences remain limited. Studies involving sex workers in Vancouver have shown that peer driven intervention (PDI) have a positive outcome on adherence although the particular study did not predict long term

treatment success. The self-reported adherence was high at 92 percent and most women reported increased adherence from the first to the last PDI meetings attended[33].

The main methods used to monitor adherence at the Majengo and the SWOP clinic are pill counts and pharmacy refills. The patients are also urged during each visit to comply with prescribed HAART regimen. This occurs in stages with adherence counseling provided on an ongoing basis over time starting before ART initiation. Adherence counseling sessions classified as adherence one to three are provided focusing on different but specific issues on the treatment plan. Adherence (1) counseling takes place before ART initiation and provides general information on HIV, nutrition and emphasizes on attitude change by encouraging positive living. Adherence (2) is used to reinforce information provided in session (1) and to assess whether information provided in Adherence (1) has been understood or retained. The session also evaluates whether the patient who meets the HAART initiation criteria is ready to start treatment. Adherence (2) also provides information about HAART. Adherence counseling session (3) starts after the first two weeks of treatment and continues for as long as the patient is on treatment. These sessions assess whether information given in counseling Adherence one and two and follow-up has been understood or retained. In some of the sessions knowledge of basic ARV mechanisms of action, and attitude towards the life long treatment is also evaluated.

There is urgent need for programs that are designed to encourage and effectively monitor sex workers adherence to ART. This would go along way in preventing the acquisition and transmission of resistant HIV virus by ensuring high adherence levels to treatment among sex workers. The adherence level among FSW in Nairobi to HAART might be lower than what is documented during pill counts. Ignorance and types of lifestyles adopted by FSW ensures that their daily needs of food, shelter, addiction far exceed the need to address their health and HIV needs and chances of them adhering might be marred by many other factors.

No single study has given us a simple strategy that will work for every patient. In contrast, the studies done have shown that an individualized and flexible approach is essential for improving adherence. Lack of standardized method of monitoring adherence and evaluation of adherence intervention tools including counseling programs and other methods like directly observed therapy (DOT) methods might be needed to improve adherence [6]. Regrettably, adherence is the single most important factor affecting the success of anti-HIV therapy but this is ultimately under the patient's control. Due to the vulnerability and position that sex workers hold in HIV transmission, it would be imperative to evaluate and understand

their knowledge, attitudes, practices towards HIV/AIDs, HIV/AIDS management and adherence to HAART.

3.0 Justification

Adherence to HAART by FSW is important so as to reduce the viral loads to a minimum level preventing the spread of resistant HIV strains. Quinn et al (2000) has shown that there is a strong association between increasing serum HIV-1 RNA levels and an increasing risk of heterosexual transmission of HIV-1. The rate of transmission increased from 2.2 per 100 person-years to 23.0 per 100 person-years as the serum HIV-1 RNA level increased from less than 3500 copies per milliliter to 50,000 or more copies per milliliter[34] . Poor adherence among the sex workers would thus result to higher transmission rates and escalating the HIV prevalence in the country. This comes with other consequences such as increased costs for treatments in particular second line treatment due to the development of resistant strains. This scenario leads to other challenges as treatment failure is associated with increased morbidity and poor productivity and mortality.

The economic burden of HAART non-adherence, combining direct and indirect costs, is estimated to be as high as $100 billion annually[35]. Industrialized countries are becoming more preoccupied with the global economic crisis, sustaining the current levels of aid for health in developing countries might be a challenge. A high demand for second line treatments due to increased transmission of resistant strains would undermine the sustainability of ART programs. On the other hand, while it is known that peer driven intervention (PDI) has a positive outcome on adherence in female sex workers in Vancouver such information is lacking in the in the Kenyan population [36].

There is an urgent need to identify context-specific constraints to adherence and implement interventions to address them. Hence the findings of the study will be used to identify strategies that can help improve health care workers objective assessment of HAART adherence among female sex workers (FSW) and also to suggest ways of improving adherence levels to HAART. The information will be useful to other scholars doing studies in this area and for planning interventions and effective strategies for maximizing long-term adherence to ART for successful treatment of HIV and AIDS.

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4.0 Research Questions

1. Does intense adherence counseling improve knowledge, attitudes and practice towards HIV therapy among FSWs?
2. Does intense adherence counseling improve rates of adherence among female sex workers?
3. Are pill counts and self reporting from FSW patients' on HAART accurate measures of ART adherence?

4.5 Research Hypothesis

Current methods of monitoring ART adherence are not adequate in detecting true compliance with prescribed medications.

4.6 Objectives

4.6.1 Main Objective

To determine knowledge, attitudes and practices on HIV/AIDS and adherence to HAART among sex workers in Majengo and SWOP clinics.

4.6.2 Specific Objectives

1. To investigate the level of knowledge, attitudes and practices towards HIV/AIDS, and adherence to HAART
2. To compare adherence levels documented in the patients charts by facility care providers versus true adherence as verified through exit interviews
3. To describe strategies adopted by sex workers to maintain adherence after they are initiated on HAART
4. To identify factors that may influence adherence to HAART among FSW.

5.0 MATERIALS AND METHODS

The study was a mixed model comprising semi – structured interviews, support/focus group discussions and retrospective cross-sectional data review to generate both quantitative and qualitative data from the respondents.

5.1 Study site.

The study was conducted at the Majengo and SWOP clinics. The Majengo clinic is situated in Pumwani Majengo slums and enrolls educationally and economically disadvantaged women who resort to commercial sex work for a living. It also serves as a research facility that studies the epidemiology and immunobiology of STIs including HIV/AIDS. Majority of the sex workers at Majengo have been enrolled into the cohort through mobilization and peer-led networks. The SWOP clinic on the other hand targets street based FSW operating within the Central Business District (CBD) and it is located within the CBD to improve access. The clinic has an active mobilization and demand creation team that utilizes peer educators to reach out to the FSW. Hence, majority of the sex workers enrolled at the site were referred through the peer educators' networks although a few are also self –identified FSWs who voluntarily visit the clinic for services on offer. Those who enroll at both sites access STI/HIV information, continuous free counseling sessions on risk reduction and adherence to therapy, screening of HIV and other STIs, treatment of STDs, management of HIV/AIDS including ART provision and follow-up. All clients also access free condoms and water based lubricants.

5.2 Study Variables

1. Dependent variable was Adherence to HAART treatment obtained at the face to face interview.
2. Independent variables were: age, marital status, level of education, duration as a sex worker, condom use, duration on HAART, medication side effects, attitude and perceptions, disclosure, support group membership and alcohol use,

5.3 Definitions for the study

1. HAART Experienced - Patients who have been continuously on HAART for more than 12 months.
2. Short Experienced on HAART - Patients who have been on HAART for less than 12months

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3. Adherence - The percentage of prescribed doses taken during the 4-week period with 95 percent adherence rate being the standard.

5.4 Target population

FSWs on ART at two clinics in Nairobi, the Majengo and the SWOP clinics were identified and interviewed.

5.6 Inclusion criteria	5.7 Exclusion Criteria
• Each participant must have had HIV prognostic indices (CD4 cell count, U/E, LFTs) measured before the first combination ART prescription. • Be on HAART for more than one year for the experienced and for less than twelve months for the shot experienced participants. • Accessing HAART at either Majengo and SWOP clinics	• Those who are not on HAART or enrolled for HIV care and management at other sites.

5.8 Recruitment procedure

The FSW were randomly selected as they visited the clinic. Those on ART have scheduled visits that follow the UOM/UON program schedule although unscheduled visits are not restricted. Developing a sampling frame (i.e. lists of all the patients on HAART) from which to draw a random sample was not generally feasible. As such, we enrolled every eligible client over a block of time (i.e. one month) to decrease any systematic bias. During the enrollment period any participant who met the enrolment criteria had a 100 percent chance of being sampled. The participants were recruited as they came to the clinics for various reasons such as routine refill and care. The female sex workers have the two clinics as their major source of health care services. Rapport between the healthcare workers and the FSW is high and none of the FSW declined to be interviewed. Face to face structured interview was carried out at the clinics as the participants left the last point of care, the pharmacy. The data was collected using a questionnaire which was completed confidentially in the absence of clinic pharmacy staff, nurses or the doctor. The participants were classified as naïve and

experienced depending on their duration on treatment. One support/focus group discussion at each site on HIV management and adherence was conducted to generate additional data enriched through the group dynamics. The groups had a maximum of 15 FSW and the duration of each session was kept under 2 hours.

5.9 Data Abstraction

Data on socio demographics, clinical profiles and adherence to HAART among the sex workers is collected routinely at the two clinics and entered into a database. In addition results from blood samples taken for HIV status, CD4 counts and other monitoring tests are also managed and stored in the same database. The information is collected using standardized questionnaires and informed consent obtained at enrolment. The tools used at the two clinics are comparable to the ones used in Government facilities (MOH 257). The differences are in coding for adherence where on the MOH 257 form, adherence is satisfactory; greater then or equal to 95 percent or unsatisfactory; less than 95 percent. The MOH 257 form also has codes on reasons for unsatisfactory adherence. The huge data is entered into an access database and managed centrally to maintain confidentiality. The data abstraction covered a 12 month period from October 1st 2008 to September 31st 2009.

The Socio-demographic information such as age, duration in sex work, marital status, and education level was abstracted. Data on CD4 cell count, types of ARVs the patients were taking was also obtained. The pre-ARV initiation CD4 cell count and the most recent CD4 count over a period of October 1st 2008 to September 31st 2009, was also collected from each patient's database record and compared with refill adherence rates. Information on duration of treatment was obtained as well to help classify the patients as experienced or short experienced. This was then linked with patient recorded ART adherence rate to HAART during the day of the interview.

The study also involved face to face (FTF) semi- structured interviews using a questionnaire. The questionnaire investigated knowledge about HIV, the current HAART regimen, reasons for non-adherence, reasons for delay in taking medication, medications reminders, beliefs about treatment, interruptions in drug supply, perceived health status and satisfaction with health care (visual analogue scale ranging from 0 (lowest satisfaction) to 10 (highest satisfaction).)

The FTF and Focus Group Discussions were documented verbatim. The additional notes (verbal and non-verbal expressions) were typed out. To check for validity of the information

gathered, a triangulation method was used where an independent transcriber trained in Research Ethics read the transcripts to minimize reporting bias.

Standardized self-reported adherence assessment methods are generally popular but patients are known to overestimate adherence [15]. Hence, face to face interviews and the support/focus group discussions provided a better understanding of the views and experiences of the patients taking HAART and thus helped explain the context in which adherence and non – adherence occurs. Therefore, this complementary quantitative and qualitative approach was used because of its obvious advantages.

5.10 Sample size estimation

Sample size calculation in a cross sectional study is based on the assumption that the test that estimates this proportion is perfectly sensitive and specific, but the calculation can also assume the proportion estimated is the apparent (test-based) prevalence.

The standard statistical approach to determination of sample size for a (descriptive) cross-sectional survey such as this one requires specification of an estimate percentage adherence among the sex workers to be estimated; the desired level of confidence desired for the proportion estimate; and a tolerance error margin or width of the confidence interval (a measure precision of the estimate), so that the necessary sample size is then calculable for a given precision level.

The sample size formula below was then used to estimate the sample size.

$$n = \frac{z^2 \hat{p}(1-\hat{p})}{m^2}$$

Where:

p = expected prevalence or proportion or an estimate percentage adherence among the sex workers that was estimated by the study.

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

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

For a 95percent CI, z=1.96

For this study, we specified the level of confidence as 95percent, an error margin of ±5percent as being considered acceptable and from a past study in Majengo clinic it had been estimated that 84percent of female sex workers adhere to their medication regime.

Using the above formula

$1.96^2 * 0.84 (1 - 0.84) / 0.05^2 = 207$

$n \approx 210$

Adjusted sample size

Numbers of patients expected at that duration of the study = N = 410

$nf = n / (1+n/N)$

$210 / (1+0.5) = 140$

Therefore $nf =$ 140 patients

5.11 Quantitative data Analysis plan

Medical records provided the demographics, risk taking behaviors, clinical profiles and outcomes, CD4+ cells counts at baseline, average increase in CD4+ cell counts, average adherence based on pill counts for most patients on HAART. Data extracted was entered into a Microsoft Access database and imported to SPSS for analysis. The data was cleaned for errors and inconsistent (conflicting) answers, missing entries and duplicate entries to ensure high quality data.

Descriptive statistics on socio-demographic characteristics (age, gender, marital status, education level, average monthly income etc) was presented to characterize the study participants. Summary statistics for the measurement scale was used to describe distribution of these variables. The characteristics of study data was described using, counts, means (± standard deviation), median (continuous variables) and proportions (categorical variables. These summary statistics were then presented in tables.

For the formal statistical inference, univariate analysis using a Pearson chi-square test of independence was done. The comparison groups were between short experienced patients and experienced patients, between Face to Face adherence rates and same date clinic record

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adherence rates and between the baseline factors with adherence. Covariates were considered if they were associated with adherence. Logistic regression was fitted to assess factors associated with adherence to HAART among female sex workers accessing HIV care in the two clinics. The comparison between face to face adherence rates and same date clinic adherence

5.12 Qualitative data analysis

Data analysis followed a Framework Analysis method. Analysis involved the following key stages as suggested by Ritchie and Spencer (1994)[37]: familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation.

1. Familiarization: interview transcription, reading and re-reading.
2. Identifying a thematic framework: Developing categories from the ideas or concepts arising from the texts.
3. Indexing: sifting the data, highlighting and sorting out quotes and making comparisons both within and between cases.
4. Charting: developing thematic charts.
5. Mapping and interpretation: searching for patterns, associations, concepts and explanations in data for observations

5.13 Ethical Issues and Confidentiality

Informed consent is obtained at enrolment and the existing database had received Kenyatta National Hospital Ethics approval, approval numbers P258/09/2008 for use of the database while the face to face interviews and the focus group discussion received additional ethical approval, number P270/09/2009. The face to face interview and support/focus group discussions were conducted in a location that afforded privacy to the clients. The participants were assured of their anonymity to ensure co-operation, therefore no reference was made to specific patients in the reports. There was no directly identifiable mark on the questionnaire. All collected data was kept in a locked drawer and only handled by qualified staff trained in Ethics. Informed consent was sought from all the study participants.

5.14 Risks to patients

The participants in the study did not anticipate direct harm by participating in the study. The main risk was the possible loss of confidentiality as being involved in the study was a form of self disclosure of their sero-status and ARV use.

6. 0 RESULTS

6.1 Descriptive Statistics

6.1.1 Patients Characteristics

156 patients were interviewed and their clinic data from the last ART management visit abstracted over the period covering October 1st 2008 to September 31st 2009. The mean age of the respondents was 39 years and a median (IQR) 38 (34.25-44). The average age at start of prostitution was 28years. The mean duration in prostitution was 10years and the median (IQR) 9 (4-15). 87 percent of them were still active in sex work. Among the respondents interviewed, 51.6 percent were naïve in ARV treatment and 47.8 percent were experienced. Refer to results on Table 1.

Table 1: Patient Characteristics

	N	Percentage
Age group		
<25	4	2.6
26-35	49	31.4
36-45	79	50.6
>45	24	15.4
Marital status		
Single	58	37.2
Widowed	18	11.5
Separated/Divorced	77	49.4
Education level		
None	9	5.8
Primary	113	72.4
Post primary	33	21.2
Duration of years as FSW		
<10	83	53.2
11-20	55	35.3
>20	18	11.5
Experienced and short experienced on ARVs		
Short experienced	81	51.9
Experienced	75	48.1

Condom use

80 percent of the respondents always used condoms with their clients while 1percent never used condoms. Refer to Figure 1.

How often do you use condoms with your clients

1% 2%

17%

□ Never 0%
■ Sometimes <50%
□ Most of the time >50%
□ Always 100%

80%
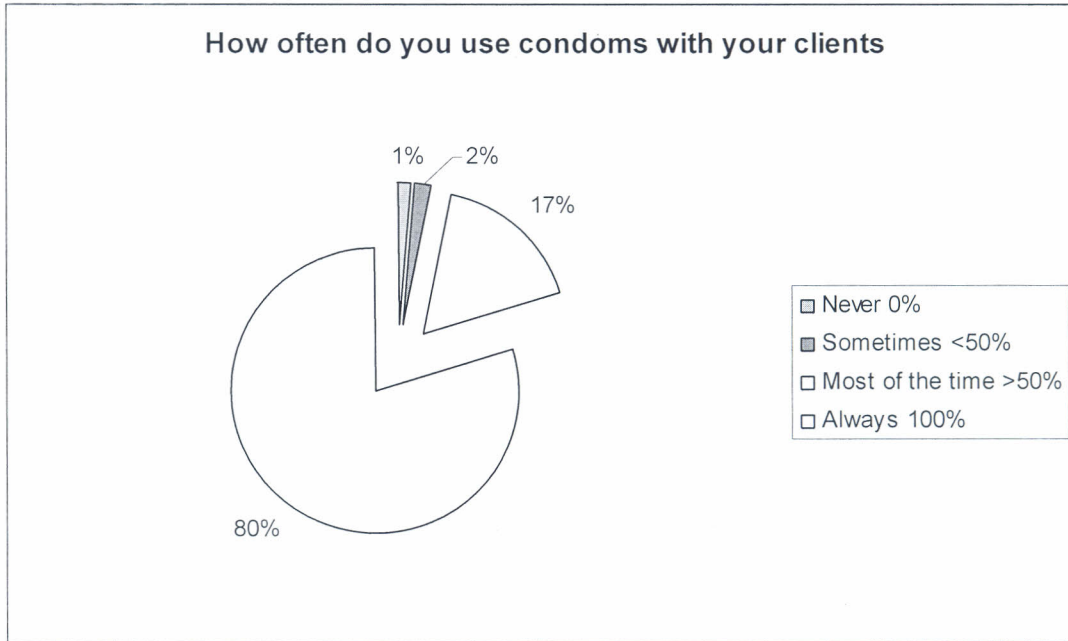
Figure 1: Distribution of respondents condom use with clients

6.2 Knowledge

Knowledge of mode of HIV transmission

62/156 of the respondents mentioned two modes of HIV transmission, 1/156 mentioned six modes while 24/156 of the respondents mentioned one mode of HIV transmission. All the respondents, 100 percent, knew that HIV is transmitted through unprotected sex while 13 percent knew that it can be transmitted through mother to child. Refer to Figure 2.
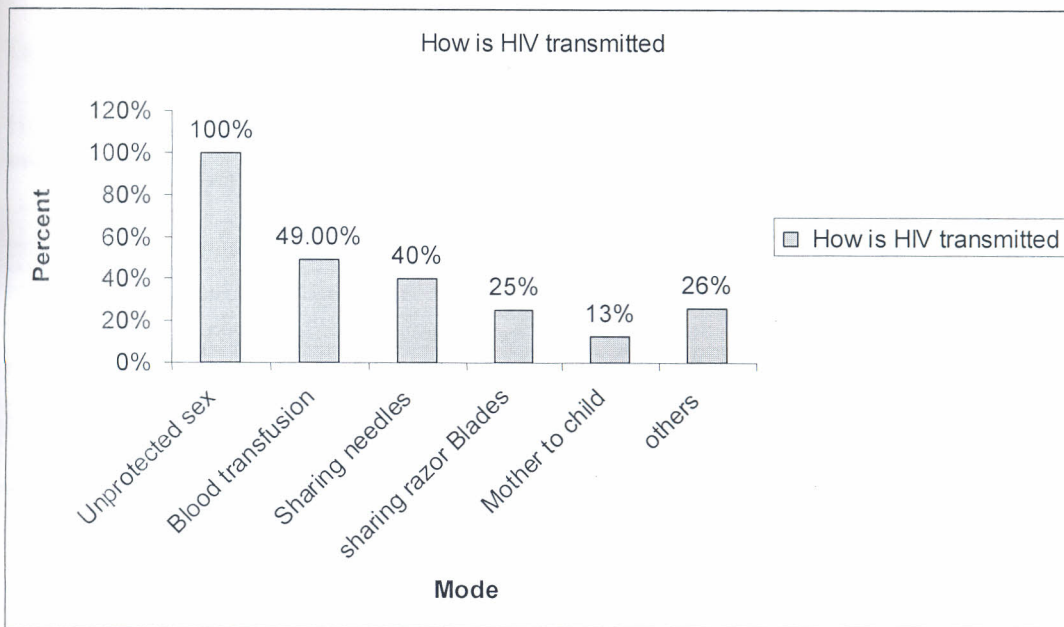
Figure 2: Distribution of respondents according to response given on how HIV is transmitted

Knowledge about how the ARVs work.

Majority of respondents, 60.4 percent knew that ARVs inhibit multiplication of the viruses and therefore reduces the viral load. 22.1 percent of respondents said that ARV treatment improves immunity while 5.2 percent said ARV treatment kills the viruses. 1.3 percent of the respondents said that the ARVs kill the viruses and hence prolong life. 9.7 percent of the respondents gave other reasons a to how the ARVs work and these included They fight the viruses and make one healthier, prevents one from getting other opportunistic infections, prevents opportunistic viruses from entering the body, prevents opportunistic viruses that will cause more infections from entering the body. Only 1.3 percent of respondents said they didn't know how the ARVs work. Refer to results on Table 2.

Table 2: Distribution of respondents suspected modes of ARV action

How do the ARVs you are taking work?	N	Percent
Doesn't know	2	1.3
Improves the immunity	34	22.1
Inhibits multiplication of the viruses	93	60.4
Kills the viruses	8	5.2
Others	15	9.7
The ARVs fight with the viruses killing them and hence prolonging life	2	1.3

Knowledge on what they should do incase they miss doses

29.9percent of those interviewed knew that three hours should not elapse before one has taken the ARVS. 11.0percent of the respondents said that they would take the missed pill when they remembered. 1.9percent said that they would report to the doctor any missed pills but take it when they remember followed by the next dose 12hours later. 16.2percent of the respondents reported that they would skip the entire dose irrespective of the length of delay while 13.6percent did not know what they would do incase they missed a dose. Refer to results on Table 3.

Table 3: Distribution of respondents according to advice given incase one misses doses

What were you advised to do in case you miss a dose?	N	Percent
An hour or less should not elapse	7	4.5
Doesn't know	21	13.6
Doesn't remember	4	2.6
More than 3 hours should not elapse	7	4.5
Other	3	1.9
Skip the dose	25	16.2
Three hours should not elapse	46	29.9
Two hours should not elapse	24	15.6
You can take the pill anytime one remember	17	11.0

Knowledge on what one should do incase they vomit the pill.

Majority of the respondents, 39 percent knew that once they vomited and the pill was visible, they could take another pill while 38.3 percent did not know what to do incase they were to vomit the pill. 13percent had other ideas on what to do incase they vomited the pill. These included; not take another because the pills have been counted and to make sure one goes to see the doctor. Refer to results on Table 4.

Table 4: Distribution of respondents according to what they should do incase they vomit the pill

What should you do if you vomit the pill?	n	Percent
does not remember	1	.6
Doesn't know	59	38.3
Others	20	13.0
Take another pill if it's visible in the vomitus	60	39.0
You should not take another pill	14	9.1

6.3 Practice

How the patients ensure that they take medications as instructed

Majority of the respondents, 40.9percent ensure that they take medications as instructed by setting the alarm on their phone. 12.3percent reported experiencing a discomfort just before the time that they are scheduled to take their dose and/or get a somatic symptom that reminds them to take the pills. 5.8percent of the respondents have synchronized the timings for taking the medications with their normal routines. Refer to results on Table 5.

Table 5: Distribution of respondents according to medication reminders

How do you ensure that you take your medication as instructed?	n	Percent
Being reminded by people close to her	17	11.0
Constantly checking her watch	26	16.9
Has been taking other chronic disease medications	1	.6
Conditioning and by experiencing a discomfort just before time	19	12.3
Listening to radio or watching the television	19	12.3
Setting the alarm clock on the phone	63	40.9
Synchronizing timing with daily activities	9	5.8

Delay in taking the pills.

Only 21percent of the FSW never delay taking their medications. Out of the ones who delay, 70percent of them take the pill so long as the delay is less than 3hours while 7.8percent will take the pill with no regards to the duration of delay. Refer to results on Table 6.

Table 6: Distribution of respondents according to actions they do when they have delayed to take the pills

What do you do if you delay taking the pills?	n	Percent
Those who do not delay taking pills	21	13.6
Alter the timings for the next scheduled dose	4	2.6
Others	6	3.9
Skip the entire dose	3	1.9
Take the pill so long as the delay is less than 3hours	108	70.1
Took the pill with no regards to the delay	12	7.8

What do you do if you miss a dose?

20.8 percent of the respondents have never missed a dose since they started taking HAART. Of those who reported missing a dose, 54.5 percent of them took the next dose as scheduled while 1.3 percent took the same pill when they remembered. Refer to results on Table 7.

Table 7: Distribution of respondents according to actions when missing treatment dose(s)

Action when they miss doses	n	Percent
Have never missed a dose	32	20.8
Others	19	12.3
Report to the clinic	17	11.0
Take the next dose as scheduled	84	54.5
Take the same pill when they remember	2	1.3

6.4 Attitude

About 70percent of the sex workers have disclosed their use of ARVs to someone else. The respondents who had not disclosed were 29.2percent. 23.4percent did not want to disclosure because they were afraid of being stigmatized. 4.5percent were still in denial and had not accepted their status. Refer to results on Table 8.

Table 8: Distribution of respondents according to reason(s) for not disclosing their use of ARVs to someone else

Why they have not disclosed	n	Percent
Disclosed	109	70.8
Because of anger	1	0.6
Still in denial	7	4.5
the only person she would have told was her boyfriend and currently is away	1	0.6
To avoid being stigmatized	36	23.4

Why did the respondents disclose their use of ARVs status?

70.8percent of the respondents had disclosed their status and taking the ARVs to members of their family and friends. 27.3percent disclosed so that they can be able to get help when they need it. 20.1percent disclosed to encourage other who were either starting ARVs or had just been tested positive for HIV. Refer to results on Table 9.

Table 9: Distribution of respondents according to reason(s) for disclosure of their ARVs use

Why Disclosure	N	Percent
Not disclosed	45	29.2
Needed to open up and share because she trusts them	21	13.6
Others.	4	2.6
They got to know by default, not by choice but other circumstances.	11	7.1
To be able to get help when needed	42	27.3
To inform, encourage others and make them aware of HIV	31	20.1

6.5 Face to face reported ART adherence versus Clinic records

From the face to face interview, 85.1percent of the respondents had a perfect adherence while 2.6percent had their adherence rate less than 80percent. Refer to figure 3.
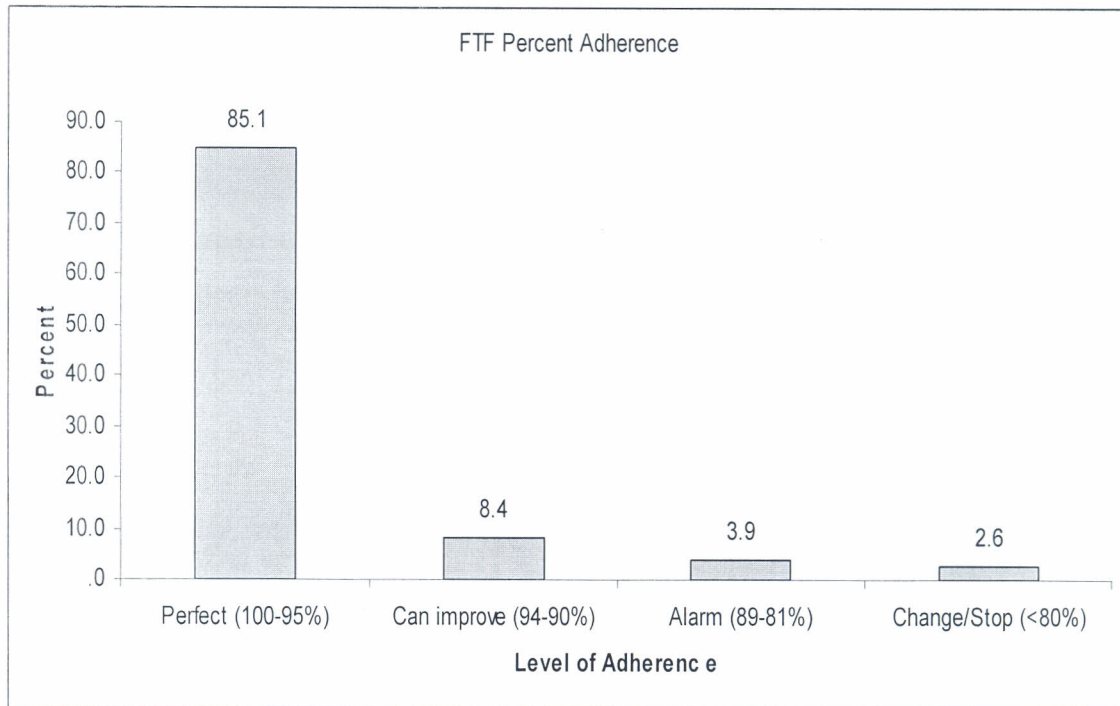
Figure 3: Distribution of respondents according to adherence to HAART

Comparing the adherence levels

Median antiretroviral adherence rate differed between the two adherence measures. The same date clinic record adherence was 98.43percent and the face to face adherence rate was 97.42percent. There was a significant disparity (p=0.002) between the two measures in terms of the adherence levels. 120 respondents had a perfect adherence as per FTF adherence but as per the clinic record, 11 of the 120 had an adherence rate between 94-90percent. Refer to results on Table 10.

Table 10: A comparison between FTF adherence and same date clinic record adherence

		Clinic record adherence rate			
		Perfect (100-95%)	Can improve (94-90%)	Alarm (89-81%)	Change/Stop (<80%)
FTF Adherence	Perfect (100-95%)	120	11	3	1
	Can improve (94-90%)	7	3	2	0
	Alarm (89-81%)	2	1	2	0
	Change/Stop (<80%)	3	1	0	0

P-value =0.002

Among the respondents who were ARV short experienced, 90.1 had a perfect adherence while those who were experience, 82.7percent had a perfect adherence. There was no significance between the FTF adherence and duration on ARVs. Refer to results on Table 11.

Table 11: A comparison between FTF adherence levels and experienced and short experienced patients in HAART

| | | Experienced and naïve in ARVs | |
		Naïve	Experienced
FTF Adherence	Perfect (100-95percent)	73 (90.1%)	62 (82.7%)
	Can improve (94-90percent)	5 (6.2%)	7 (9.3%)
	Alarm (89-81percent)	1 (1.2%)	4 (5.3%)
	Change/Stop (<80percent)	2 (2.5%)	2 (2.7%)

P-value =0.079

6.6 Univariate Analysis

There were only two factors that were found statistically significant in influencing adherence to ARVs. These are taking alcohol (P= 0.032) and remembering to take medication (P=0.05). Refer to Table 12 for results

Table 12: Correlates of Adherence

		Adherence		P-value
		No	Yes	
Education Level	None	1	8	
	Primary	15	98	
	Post primary	5	28	0.939
Marital status	Single	9	49	
	Widowed	1	17	
	Separated/Divorced	10	67	0.549
Age group	<25	1	3	
	26-35	8	41	
	36-45	9	70	
	>45	3	21	0.774
Experienced versus short experienced in ARVs	Short experienced	8	73	
	Experienced	13	62	0.173
Have you experienced any of these side effects since you started taking the ARVs?	No	11	67	
	Yes	10	68	0.815
Do you take alcohol?	No	10	96	
	Yes	11	39	0.032
Have you ever been given the wrong ARV medications from the clinic?	No	21	134	
	Yes	0	1	0.692
Duration in years as FSW.	<10	14	69	
	11-20	6	49	
	>20	1	17	0.35
How hard or easy is it to remember to take Medication?	Very hard	2	1	
	Hard	3	19	
	Easy	15	102	
	Very easy	1	12	0.05
Average Monthly income	<10000	17	100	
	10001-20000	2	24	
	>20000	1	7	0.647
Are you a member of any support group?	No	16	93	
	Yes	5	42	0.498
Have you ever disclosed to anyone that you are on ARVs?	No	5	42	
	Yes	16	93	0.498
Have you ever disclosed your HIV status to anyone?	No	5	41	
	Yes	16	94	0.54

7.0 DISCUSSION AND CONCLUSION

7.1 Discussion

Measurement of adherence to HAART between studies is fraught with many obstacles including differences in study population and design, socioeconomic factors, definition and measurement of adherence, as well as differences in sample size[10]. Nevertheless the same date clinic record mean adherence rate was 98.4 percent while the face to face interview mean adherence rate for the respondents was 97.4 percent. This was relatively high compared to findings of a study in African countries on HIV- patients among whom ART adherence was 77 percent while those in developing countries was 55 percent. [38]. The study had omitted specific populations such as drug users and homeless individuals. The high mean adherence rates could be attributed to the intense counseling that the patients get at the clinics. Availability of stocks in the clinic could also play a role. All the respondents reported that they had never missed ARVs and hence had confidence with healthcare facility.

We had hypothesized that the current methods of monitoring ART adherence are not adequate in detecting true adherence with prescribed medications. From the study there was disparity between the adherences rates recorded during the face to face interviews compared to same day adherence rate recorded by clinic staff through pill counts. There was a significant difference ($p=0.002$) between the face to face adherence rates and that of the same date- clinic record adherence rates. Previous studies by Liu et al (2001) have shown that pill counts tend to over estimate or under estimate adherence and there is no gold standard way of evaluating adherence. Patients who are aware that pill counts are being conducted might engage in "pill dumping" to appear adherent. The simplest and most practical suggestion for Clinician's is to ask patients non-judgmentally how often they miss doses. Patients generally want to please their physicians and will often say what they think their doctor wants to hear. And it's possible that the patients cheat the providers by pill dumping. Missed pills or the return of excess pills provides tangible evidence of non-adherence and clinicians should not be lulled into complacency by the high adherence rates.

Among the respondents, 90 percent of the short experienced patients had perfect adherence while 82.7 percent of the experienced patients had a perfect adherence. Duration on treatment had no statistical significant influence on adherence rates. None of the socio-demographic, socioeconomic factors were associated with adherence levels.

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Respondents demonstrated substantial knowledge about ARVs. However, no significant association existed between knowledge about ARVs and adherence. In the focus group discussion some of the respondents had this to say; For the ARV names;

"That's the first thing you are told to know by the doctor."

" Pronouncing the names is the problem, but if they are in a box and a container, I can comfortably identify them. "

"When I'm being dispensed for the drugs, I have to confirm the drugs. If I see that they are different in any way from the last ones that I got during refill, I always ask the nurse whether the drugs are the same. She always tells me that the drug is the same but the difference is the manufacturing company. "

"They said it's important to know the names because you can go somewhere and forget to carry your medication and you can always enter a government hospital and be given some pills so long as you know the names of the drugs."

Some authors argue that there are no predictors of adherence to medication, while others proffer indicators of likely adherence. Despite the respondents knowing how the ARVs work and the importance of adherence, there were other factors like personal barriers and attitudes that played a role in adherence. Among the respondents who had not disclosed, 16/156, were afraid off being stigmatized. However there was no significance between adherence and disclosure. We did not control for all the potential confounders that could confound the association between adherence to antiretroviral therapy and disclosure such as social networks. From this study 94/110 of the respondents who had disclosed, 85.5 percent of them had adhered while 41/46 of the ones who had not disclosed, 89.1 percent had adhered to HAART. Among the respondents who were members of a support group, 89.4 percent had adhered to their medication. Privacy and confidentiality may obstruct efforts to bring female sex workers women together in support groups. The FSW lack self esteem and because of the prohibitive legislation in prostitution they are unwilling to join support groups. These support groups act as disclosure avenues. Some of the respondents interviewed said they were afraid of disclosure because other FSW would use the information they have to compete for their regular clients. Involving sex workers directly in HIV management can raise their self-esteem and empower them, thereby encouraging them to look after their health and to access services that could help them.

Among the respondents who take alcohol (32.1 percent), there was a statistical significant difference in the adherence levels compared to those who didn't take alcohol (p= 0.03). Studies about barriers to antiretroviral adherence did not report substance abuse as an important factor while other instruments were not asking about the effect of drugs and alcohol [20]. Despite 98 percent of the respondents knowing that there exists an interaction between alcohol use and ARVs, the FSW find it hard to stop taking the alcohol. From the focus group most of the participants agreed that their profession requires one to take alcohol. Some said that;

"You are advised not to take alcohol but when you go to the club, you need to feel a bit high so that you can get the guts to approach a client. Sometimes the client insists you have a drink, how will you refuse? You can even exchange the drink for money later.

"If you don't take alcohol the client will think that you want to steal from them or you have drugs that you want to put in his drink. They can change their mood once they know you do not want to take alcohol."

"You could be waiting for a client and you have to order a drink because most clubs will not allow one to sit idle or take sodas. They chase you even when you are taking the sodas. "

"Sometimes you take the pills then take the alcohol, you get a client and you have to travel out of town. The condom might burst and of course you are too drunk you forget to take the morning dose."

From the focus group discussions alcohol was used as a disinhibitor and a sex facilitator. Intoxication, be it on single occasions or regularly, leads to reduced self control and difficulties to follow up routines and duties.

The relative odds ratio of adhering to HAART among the patients who found it hard to remember to take medication was 0.04 (95 % CI 0.002 – 1.001) compared to those who found it very hard to remember to take their medication. These results are similar to other interview studies of barriers to adherence where respondents acknowledged the enormous burden of remembering to take HAART[20]. Malcolm et al (2003) found that patients with perfect adherence to HAART differ from their less adherent counterparts in terms of key health-related attitudes and beliefs[39].

The respondents had adopted certain behaviours to ensure they adhere to their medications. Most of them set alarms to remind them at the scheduled time (40.9 percent) while others conditioned themselves to remember to take the medications or even synchronized their daily routines with the medication timing schedules. The respondents who set alarms as medication reminders, 85.3 percent had adhered to their medication. A study to assess the efficacy of 2 adherence interventions, medication managers (MM) and medication alarms (ALR) found that more frequent contact and social support provided by MM intervention resulted to better ART adherence compared with alarm intervention [40]. This was a longitudinal cohort study in a public clinic and they only had an intermittent measure of self report adherence that may have missed early or late adherence.

From the focus group discussions, the respondents had different ways of reminding themselves. "I have a bottle that I put water for taking the medications and once I have taken, I leave it half full until the next scheduled dose when I'll top it up after I have taken the medication." Another respondent had this to say; "I have a weakness, where I cannot take these pills without having eaten something. So I set my timings to 11am and at that time I will have taken breakfast."

27.3 percent of the respondents, who had disclosed their status, did so in-order to get help with their medications when they are sick. One of the respondents who had disclosed to the sister said, "She gives me morale. I used to forget to take the drugs when I was starting and she used to call me to find out whether I have taken the drugs"

The study was based on recall of activities happening over a four weeks period for the adherence rate calculation and this could have introduced a recall bias. Our sample size was relatively small, and hence the findings cannot be generalized. However, this study is unique in employing the two analytic approaches to examine the range of issues that affect adherence. The measurement and definition of adherence to antiretroviral therapy may have introduced bias since there is no gold standard for measuring adherence to antiretroviral therapy. The type of regimen patients were taking could have had an impact on their adherence and hence distorted our estimates. The effect modifiers that would have affected the results include duration on sex work and presence of other chronic illness such as hypertension.

7.2 Conclusion and Recommendations

Factors beyond poverty play an important role in adherence among FSW. It was found that adherence was more related to attitudes about health and illness and alcohol than to other factors. Given the relatively high levels of adherence in the FSW documented in this analysis, the priority must now be to maintain these ART adherence rates by increasing the support group membership and frequency of these meetings. The patients', who do not disclose their HIV status due to fear of stigma, will need other adapted innovative adherence support mechanisms. Care adherence interventions should include assessment of patients' attitude toward medication and their health beliefs. Clinicians should assess for alcohol problems, link alcohol use severity to potential adherence problems, and monitor outcomes in both alcohol consumption and medication adherence. Continuous operational research on adherence should be done since adherence is dynamic. Studies involving two day and five day recall can be done to obtain the optimal adherence. The sample size does not represent all the levels of sex workers in Kenya and it would be interesting to do the study in a multi-center study involving various categories of sex workers.

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[40] Sharon B .M., Morse E., Malts J.P., Adrew L., Child C., Schmelter B. (2006). Sustained Benefits from a long-term antiretroviral adherence intervention.

Risks

I am asking you to share with me some very personal and confidential information, and you may feel uncomfortable talking about some of the issues. You do not have to answer any question or take part in the discussion if you don't wish to do so, and that is also fine. You do not have to give me any reason for not responding to any question, or for refusing to take part in the interview.

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about how to improve the adherence counseling sessions.

Confidentiality

The information that we collect from this research project will be kept private. Any information about you will be reported anonymously and no names will be used.

You can ask me any questions about any part of the research study, if you wish to. Do you have any questions?

Whom Do I Call if I Have Questions or Problems?

For questions about the study or a research-related injury, call or contact Dr Josephine Wahito, UNITID, University of Nairobi, Tel: 020 2726765.

For questions about your rights as a research participant, contact Professor Bhatt, who is the chairperson of the Ethical Review Committee at the University of Nairobi, by calling 2725452, or make an appointment to see her in the Department of Medicine, at the University of Nairobi.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Name of Participant_____
Signature of Participant _____
Date _____
Signature of Researcher /person taking the consent_____
Date_____

ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY AMONG FEMALE SEX WORKERS ACCESSING HIV CARE IN TWO CLINICS IN NAIROBI, KENYA

"A KNOWLEDGE, ATTITUDES AND PRACTICES STUDY"

Date: _____

Face to Face Exit Interviews

Participant's Identification No   _____

Name of Clinic   _____

Knowledge

1. How is HIV transmitted?

2. How often do you use condoms with your clients?

☐ Never – 0percent
☐ Sometimes -<50percent
☐ Most of the time ->50percent
☐ Always – 100percent

3. Is there a cure for HIV/AIDs?

☐ Yes
☐ No

If Yes – Specify: _____
_____

4. What was your CD4+cell count when you started ARVs? _____

5. What is your current CD4+ cell count? _____

6. Please name the ARVs that you are taking? _____

7. How many times per day are you expected to take the ARVs? _____

8. How do the ARVs you are taking work in your body?

9. What are some of the possible side effects of the ARVs you are currently taking?

10. Have you experienced any of these side effects since you started taking the ARVs?

☐ Yes
☐ No

11. Do you take alcohol?

☐ Yes
☐ No

12. Is there any interaction between your ARVs with alcohol or street drugs?

☐ Yes
☐ No

13. For how long will you be on ARVs?

14. What **were you advised to** do in case you miss a dose?

15. Why should one on ARVs try their best not miss any doses?

16. What should you do if you vomit the pill?

Practice

17. What time have you been taking your medications in the last 72 hours (3days)?

18. How do you ensure that you take your medication as instructed? **(Probe)**

19. How many tablets were you given during the last visit?

20. How many tablets did you **honestly** miss from the last visits refills?

FTF Adherence	Same Date Adherence- clinic Records

21. Have you delayed to take the pills in the last one month?

☐ Yes
☐ No

22. What do you do if you delay taking the pills?

23. Have you forgotten to take the pills in the last one month?

☐ Yes
☐ No

24. If yes, what were the reasons for missing the pills?

25. If no, when was the last time you forgot to take the pills?

26. What do you do if you miss a dose?

27. Have you ever disclosed your HIV status to anyone?

☐ Yes
☐ No

If yes, to whom did you disclose to? _____

28. Have you ever disclosed to anyone that you are on ARVs?

☐ Yes
☐ No

If No – Why? _____

If yes,   i) To whom did you disclose to?_____
           ii) Why did you share that information?_____
           _____
           _____

29. Are you a member of any support group?

☐ Yes
☐ No

30. Why did you join the ART support group?

Please rate the following questions:
31. How hard or easy is it for you to:

   a) Remember to take your medications   -----------------------
   (Very hard, hard, easy, very easy)

   b) Take ARVS that are hard to swallow or taste bad -----------------------
   (Very hard, hard, easy, very easy)

   c) Take medications when your routine changes   -----------------------
   (Very hard, hard, easy, very easy)

   d) Take medications when feeling bad emotionally -----------------------
   (Very hard, hard, easy, very easy)

   e) Take medications when feeling bad physically   -----------------------
   (Very hard, hard, easy, very easy)

32. Does planning your life around the ARVs frustrate you?

☐ Yes
☐ No

Explain:

33. Does the idea of taking the ARVs for life frustrate you?

☐ Yes
☐ No

Explain:

34. Do you hate the drugs as they remind you of your HIV infection?

☐ Yes
☐ No

Explain:

35. Have you ever missed ARV drugs from the clinic?

☐ Yes
☐ No

36. Have you ever been given the wrong ARV medications from the clinic?

☐ Yes
☐ No

37. How would you like the Adherence counseling services improved at this clinic?

38. How would you rate the general services at this clinic on a scale of 1 to 10? _____

ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY AMONG FEMALE SEX WORKERS ACCESSING HIV CARE IN TWO CLINICS IN NAIROBI, KENYA

"A KNOWLEDGE, ATTITUDES AND PRACTICES STUDY"

Support/Focus Group Discussion

NB: This information will be communicated orally in English, Swahili or other Kenyan dialect of potential participant's preference.

INFORMATION AND CONSENT FORM

Introduction

Hello. My name is _____ from the University of Nairobi. I am currently conducting a research on adherence to antiretroviral drugs, medications used in HIV management. The goal of the project is to help us understand the challenges and measures adopted by people like you to remember to take their ARVs daily. During this meeting everybody will be expected to share their experiences on the drugs. However, no one is obligated to participate and individuals can refuse to answer any question or withdrawal from the interview at any time.

Purpose of the research

ARVs are key stone in managing HIV/AIDS. I believe that you can help me by sharing what you know about ARVs and the challenges people encounter while taking these drugs. I want to learn what you do to adhere to these drugs. This information will be used to help others and/or to improve the program.

Type of Research Intervention

This research will involve your participation in a group discussion that will take about one and a half hours to finish.

Participant Selection

You are being invited to take part in this research because we feel that your experiences with the ARVs can contribute much to our understanding and knowledge of what other sex workers go through.

Voluntary Participation

Your participation as an individual or group in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this clinic will continue and nothing will change.

Procedures

I would like to invite you to participate because your opinions and views of other people like you will help in advising the improvement of these services. If you accept, you will be sharing your opinion and views with 12 other persons who are also HIV positive and are taking ARVs. This discussion will be guided by me. The discussion will take place in clinic, and no one else but the

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people who take part in the discussion and me will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The information recorded is confidential, and only the research team will have access to the tapes as they will be in a locked cabinet. Please be assured that the information you give me will not be linked to any names or other identifying information.

Risks

I am asking you to share with me some very personal and confidential information, and you may feel uncomfortable talking about some of the issues. You do not have to answer any question or take part in the discussion if you don't wish to do so, and that is also fine. You do not have to give me any reason for not responding to any question, or for refusing to take part in the interview.

Benefits

There will be no direct benefits to you, but your participation is likely to help us find out more on how to improve the adherence counseling sessions

Confidentiality

The information that is collected from this research project will be kept private. Any information about you will be reported anonymously and no names will be used. Also, I will ask you and others in the group not to talk to people outside the group about what was said in the discussion.

You can ask me any questions about any part of the research study, if you wish to. Do you have any questions?

Whom Do we Call if we Have Questions or Problems?
For questions about the study or a research-related injury, call or contact
Dr Josephine Wahito, UNITID, University of Nairobi, Tel: 020 2726765

For questions about your rights as a research participant, contact Professor Bhatt, who is the chairperson of the Ethical Review Committee at the University of Nairobi, by calling 2725452, or make an appointment to see her in the Department of Medicine, at the University of Nairobi.

The foregoing information has been read to us. We had the opportunity to ask questions about it and any questions we had have been asked and answered to our satisfaction. We consent voluntarily to be participants in this focus group discussion.

Signature of FGD leader_____
Signature of one Participant _____
Date _____

ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY AMONG FEMALE SEX WORKERS ACCESSING HIV CARE IN TWO CLINICS IN NAIROBI, KENYA

"A KNOWLEDGE, ATTITUDES AND PRACTICES STUDY"

Date: _____

<u>Support/Focus Group Discussion</u>

Name of Clinic   _____

Knowledge

1. How is HIV transmitted?

2. How often are condoms used on average with the following types of clients?

Casual Clients	Regular Clients	Boyfriend/ Husband
☐ Never – 0percent	☐ Never – 0percent	☐ Never – 0percent
☐ Sometimes - <50percent	☐ Sometimes - <50percent	☐ Sometimes - <50percent
☐ Most of the time - >50percent	☐ Most of the time - >50percent	☐ Most of the time - >50percent
☐ Always – 100percent	☐ Always – 100percent	☐ Always – 100percent

3. Have many of you know the names of your ARVs?

☐ <50percent
☐ 50percent - 70percent
☐ >75percent
☐ 100percent

4. What are some of the possible side effects of the ARVs that you are currently taking?

5. Has anyone experienced any of these side effects since they started taking the ARVs?

6. When one is started on ARVs how long must one continue with the treatment?

7. What **were you advised to** do in case you miss a dose?

8. Why should one on ARVs try their best not miss any doses?

9. What should one do if they vomit the pill?

Practice

10. How do you ensure that you take the medication as instructed? (**Probe**)

11. What do you do if you miss a dose?

12. What factors/circumstances prevent you from returning to the clinic with all the remaining pills on the refill date?

13. Have you forgotten to take the pills in the last one month? If yes, what were the reasons for missing the pills?

Attitude

14. How many have disclosed that they are on ARVs? Why?

15. Are you members of ART support groups? Why?

16. How hard or easy is it to remember to take your medications?

17. How do you take your medications when your routine changes?

18. How many of us experience difficulties in taking medications when feeling bad emotionally?

19. How many of us experience difficulties in taking medications when feeling bad physically?

20. Does the idea of taking the ARVs for life frustrate you?

21. Do you hate the drugs as they remind you of your HIV infection?

22. How many of you have ever missed ARV drugs from the clinic?

23. How would you like the Adherence counseling services improved at this clinic?

24. How would you rate the general services at this clinic on a scale of 1 to 10?

Client's ID Number: _____   **ART** no._____

<table>
<tr><td><u>Comment:</u></td></tr>
<tr><td></td></tr>
</table>

ADHERENCE COUNSELING VISIT Date _____/_____/_____

COUNSELING ADHERENCE #1: MAJENGO/PUMWANI-MCH

Checklist	Tick one
Explain about HIV and how it infects the body	☐ 1-Yes ☐ 0-No
Expound on the importance of living positively	☐ 1-Yes ☐ 0-No
Describe the role of balanced diet/supplements in HIV Management	☐ 1-Yes ☐ 0-No
Explain about CD4 cells and why it is necessary to measure the CD4 count	☐ 1-Yes ☐ 0-No
Explain the difference between HIV and AIDS	☐ 1-Yes ☐ 0-No
Clarify the effect of other infections on HIV disease progression	☐ 1-Yes ☐ 0-No
Mention the risk of transmission and/or re-infection and importance of condoms use	☐ 1-Yes ☐ 0-No
Explain about ARVs and confirm not a cure for HIV/AIDS	☐ 1-Yes ☐ 0-No
Explain basis of ARV resistance and importance of adherence to therapy	☐ 1-Yes ☐ 0-No
Mention importance of disclosing previous history of Antiretroviral use	☐ 1-Yes ☐ 0-No
Explain treatment failure	☐ 1-Yes ☐ 0-No
Explain problem of side effects	☐ 1-Yes ☐ 0-No
Have patient think about life long commitment to prescribe therapy	☐ 1-Yes ☐ 0-No
Have patient think about ability to follow-up care	☐ 1-Yes ☐ 0-No
Explain the role of contraception in HIV management and emphasize importance of dual protection	☐ 1-Yes ☐ 0-No

Comments_____

_____

Next Appointment date ____/____/_____

ARV counseling Adherence #2: Majengo/pumwani MCH clinics

(All Patients)

Name_____   Visit date: _____ / _____ / _____

Questions	Rationale	Tick one
What does the client know about HIV/AIDS infection?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
Can the client describe his/her role in HIV disease prevention?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
Does the client know the importance of balanced diet in HIV management	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
Can the client relate his/her **own** CD4+ cells counts and HIV disease?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
What does client know about ARVs?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
Does client know how ARVs work?	Assess client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection).	☐ 1-Yes ☐ 0-No
Is the client aware that ARVs have side-effects and what to do if any experienced?	Assess client's knowledge that ARVs like any other drugs have potential side effects and the appropriate responses on how to deal with them (side effects). Special mention of "*IRIS*"	☐ 1-Yes ☐ 0-No
Does client know how long they will be on ARVs?	Assess whether client knows that management with ARVs is life-long!	☐ 1-Yes ☐ 0-No
Does client know the importance of taking ARVs consistently?	Assess whether client understand the problem of resistance if ARV therapy is interrupted	☐ 1-Yes ☐ 0-No
Does client know the purpose of checking CD4 counts when one is on ARVs?	Assess whether client knows that CD4 counts are used to monitor the effect of ARV.	☐ 1-Yes ☐ 0-No
Is client interested with the potential benefits of taking ARV?	Assess whether client is motivated to begin or continue ARV treatment.	☐ 1-Yes ☐ 0-No
What are the client's expectations from taking ARVs?	Assess whether client has realistic expectations, e.g., prolonging life, keeping them well enough from their family, etc. Assess for false expectations, e.g., a cure for HIV, etc.	☐ 1-Yes ☐ 0-No
Ask the client whether s/he feels ready for long term care and /or ART management with expected regular follow up.	Assess commitment for long-term treatment.	☐ 1-Yes ☐ 0-No
Assess for factors that help determine capability for follow up	Assess whether client can attend HIV clinic for care and ART follow –up?	☐ 1-Yes ☐ 0-No
Ask the client whether s/he has a relative/friend whom s/he can rely on for support when on care and/or ART	Assess availability of support at home.	☐ 1-Yes ☐ 0-No

Decision on management

Illegible for HIV Care	☐ 1-Yes ☐ 0-No	
Illegible for ART program	☐ 1-Yes ☐ 0-No	
Is the patient ready for Care / ARVs?	☐ 1-Yes ☐ 0-No	

Additional note/remark

Client's ID Number: _____   **ART** no._____

ARV counseling Adherence #3: Majengo/pumwani MCH clinics

(ARV patients - *To be performed 1 month after starting ARVs*)

Name_____ Visit date: _____ /_____

/_____

Questions	Rationale	Tick one
What does the client know about HIV/AIDS infection?	Assess whether information given in Counseling Adherence #1 has been understood and retained.	☐ 1-Yes ☐ 0-No
Can the client describe his/her role in HIV disease prevention?	Assess whether information given in Counseling Adherence #1 has been understood/ retained	☐ 1-Yes ☐ 0-No
Does the client know the importance of balanced diet in HIV management	Assess whether information given in Counseling Adherence #1 has been understood/ retained	☐ 1-Yes ☐ 0-No
Can the client relate his/her **own** CD4+ cells counts and HIV disease?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
What does client know about ARVs?	Assess whether information given in Counseling Adherence #1 has been understood.	☐ 1-Yes ☐ 0-No
Does client know how ARVs work?	Assess client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection).	☐ 1-Yes ☐ 0-No
Is the client aware that ARVs have side effects and what to do if any experienced?	Assess client's knowledge that ARVs like any other drugs have potential side effects and the appropriate responses on how to deal with them (side effects).	☐ 1-Yes ☐ 0-No
Does client know how long they will be on ARVs?	Assess whether client knows that management with ARVs is life-long!	☐ 1-Yes ☐ 0-No
Does client know the importance of taking ARVs consistently?	Assess whether client understand the problem of resistance if ARV therapy is interrupted	☐ 1-Yes ☐ 0-No
Does client know the purpose of checking CD4 counts when one is on ARVs?	Assess whether client knows that CD4 counts are used to monitor the effect of ARV.	☐ 1-Yes ☐ 0-No
Is client still interested with the potential benefits of taking ARV?	Assess whether client is still motivated to continue with ARV treatment.	☐ 1-Yes ☐ 0-No
What are the client's expectations from taking ARVs?	Assess whether client still has realistic expectations, e.g., prolonging life, keeping them well enough from their family, etc. Assess for false expectations, e.g., a cure for HIV, etc.	☐ 1-Yes ☐ 0-No
Investigate whether s/he feels ready to continue with long term care and /or ART management with expected regular follow up.	Assess commitment for long-term treatment.	☐ 1-Yes ☐ 0-No
Assess for factors that help determine capability for follow up	Assess whether client can still attend HIV clinic for care and ART follow –up?	☐ 1-Yes ☐ 0-No
Ask the client whether the relative/friend identified for support with care and/or ART has be helpful	Assess for factors that indicate continued support for care / ART at home.	☐ 1-Yes ☐ 0-No

Notes/remarks:

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*Clinician*_____ **Signature** _____

ART/CARE EXPERIENCE INDICATORS – PILL COUNTS

MAJENGO/PUMWANI ART/ CARE EXPERIENCE INDICATORS:
(Pills pick up visits only)

1. Visit Date: _____/_____/_____

2. Name_____

3. Date of appointment _____

4. Date came _____

5. Date of last drug collection:___/___/___

6. Side-effects
Have you experienced any of the following?

	1-Yes	0-No
Nausea	☐	☐
Vomiting	☐	☐
Fatigue/Malaise	☐	☐
Elation (Euphoria)	☐	☐
Headache	☐	☐
Dizziness	☐	☐
Double vision	☐	☐
Bad dreams	☐	☐
No strength	☐	☐
Swellings of legs	☐	☐
Rash	☐	☐
Hair loss	☐	☐

Others Specify _____

7. Medications
What time have you been taking your medications in the last 72 hours?

Last 72 hour pill(s) swallow recall

Name (s) of Medication	Time of medication	With food
Yesterday	AM Approximate time _____	☐ 1-Yes ☐ 0-No
	Noon Approximate Time _____	☐ 1-Yes ☐ 0-No
	Evening Approximate time _____	☐ 1-Yes ☐ 0-No
Day before Yesterday	AM Approximate time _____	☐ 1-Yes ☐ 0-No
	Noon Approximate Time _____	☐ 1-Yes ☐ 0-No
	Evening Approximate time _____	☐ 1-Yes ☐ 0-No
Previous Day	AM Approximate time _____	☐ 1-Yes ☐ 0-No
	Noon Approximate Time _____	☐ 1-Yes ☐ 0-No
	Evening Approximate time _____	☐ 1-Yes ☐ 0-No

8. Pill count table

DATE	DRUGS	PRESENT COUNT	PILLS expected to have been taken (PE)	Actual pills taken (AP)	Missed pills	Refill count	Total pills taken home	percent evaluation
Total								

Evaluation percent = **AP /PE** x 100percent; [*100percent-95percent-perfect*]; [94percent-90percent *-can Improve*]

[89percent–81percent *-alarm*] ;[< *80percent-change/stop*]

Level of Adherence:_____

Medications Provided: _____

Next Appointment Date: _____

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*Clinician*_____ **Signature** _____
ARV ART Adh Indicator version   Apr 2008