CHARACTERISTICS AND OUTCOMES ASSOCIATED WITH LOSS-TO-FOLLOW-UP ART PATIENTS AT MBAGATHI HOSPITAL

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Characteristics and Outcomes Associated with Loss-to-Follow-Up
Art Patients at Mbagathi Hospital

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A thesis submitted in Partial Fulfilment for the Degree of Master of Science in Public Health in the Jomo Kenyatta University of Agriculture and Technology

2017
DECLARATION

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

Signature………………………… Date…………………………

Serah Njoki Gathu

This thesis has been submitted with our approval as University Supervisors

Signature………………………… Date…………………………

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JUAT, KENYA

Signature………………………… Date…………………………

Mr. Lawrence Muthami

KEMRI, KENYA
DEDICATION

I would like to thank the members of my family, Christopher Gathu, Mercy Gathu, Christeen Selin, Kathy Gathu and Grace Gathu for your love, understanding and support during the process of the study. I am greatly indebted to you for the continuous support and encouragement.
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### ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>3TC</td>
<td>Lamivudine</td>
</tr>
<tr>
<td>ADR</td>
<td>Adverse drug reactions</td>
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<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<td>ART</td>
<td>Antiretroviral therapy</td>
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<tr>
<td>ARV’s</td>
<td>Anti-retroviral drugs</td>
</tr>
<tr>
<td>AZT</td>
<td>Zidovudine or azidothymidine</td>
</tr>
<tr>
<td>CCC</td>
<td>Comprehensive Care Clinic</td>
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<tr>
<td>CD4</td>
<td>Cluster of differentiation 4</td>
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<tr>
<td>D4T</td>
<td>Stavudine</td>
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<td>EFV</td>
<td>Efavirenz</td>
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<tr>
<td>HAART</td>
<td>Highly Active Antiretroviral Therapy</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>KEMSA</td>
<td>Kenya Medical Supplies Agency</td>
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<tr>
<td>LTFU</td>
<td>Loss-to-follow-up</td>
</tr>
<tr>
<td>PLWHA</td>
<td>Persons Living With HIV/AIDS</td>
</tr>
<tr>
<td>MSF</td>
<td>Médecins Sans Frontières</td>
</tr>
<tr>
<td>NNRTI</td>
<td>Non-nucleoside Reverse Transcriptase Inhibitor</td>
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<tr>
<td>NRTI</td>
<td>Nucleoside Reverse Transcriptase Inhibitor</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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</tr>
<tr>
<td>NVP</td>
<td>Nevirapine</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>The U.S. President's Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TDF</td>
<td>Tenofovir Disoproxil Fumarate</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
**OPERATIONAL DEFINITIONS**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Loss-to-follow-up</td>
<td>Occurs when researchers lose contact with some participants. Patients who at one point in time were actively participating in a clinical intervention, but have become lost or unreachable at the point of follow-up. These patients can become lost for many reasons such as opting to withdraw from the clinic and are unable to communicate or are deceased. Patients are lost-to-follow-up or defaulter, if they have missed two or more clinical appointments.</td>
</tr>
<tr>
<td>Adherence</td>
<td>Adherence in this study is defined as the active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a therapeutic result.</td>
</tr>
<tr>
<td>Patients’ outcomes</td>
<td>In this study, the loss to follow up outcomes are classified as alive, dead, non-traceable.</td>
</tr>
<tr>
<td>Non-defaulter</td>
<td>Patient who adheres to medical appointments.</td>
</tr>
<tr>
<td>Ever married</td>
<td>This includes divorced, separated and widow(ed).</td>
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ABSTRACT

The purpose of this study was to determine the characteristics and outcomes associated with loss-to-follow-up (LTFU) patients on antiretroviral therapy (ART) at the Hospital’s. This was a hospital-based cross-sectional study involving the retrospective review of the clinical records of adult HIV-positive patients who were on Highly Active Antiretroviral Therapy (HAART) during the year 2003 to 2009. Sample size of 398 patients were included from a study population of 4925 and qualitative follow-up interviews were conducted to patients who had defaulted from treatment. Social-demographic and clinical risk factors included in this study are: age, gender, level of education, marital status, employment status, changing of first type of regimen, reasons to change regimen and WHO clinical staging. These variables were used to delineate the factors that were closely associated with patient loss-to-follow-up. In conclusion, factors that were independently associated with defaulting treatment include marital status (ever married), unemployment and changing first type of regimen. Out of the 398 patients, 39 were lost to follow up of which 9 had died, 18 were alive and 12 could not be traced due to wrong physical address or wrong mobile numbers. Recommendations suggested in this study include; reduce stigma, strengthen family social support, provide income generating activities, record accurate contact information, provide intensive counselling on drug side effects and improve communication links among caregivers.
CHAPTER ONE

INTRODUCTION

1.1 Background Information

Globally over the past few years, the huge number of patients enrolled to Antiretroviral Therapy (ART) care has challenged the ability of clinics to keep track and retain individuals who are at risk of Loss to Follow Up (LTFU) (Myer & El-sadr, 2004). In the recent past, ART has significantly reduced mortality and improved life expectancy in People Living with HIV/Aids (PLHWA) (May et al., 2007) and Loss to follow-up of patients is one of the major challenges of ART programs in Sub-Saharan Africa (Rosen, Fox, & Gill, 2007).

Loss to follow-up (LTFU) is closely related to ART adherence and is becoming an increasing problem in Sub-Saharan Africa as ART programmes expand and staff-to-patient ratios decrease. (Brinkholf et al., 2008). With the large proportion of clinics in settings with high demand for ART but with limited human resources workers may decide to focus on equipping patients initiating ART with knowledge about adherence rather than investing limited resources in efforts to follow-up mobile patients in their communities (Yu et al., 2008).

In a systematic review of ART in Sub-Saharan Africa, the authors established that up to 40% of patients were loss to follow-up, with large variation in retention rates between programmes (Rosen et al., 2007). The risk of LTFU is usually highest during the first 6 months after starting ART (Brinkholf et al., 2008).

The Kenya guidelines for ART objectives of Anti-retroviral (ARV) treatment were summarized to: improve quality of life, reduce HIV related morbidity and mortality, suppression of viral load replication and improve immunological function.
1.2 Statement of the Problem

Antiretroviral therapy (ART) programmes in resource-constrained settings need major improvements, particularly the need for active tracing. The Comprehensive Care Clinic (CCC) provides accessibility of ART services to patients but follow up on defaulters is not actively conducted, while the reasons for defaulting are not clearly understood (Barnighausen et al., 2011).

As of 2009, 4925 patients were on Anti-retroviral drugs (Arvs) of which from these group, the status 500 patients was unknown. Loss to follow up (LTFU) may cause late presentation after deterioration of HIV/AIDS or even worse spreading a drug resistant strain of the virus due to non-adherence (Oyugi et al., 2007).

The economic burden of HIV/AIDS includes allocation of more resources in tracing the defaulters, early deaths and debilitation of patients who would otherwise be economically productive. (Myer & El-sadr, 2004).

1.3 Justification

Despite patients’ understanding the consequences of missing medical appointments and adherence to medication, defaulting rates are quite alarming hence interventions are needed for durable effect, particularly in long term diseases such as HIV (Mannheimer et al., 2006). Various approaches have been tried to reduce the rate of LTFU including adherence support workers (Torpey et al., 2008) mobile telephone messaging (Lester et al., 2010) but resource-limited settings may not have financial resources to support this without increasing donor support. Treating the maximum number of new patients has been a priority for many public sector programs, as a result documenting and tracing patients LTFU is inadequate. (Myer & El-sadr 2004).

In this study the researcher set out to find the characteristics of loss to follow up ART patients and their outcomes at the Mbagathi Hospital.
1.4 Research Questions

- What are the socio-demographic factors associated with Loss to Follow Up patients on Anti-retroviral Therapy?
- What are the clinical factors associated LTFU patients on ART?
- What are the outcomes of the LTFU patients on ART at the Comprehensive Care Clinic?

1.5 Objectives

1.5.1 General Objective

To determine the characteristics and outcomes associated Loss to Follow Up patients on Anti-Retroviral Therapy at the Comprehensive Care Clinic

1.5.2 Specific Objectives

1. To determine socio-demographic characteristics associated with Loss to Follow-up patients on Anti-Retroviral Therapy.
2. To determine clinical factors associated with LTFU patients on ART.
3. To determine outcomes of the LTFU patients on ART at Comprehensive Care Clinic.
CHAPTER TWO

LITERATURE REVIEW

2.1 Overview on Loss-to-follow-up (LTFU) Patients

In this study, Loss to follow up (LTFU) is defined as patients who have not been seen at least two/three months from booking appointments (Calmy et al., 2006) while adherence in this study is defined as the active, voluntary and collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a therapeutic result.(Delamater, 2006).

The effectiveness of ART programmes is evaluated using key indicators which include percentage of deaths, LTFU and retention of patients on ART care. Among these, retention is crucial because poor retention shows poor survival rates of HIV infected patients (Giordan et al., 2007).

A systematic review of patient retention in antiretroviral therapy in programs in sub-Saharan Africa indicated that the rate of LTFU was 40% (Rosen et al., 2007). LFTU was the major cause of attrition followed by death. Better patient tracing procedures, better understanding of loss to follow-up and earlier initiation of ART to reduce mortality are needed if retention is to be improved. (Rosen et al., 2007).

Despite the improved progress in expansion of ART, limited uptake and poor retention, accessing HIV clinics remain a serious challenge in the resource limited ART programs (Barnighausen et al., 2011). Long-term retention of patients in treatment programs has received far less attention perhaps because most large scale treatment providers have few resources available to track missing patients (Barnighausen et al., 2011).

Obtaining the full benefits of ART is determined by patient attributes and attitudes towards health care systems. Inadequate knowledge and negative attitudes towards ART, drug side effects, financial constraints, service-related factors, stigma,
discrimination, inability to disclose (HIV) status and various socio-cultural issues may prevent patients from seeking treatment (Mills et al., 2004).

Different studies across sub-Saharan Africa estimated the rate of LTFU patients to be 19%, 24% and 31% at 6 months, 12 months and 24 months of treatment, respectively (Brinkhof et al., 2010). There has also been an increase in patients LTFU due to increasing problems such as expanding programmes and declining staff-to-patient ratios (Brinkhof et al., 2008). In Kenya, studies have shown that proportions of patients LTFU differ between clinics ranging from 7% in Médecins Sans Frontières (MSF) programmes, Busia hospital (Rosen et al., 2007) to 40% in Migori Hospital (Karcher, Omondi, Odera, Kunz, & Harms, 2007).

2.2 Factors associated with defaulting treatment

Missed appointments are known to interfere with appropriate care of acute and chronic health conditions and to misappropriate resources at medical and administrative levels. They represent a major burden on health care systems and costs by reducing the effectiveness of outpatient health care delivery (Atun & Mohan 2005).

2.2.1 Social demographic factors.

In Nigeria, a study conducted on ART patients identified the reasons for defaulting treatment as follows: opting for spiritual/faith/alternative healing (8%), loss of interest in the program, financial challenges (7%), movement to new home (6%), changed address (5%), untraceable home address or name (5%) and widowhood rites (1%). About a third of People living with HIV/AIDS (PLHWA) defaulted treatment. The major reasons for default were psychosocial factors were associated to the treatment regimen (Daniel et al., 2008). Another study in Nigeria concluded that the reasons for defaulting from treatment were increased cost, transport, long waiting hours at the clinic, stigma, family pressures, religious beliefs and illness (Charutat et al., 2010).

At St. Helen’s hospital in Johannesburg South Africa, patients facing financial
difficulties were likely to default their medical appointments (Maskew, MacPhail, Menezes, & Rubel. 2007). Despite of ARV treatment been free, poor patients in Haiti had challenges of keeping their medical appointments due to other associated costs (Fitzgerald & Krain, 2005).

Lack of food, mental illness, having a partner whose HIV status was unknown, excessive consumption of alcohol and using substances of abuse like cocaine were also associated with defaulting ARV treatment at Jimma University hospital, Ethiopia (Deribe et al., 2008). In gender and poverty, poor women more likely to be less compliant to treatment plans than the male counterparts (Skhosana, Struthers, Gray, & McIntyre, 2006)

In South Africa, the high rate of unemployment (41%) caused patients to be away from home looking for jobs hence couldn’t attend their medical appointments (Nachega et al., 2004).

Patient treatment literacy, disclosure, lifestyle have shown increase in patients sticking to treatment plans. Provision of several months’ supply of drugs would ease the burden of travelling to the clinic frequently, thus minimizing transport cost and default incidences (Skhosana et al., 2006).

In the United Kingdom, social discrimination of people of Black race, been recently diagnosed of HIV infection and acquiring HIV infection from outside United Kingdom were the main reasons for missing medical appointments in the clinic. (Brian, Valerie, Timothy & Jonathan, 2011).

**2.2.2 Clinical risk factors**

Doctor to patient relationship has been proven to negatively affect the patients’ attitudes towards health care given. In Geneva university Hospital, a study indicated that patients were less interactive with junior doctors (interns) as opposed to senior doctors, due to frequent changing of the junior doctors (interns). With lack of interpersonal continuity, junior doctor patients were more likely to miss appointments than the senior doctors (Perrone et al., 2010).
A study in Tanzania indicated that treating patients in a negative discriminative way affects them and they eventually drop out from treatment plan (Hardon et al., 2006).

Adverse drug reactions (ADRs) most commonly found in patients on ARVs include headaches, nausea, rash, peripheral neuropathy, lipodystrophy and lactic acidosis (Sherer & Max, 2000). Adverse drug reactions have led to discontinuation of HAART (D’Arminio et al., 2008). A Botswana study showed that adverse drug reactions contributed to the fifth most mentioned reason for missing doses and adherence (Weiser et al., 2003) while another study shows that side effects of ART on patients on developed nations were associated with poor adherence (Ammassari et al., 2001).

Traditional/herbal medicine may cause severe adverse reactions on patients and may also contain adulterated products (Peters, Immananagha, Essien, & Ekott, 2004). Patients who were visiting traditional healers and using traditional medicine were also found to be defaulters (Worley et al., 2007). Murchison hospital study in South Africa indicated that patients who preferred traditional medicine contributed to non-attendance by 7.4% (Kahelo, 2009).

Nigerian study indicated that LTFU was associated with being male, younger, having CD4 count level of \( \leq 100 \) cells/µl or CD4 count of \( \geq 350 \) cells/µl at ART initiation. Risk of defaulting treatment was observed to be the highest in the first six months after ART initiation suggesting importance of adherence been emphasized in the beginning of the treatment (Charurat et al., 2010). In South Africa, factors associated with LTFU patients included prior exposure to TB and prior exposure to ART medication. (Dalal et al., 2008). In France, a study concluded that men who have sex with men (MSM) and immigrants were the main predictors and risk factors of defaulting treatment (Lebouche’ et al., 2006). In Mozambique, the risk factors associated LTFU were, CD4 count <50 cells/µl, time on ART <3 months and tuberculosis infection. (Fernando et al., 2007). Social and behavioural studies have concluded that being of younger age group, being a foreigner, patients with initial CD4 count at that time to be less than 500 cells/µl were likely not to come back for a period of more than one year, (Nacher et al., 2006).
2.2.3 Other Factors Contributing to Defaulting Treatment

The influence of religion has been observed to have different impact in various regions. Murchison hospital study in South Africa showed that 1.1% of patient who defaulted cited religious beliefs and all were female patients (Kahelo, 2009). Treatment programmes obtained positive outcomes by using religious organization to provide adherence education and HIV support programmes (Karpf, 2007). However, religious beliefs may also play a negative role in treatment programmes due to stigma attached to HIV disease, particularly in geographical areas and in population subgroups where religious practices are strong (Karpf, 2007).

2.3 Outcomes of Loss to Follow Up Patients (LFTU)

The outcomes of LTFU patients were classified as alive, dead or not traceable. A study done in Malawi had the following observations. Overall main outcome for LTFU was death, this being the case for 50% of patients. Fifty-eight patients were still alive; about one-third had transferred to other clinics and about two-thirds had stopped therapy. Of the patients who had stopped ART, reasons included the high cost of transport to the clinic (13 patients; 35%), religious beliefs (4 patients; 11%), persuasion by relatives to stop ART (4 patients; 11%) and other reasons (16 patients; 43%). The remaining 68 patients (27%) could not be traced, most frequently because of an incorrect address in the ART register (Yu et al., 2007).

In Nigeria, Sagamu, the outcomes of 100 cohort patient that were followed up for twelve months, were as follows: 36% defaulters, 18% dead, 46% alive. The main reasons for defaulting treatment were: opted for spiritual/alternative healing (8%), loss of interest in the programme (7%), moved to home town of origin (6%), changed address (5%), untraceable home address or name (5%), side effects of ART (2%), widowhood rites (1%). (Daniel et al., 2008). The above studies were done at resource limited facilities that need intervention during care on ART indicating the need for retention of patients to show the efficacy of ART programmes.
CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

Mbagathi Hospital was built in 1956 as the infectious disease wing of the Kenyatta National Hospital. In 1997 Mbagathi Hospital became the first District Hospital of Nairobi.

Services offered at the comprehensive care clinic

- Pharmacy services

HIV pharmacy has been an important factor in maintaining the quality of services. Clients receive uninterrupted supply of ARV drugs. The government through Kenya Medical Supplies Agency (KEMSA) has been supplying the ARVs first line regimen drugs while the PEPFAR programmes supplies the ARV paediatric drugs and second line regimen drugs.

- Laboratory services

The laboratory provides full range of tests necessary for HIV care. Haematology for full blood counts, biochemistry for liver and renal functions tests, HIV and CD4 count tests.

- Educational

Health promotions materials have been offered at the clinic to support education. These materials include booklets, poster series, DVDs. counselling services are given to patients before and during treatment. Support groups have also been formed to deal with social welfare of the patients.
Clinical services

Medical consultations are available for the patients. Monthly and weekly clinical meetings are organized by the CCC clinical team to update the staff of any relevant information.

The Comprehensive Care Clinic (CCC) is an outpatient medical facility that continuously offers ART therapy. An average of 30 patients are started on HAART every month. The clinic serves a diverse population of patients from Kenya.

3.2 Study design

This was a cross-sectional study involving the review of the clinical records of patients who were on HAART between 2003 and 2009 followed by assessment of the LTFU patients characteristics and outcomes. This study included both patients that were active on HAART and those that were LTFU. A list was generated from facility databases of 4925 patients initiated on ART during the period. Patients were contacted by phone and traced through the physical address given on their files.

3.3 Study population

The study population included patients who were on HAART at that period (2003-2009). The patients’ files were used to collect data. According to the ART 2002 guidelines at the time, the eligibility criteria for HAART was CD4 count <200 cells/mm3 irrespective of the WHO clinical stage; WHO clinical stage 3 with CD4 <350 cells/mm3 or WHO clinical stage 4 irrespective of CD4 count at least two adherence counselling sessions and willingness to start HAART. In the event of treatment failure, switching to second regimen was done. Individual drugs were substituted in the event of adverse drug reactions. With every medical appointment, both clinical and social assessments were done to ensure patient well-being. Supply of medicine was given to the patient for a specific period as per the medical appointment.
3.4 Eligibility criteria of study participants

3.4.1 Inclusion criteria

- Both male and female HIV adult patients 18 years of age and above
- HIV adult patients receiving HAART
- Informed consent

3.4.2 Exclusion criteria

- Patients below 18 years of age
- Patients who are not on HAART

3.5 Sample population

Three hundred and ninety eight patients (398) patients were included in the study after acquiring the minimum sample size. The proportion of LTFU used was based on the percentage from a study done in Migori Hospital which had an estimate of 40% on Loss to Follow Up patients (Karcher et al., 2007). The calculation of minimum sample size and the desired degree of precision was based on the formula initially developed by Cochran (Cochran, 1963)

\[ N = \frac{Z^2}{\delta^2} \times P \times (1-P) \]

Whereby;

- \( N \) is the maximum sample size
- \( \delta^2 \) is the degree of precision, which is 5%
- \( \alpha \) is the level of significance (95%) +-
- \( Z \) is the standard normal deviate that corresponds to 95% confidence interval
P = Proposed percentage of the patients who are loss to follow up

\[ n = \frac{(1.96)^2 \times 0.4(1-0.4)}{0.0025} = 369 \]

The calculated minimum sample size of 369 was required to obtain the desired precision or confidence interval, assuming that there were no missing values. However, the sample size was increased by a factor of approximately 8% adjustment for incomplete and inaccurate data or failure to trace respondents, the final calculated sample size to 398. (Niang, Winn, & Rusil, 2006)

### 3.6 Sampling Procedures

In the selection of study subjects, a systematic sampling procedure was adopted using the files from the 4925 patients. Using the simple random method, subsequent samples were selected using the sequential sampling up to nth number thus:

\[ n^{th} = R, R+k, R+2k, (n-1) k. \]  (Kirkwood & Sterne, 1988). This process was maintained until all the samples were selected. This sample included both LFTU (39) and patients on HAART (359). The sampling interval \( k = \frac{N}{n} = \frac{4925}{398} = 12 \). From this interval every 12 patient was included in the study.

### 3.7 Data Collection

A pre-coded interviewer administered questionnaire was used to collect data (Appendix 2). The patients who were traced and interviewed were taken through the informed consenting procedure (Appendix 3) which observed ethical considerations (Appendix 1).
3.8 Data Management and Analysis

3.8.1 Data entry and storage

Data was entered into Microsoft excel sheet and classified according to the socio-demographic and clinical data. Back-up electronic copies were created for storage and for analysis purposes. Data was cleaned, entered into a computer and analysed using SPSS version 18.0.

3.8.2 Data analysis

Descriptive statistics were done and presented as proportions and mean. Bivariate analysis (chi square test) was done to determine presence of statistical significant association between explanatory variables and the outcome variable.

Multivariate analysis (Logistic regression models) were performed to identify independently associated factors.

3.8.3 Data presentation

- Dependent variables; defaulter and non-defaulter
- Independent variables; Gender, marital status, level of education, employment status, WHO classification OF HIV/AIDS, baseline regimen, changing of regimen during treatment, reasons for changing baseline regimen.

3.9 Ethical consideration

Ethical clearance from the Science and Ethics Committee was obtained prior to the start of the research. A letter of approval to conduct the study was issued by the Committee (Appendix 3).
3.10 Benefits and limitations of the study

3.10.1 Benefits of the study

- It is hoped that the results of this operational research will inform, guide ART program on the need to have increase retention, as an indicator for measuring the efficiency of ART services. Loss-to-follow-up patients who were located were encouraged to return to the health facility for step-up adherence counselling and possible re-initiation on ART if willing to re-enrol into care.
- Our study also benefited from timely assessment of reasons for loss to follow up. A major strength was the ability to define outcomes and assess the characteristics of individuals in these groups compared to retained participants.

3.10.2 Limitations of the study

- Being a retrospective study, recall bias might have been introduced by failure of participants to accurately remember the facts surrounding their defaulting treatment it was difficult to reach some potential participants lost to follow-up due to lack or change of contact details.
- Another reason is the study has participants enrolled from the year 2003 to 2009, few clinics were available in that period and the ART guidelines used then have been updated.
- These study includes participants on HAART, of which cannot be extrapolated to those not on HAART, hence further exploration is required.
CHAPTER FOUR

RESULTS

A total of 398 patients were recruited into the study with 39 being LTFU (defaulters) and 359 (90%) being in active treatment (non defaulters)

4.1 Descriptive statistics of the study sample

The sample size of 398 respondents had a gender distribution of male (131) and female (267) of 67% and male 33% respectively. In the age group category, the above 40 years (140) had the highest percentage of 35%, followed by age group 35-39 years (106) 27 %, 30-34 years (105) 26% and less than 29 years (47)12 % with a mean of 37.58. For marital status, the proportion for single (65), married (198) and ever married (135) was 16%, 50% and 34% respectively.

Forty three percent of study participants reported having low education i.e informal education and primary level of education while 52% had secondary education. Only 5% had tertiary education. The unemployed (273) and employed (125) were at 69% and 31% respectively. As for the WHO clinical classification (HIV/AIDS) stage I and II had 62 patients, stage three (III) had 295 patients and stage four (IV) had 41 patients with percentages of 16%, 74% and 10% respectively. The baseline regimen had three categories of which Stavudine/Lamivudine/Nevirapine (d4t/3tc/nvp) had highest number of 308 patients, followed Stavudine/Lamivudine/Efavirenz (d4t/3tc/efv) with 74 patients and other regimens had 16 patients. Three hundred and forty (340) patients changed their regimens while 58 patients did not change regimen. The main reasons for changing regimens were adverse drug reactions with 252 patients, TB disease with 72 patients and treatment failure with 16 patients.(Table 4.1).
Table 4.1: Socio-Demographic and Clinical Characteristics Sample Population

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<th>N%</th>
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<tr>
<td>treatment failure</td>
<td>16</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
4.2 Proportions of the Sample Population

The gender category, 77% (30/39) were female while those in active treatment were 66% (237/359). In both groups, female percentage was higher than the males. The 30-34 year group (38%) was the highest in the defaulter group followed by 35-39 year group (28%). As with non defaulters, the age group above 40 years had the highest percentage (38%) followed by 35-39 years group at 26%.

Forty nine percent of the defaulters had ever married, while 30% were married. Fifty two percent of the non defaulters were married while 32% had ever married. Single patients had the lowest numbers in both categories. Low education represented those who had no formal education and primary school education had a percentage of 44% and 43% of defaulters and non defaulters groups respectively. Tertiary education presented low numbers 15% and 4% at defaulters and non defaulters groups respectively. For employment status, there was a slight difference in the defaulter group, presenting 49% for unemployed and 51% for employed.

In the two groups of the defaulters and non-defaulters, the WHO clinical stage III presents high number at 59% and 76% for defaulters and non-defaulter groups respectively, while the stage IV presents 13% and 10% for defaulters and non-defaulters group respectively.

Over 75% of the patients in both defaulter and non-defaulter groups were started on the Stavudine/Lamivudine/Nevirapine (d4t-3tc-nvp) regimen of which 15% of the patient defaulted treatment while 19% did not. Percentages of 10% and 3% were found respectively for ‘other regimens’ in defaulter and non-defaulter groups. Other regimens include Zidovudine/Lamivudine/Nevirapine (Azt-3tc-nvp) and Tenofovir/ Lamivudine/Efavirenz (Tdf-3tc-efv).

A higher number of non defaulters (90%) changed their regimens compared to 41% defaulters. The reasons for changing regimens were Adverse Drug Reactions (ADR), TB infection and treatment failure. ADR was the main reason (69%) among
the defaulters, followed by (21%) TB infection. As for the non-defaulters, TB infection was main reason (53%) followed by ADR at 39%.(Table 4.2)

Table 4.2: Proportions of defaulters and non-defaulters

<table>
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<tr>
<th>VARIABLES</th>
<th>CATEGORY</th>
<th>Defaulters (n %)</th>
<th>Non defaulters (n %)</th>
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4.3 Bivariate Analysis

A chi square test for association between the follow up status and the various socio-demographic and clinical categorical variables identified a significant association (p value <0.05) for, the patient’s age (p<0.01), marital status (p<0.04),
Level of education (p<0.002), employment status (p<0.005), WHO classification of HIV/AIDS (p=0.005), changing first type of regimen (p<0.00), reasons to change baseline regimen (p<0.0009) (Table 4.3)

Table 4.3: Bivariate analysis using chi square test of association

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<th>P value</th>
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4.4 Logistic Regression Analysis

Logistic regression models were performed to identify independently associated factors. Factors that were independently associated with defaulting treatment were unemployment, ever married patients and changing the first type of regimen. (Table 4.4)

Table 4.4: Multivariate analysis

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4.5 The Outcomes of HIV-Positive Adult Patients who were LTFU.

Out of the 39 patients who were lost to follow up, 9 had died, 18 alive and 12 could not be traced due to wrong physical address and mobile numbers (Table 4.5).

Patients found alive had either stopped their ARVs or transferred to other facilities.
Table 4.5: Outcomes of Patient Loss to Follow Up.

<table>
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<th>CATEGORIES OF LTFP</th>
<th>NUMBER OF PATIENTS</th>
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<td>Alive</td>
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</tr>
<tr>
<td>Dead</td>
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</tr>
<tr>
<td>Not traced</td>
<td>12</td>
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</tbody>
</table>

Among the LTFU records, 46% (18/39) of the patients were traced by community health workers.

Of the patients who were traced 67% (12) reported having accepted their HIV status while 28% (5) reported having been stigmatized and 5% (1) of the patients were still in denial of their HIV status (Figure 4.1).

Figure 4.1: HIV Psycho Social Status of Patients
The main reasons given for missing medical appointments by the 18 patients were psychosocial challenges (stigma and lack of family support) 67 % (12), clinical reasons (illness, ADRS) 11 % (2) and economic challenges (financial instabilities) 22% (4)(Figure 4.2).

![Figure 4.2: Reasons for missing medical appointments](image)

Among the patients 18 patients traced, 61% (11) reported to be still taking ARVs, while 39 % (7) were not taking ARVs (Figure 4.3).

![Figure 4.3: Proportion of patients on Anti-retroviral drugs](image)

Patients also mentioned to have problems while taking the ARVs. Economic problems at 28% (5) (lack of food and money) while psychosocial problems at 11%
(2) and clinical problems (ADRS, TB infection, pill burden) at 61%, (11) (Figure 4.4).

Figure 4.4: Challenges Faced by Patients while on Arv’s.

Among the 18 traced patients, (11) had not disclosed their HIV status to family or friends while (7) had disclosed their HIV status to family/friends. (Figure 4.5)

Figure 4.5: Disclosure of HIV Status
Among the 18 patients 78% (14) had not joined any support group with 22 % (4) joined support group.(Figure 4.6)

Figure 4.6: Patients on Support Group

Among the 18 patients, only one patient claimed to have ever substituted ARVS(used herbal medicine) while majority (17) did not (Figure 4.7)

Figure 4.7: Substitution of ARVs by Patients
Among the 18 patients, 11% (2) reported having spiritual beliefs that influenced their taking medication, while 89% (16) did not have any spiritual beliefs that could have influenced the medication (Figure 4.8).

Figure 4.8: Influence of Spiritual Beliefs on Patient Treatment
CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

This study established that there was default rate of 10% (39 out of 398 patients) among adults on ARVs in the period reviewed. This rate of LTFU is much lower than that documented by Rosen et al. (2007). In this systematic review of default rates in sub Saharan Africa, Rosen and Colleagues recorded high figure of 40%. The difference could be due to the numbers reviewed and differences in methodologies.

Inadequate knowledge and negative attitudes towards ART, drug side effects, financial constraints, service-related factors, stigma, discrimination, inability to disclose (HIV) status and various socio-cultural issues may prevent patients from seeking treatment (Mills et al., 2004). Other researchers have reported that loss to follow-up has been one of the major challenges in HIV care owing the problems of lack of disease control and the emergence of resistant strains with poor medication compliance (Hogg et al., 2002). Our study sought to identify the characteristics and outcomes of such adult patients who were LTFU at the Mbagathi Hospital.

5.1.1 The socio-demographic characteristics associated with LTFU patients

In relation to marital status, our study showed that patients who were ever married were likely to default treatment. (OR=0.284, 95% C.I, 0.117-0.688). This group included those who were divorced, separated and widowed. This could be associated with stigma and lack of disclosure of the HIV status among ever married partners. Our study compares with others showing adults who were previously married were likely to default. Daniel et al. (2008) attributes this to lack of resources, widowhood rights and extreme stigma. Sixty seven percent (12) of the eighteen patients interviewed cited psychosocial challenges of stigma as the most common reason for missing medical appointments. Psychosocial challenge was compounded by the disclosure of HIV/AIDS status to spouse/family and joining a support group. 14 did not join any support group while 11 patients had not disclosed their status.
Stigma is connected from the values and norms of a community and known as a risk factor of defaulting to treatment especially, ARVs. (Kagee, 2007) while good adherence is associated with disclosure of HIV status to either spouse or family member (Charurat et al., 2010). The decision of PLWHA not been in support group could indicate non-disclosure while stigma affects social support they are meant to receive from family/friends. Because of stigma among PLWHA, patients often miss their doses or clinical appointments as a result of fear of being identified as HIV positive, or seen at the clinics and being on ARVs for the rest of their lives (Monjok, Smesny, Okokon, Mgbere, & Essien, 2010). The role of family support has also been argued by Goldsmith and Albrecht (2011) that family support boosts the patients’ self-esteem and it becomes easy for the patient to stay on treatment and believing that he/she will have a long and healthy life.

Our study also identified that disclosure of HIV status between couples and social support from family/spouses is important in facilitating access to ART. A study carried out in Tanzania also concluded the importance for People Living with HIV and Aids to inform others of their condition in order to receive necessary emotional and physical support (Antelman et al., 2001). It is necessary to disclose HIV positive status to a spouse in order to facilitate access to anti-retroviral treatment (Farquhar et al., 2000). Effective social support becomes a key factor because it avoids mental and behavioural change which leads stigma among married people. (Murray et al., 2009). Intensifying counselling and social support of patients before initiating and during treatment reduces stigma. (Wouters, VanLoon, Van Rensburg, & Meulemans, 2009).

Despite the hospital offering free services in the clinic, which includes free regular uninterrupted supply of quality (ARV) drugs, medical laboratory tests, intensive counselling and health education, the issue of unemployment was associated to defaulting treatment (OR=0.3, 95% CI 0.15-.752). Financial difficulties have become a challenge to poor patients who require this services (Fitzgerald & Krain, 2005). Studies have cited unemployment and poverty as key impediments to LTFU. Nachega et al. (2004) argued that lack of employment made search for jobs a priority.
thus patients are not able to follow appointments.

The link between unemployment and LTFU established in this study is in similar with other findings implying that attempts should be made to provide economic empowerment as a means of reducing the LTFU rates.

5.1.2 The Clinical Factors Associated with LTFU Patients

Changing the regimen during ART was associated with defaulting treatment (O.R=0.06, 95% C.I 0.027-1.138). Three main reasons for switching regimens in this study were adverse drug reactions (lipodystrophy) TB infection and treatment failure. Among the 18 patients who had regimen change traced, 11 reported to be still taking ARVs, while (7) were not taking ARVs. Majority of these patients had continued with ARVs but it was evident that the side effects/ADRs from ARVs contributed to missing to clinical appointments. This finding agrees with those documented from other studies (Weiser et al., 2003). According to Ammassari et al. (2001) the negative outcome of both side effects and ADRS affects individual’s continuity on HAART. Not only can the side effects of ARVs be intolerable, but they can also cause ADRs such as lipodystrophy which add onto the existing stigma that one may perceive or receive as a person living with HIV infection (Holzemer, et al., 2007).

Among these 11 out of 18 patients, those who had TB co infection contributed to drop out because of been weak from the pill burden and side effects from the ARVs and TB drugs. These patients were unable to continue with appointments at the clinic. Studies have observed that patient who had TB co infections eventually dropped out of ARVS treatment. In Mozambique, a retrospective study concluded that the risk factors associated LTFU were mainly, CD4 count <50 cells/µl, time on ART < 3 months and tuberculosis infection (Fernando et al., 2007). A similar study done in Brazil showing that taking more than 12 prescribed pills per day, reporting three or more adverse reactions and switching ART leads to defaulting treatment (Bonolo et al., 2005).
5.1.3 The outcomes of LTFU patients

Out of the 39 patients who were lost to follow up, 9 had died, 18 alive and 12 could not be traced due to wrong physical address or wrong mobile numbers.

In the presence of a passive reporting system for defaulters, it is believed that unreported deaths and untraceable patients (incorrect address) are contributing factor to the reported loss to follow-up patient in the clinic. This is consistent with a study done in Jimma University Hospital that identified incorrect address as a hindrance to tracing patients (Deribe et al., 2008) while Nigeria study indicated that movement of patients and changed address contributed to high rates of LFTU patients in the ART programme (Daniel et al., 2008).

Although the results from risk factors for LTFU are just descriptive and are from a limited number of patients, they should be considered as important insight into reasons to investigate keeping in mind that a third of the patients were not traced highlighting a challenge in reducing the possibility of drug resistance in this population and hence moving them into second line treatment, or even worse spreading a drug resistant strain of the virus.(Oyugi et al., 2007).

From a public health perspective, assuming these results are extrapolated to all loss to follow up patients in the country, this would then present a grim picture of high costs of providing HAART due to more patients being on the more expensive second line treatment. Therefore factors highlighted in this patient group should be explored further in a bigger population of LFTU. A closer look at the patient’s dynamics could inform programs to stem the high rates of LTFU.

The main factors in the descriptive or observational analysis identified as being associated with loss to follow up could be classified into psychosocial, clinical and economic factors.

Psychosocial factors mentioned by participants included not being in a support group
and not disclosing their HIV status. According to Charurat et al., (2010), good adherence was associated with disclosure of HIV status to either spouse or family member. A Nigerian study concluded that up to one third of the patient’s defaulted treatment due to psychosocial factors (Daniel et al., 2008). The failure to disclose HIV status, often results to patients missing drugs or even clinic appointments to avoid suspicion or indirect disclosure as well as stigma depending on the community/family support existent (Monjok, et al., 2010). DOT-ART helps to improve or maintain high levels of ART adherence. This is another way suggested for delivering ART and dealing with the non-adherence issue is the directly observed treatment short course (DOTS) strategy, developed to monitor treatment for tuberculosis though this has had limited success. (Charurat et al., 2010).

Economic challenges mentioned by patients were lack of money. The majority of patients said financial instability was due to job loss or change in employment. This reflects the substantial impact of unemployment on urban African population. (Nachega et al., 2004)

Clinical challenges include side effects/adverse drug reactions, co infection due to tuberculosis infection (Charurat et al., 2010). These problems have been consistently identified by patients as interfering with their medication and failure to keep clinic appointments. These factors highlight the need for a holistic approach to provision of care to patient in order to improve the coping mechanisms for the patient.

In the absence of HIV cure it is important to ensure that patients who are diagnosed or on treatment are not lost to follow-up to avoid losing the gains already being achieved in the fight against HIV. The clinic should offer continuous follow up of patients who have defaulted.
5.2 Conclusion

- The findings in this study concluded the socio-demographic characteristics independently associated with LTFU include ever being married and unemployed.
- This study also demonstrated that clinical factors associated LTFU were those that had their first type of regimen changed.
- The outcome of 39 patients lost to follow up was that 9 had died, 18 alive and 12 could not be traced due to wrong physical address and mobile numbers.

5.3 Recommendations

5.3.1 Recommendation for Improving Social Demographic Characteristics of Defaulters

1. That the care givers research on and implement measures to reduce stigma and strengthen family social support system among the persons on ARVs to enhance compliance.
2. Introduction of income generating activities programmes by the government may address financial instabilities among the patients

5.3.2 Recommendations for improving clinical characteristics of defaulters

1. Level of complexity of drug regimen needs to be explained to the patients before switch including side effects and ADRS. Proper counselling should be intensively done to those patients presenting severe ADRS

5.3.3 Outcomes of patients loss to follow up

Recommendations

1. Strengthening communication (links) among care givers to quickly get notification where patients transfer or opt out of the program, or die.
2. Stringent measures to be implemented at the point of enrolment to ART program to record accurate contacts for patients and next of kin for easy tracing.
REFERENCES


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APPENDICES

Appendix I: Ethical considerations

Risk factors and outcomes associated with lost-to-follow-up patients among ART patients at Mbagathi District Hospital.

Human rights

All women and men irrespective of age, sex or social status have a right to good health. A research recognizes ARV treatment as part of integral part of protection of basic human rights for life, health, dignity and equality.

Risks

There are no major risks involved in this study data that used will be secondary data and the patient assessment will be used during the interview.

Benefits

Findings of the study will enable health providers to improve clinical and monitoring evaluations procedures that should focus on improving quality of life for PLWHA. ART therapy transforms the life which is independent on the help of the family and community to an active life of self-dependence.

Confidentiality

Patient’s records will be handled confidentially. Codes will be used instead of the patient’s name. Only assigned persons (data analyst) will have the access to information.

The following information will be available at these addresses,

Director, Institute of Tropical Medicine and Infectious Diseases (ITROMID),

Jomo Kenyatta University of Agriculture and Technology,  
P.O BOX 6200- 00200, Nairobi  
Tel: 067-52711  
Email: info@jkuat.ac.ke OR  
Serah Njoki Gathu  
P.O box 50605-0100  
NAIROBI, KENYA
Appendix 2: Questionnaire

Risk Factors and outcomes Associated with HIV Positive Adult Patients Who Were Lost-To-Follow-Up on Antiretroviral Therapy at the Mbagathi District Hospital Comprehensive Care Clinic, Nairobi, Kenya, 2003-2009

PART A

*Demographic information*

1. SERIAL NO ………………..
2. AGE ……………
3. SEX /JINSIA (i) male (ii) female
4. MARITAL STATUS (i) single (ii) married (iii)widower(ed) (iv)divorced
5. LEVEL OF EDUCATION (i)primary (ii)secondary (iii)higher education (iv)none
6. SOURCE OF INCOME (i) employed (ii) unemployed

PART B

*Clinical information*

6. BASELINE W.H.O CLINICAL STAGING ON STARTING HAART
   W.H.O Stage (I) (II) (III) (IV)
7. TYPE OF REGIMEN USED WHEN STARTING HAART.
   (i) D4t/3tc/nvp (ii) D4t/3tc/efv (iii) others
8. CHANGING OF REGIMEN DURING TREATMENT-(i)Yes (ii)No
9. REASON FOR CHANGING REGIMEN
   (i) Adverse drug reaction (ii) TB (iii) Treatment failure
PART C

10. How do you feel currently about your HIV status?
   (i) Accepted   (ii) stigma   (iii) denial

11. Why did you leave the clinic?
   (i) Psychosocial reasons   (ii) clinical reasons   (iii) economic reasons

12. Are you still taking ARVs?
   (i) Yes   (ii) No

13. Have you experienced problems while taking the ARVs?
   (i) Psychosocial reasons   (ii) Clinical reasons   (iii) Economic reasons

14. Have you disclosed your status to closed relatives/friends?
   (i) Yes   (ii) No.

15. Are you currently in any support group?
   (i) Yes   (ii) No

16. Have you ever substitutes the ARVs with any other substance/herbs?
   (i) Yes   (ii) No

17. Do you have any faith/spiritual beliefs that have influenced taking the ARVs?
   (i) Yes   (ii) No
Appendix 3: Informed Consent

Study title:

Risk Factors and outcomes Associated with HIV Positive Adult Patients Who Were Lost-To-Follow-Up on Antiretroviral Therapy at the Mbagathi District Hospital Comprehensive Care Clinic, Nairobi, Kenya, 2003-2009

Madhara na matekeo zinazosabisha wagonjwa ambao, wametoweka kwa kiliniki ,wanao kunywa vidongwe vya dawa za ukimwi wa Hospitali ya mbagathi Wilaya ya-Nairobi

PART A

Introduction

You are asked to participate in this study because health professionals have realised that some patients have not maintained medical appointments from the clinic and i have to investigate through some questions about the reasons as to why they have left. Your contribution to giving information will guide us.

Sehemu ya kwanza

Unaulizwa kujumika Kwa utafiti huu Kwa sababu wa hudumu wa afya wamegunduwa kuna wagonjwa wengine amabao hukosa kutii magizo ya kurudi kliniki.tugependa ujibi maswali amabayo yatasaidia utafiti huu.

Being in the study is your choice

This consent form gives you information about the study, the risks and benefits, and the process that will be explained to you. Once you understand the study and if you agree to take part, you will be asked to sign your name or make your mark on this form. You will be given a copy to take home. Before you learn about the study, it is important that you know the following:
Your participation in this study is entirely voluntary.

You may decide to withdraw from the study at any time, without facing any consequences.

Utafiti wa hiari

Kushiriki katika utafiti huu ni wa hiari. Uamuzi wako kushiriki au kutoshiriki katika utafiti huu hautaatathiri huushiano wako sasa au katika nyakati zijazo na hospitali hii au vitengo vingine vinavyohusika ikiwa utakubali kushiriki, unahaki kuacha kushiriki wakati wowote bila kuhujumu husiano wako.

Purpose of the study

The purpose of the study is to determine risk factors and outcomes of LTFU adult’s patients on antiretroviral therapy, at comprehensive care clinic Mbagathi District Hospital, Nairobi, Kenya.

Kusudi la utafiti

Madhara Na matekeo zinazosababisha wagonjwa ambao, wametoweka Kwa kiliniki, wanao kunywa vidongwe vya dawa za ukimwi wa Hosipitali ya Mbagathi Wilaya ya-Nairobi

If you choose not to participate or to leave the study

You have the choice to or not to participate in this research study. If you choose not to participate in this study or to leave the study during the interview process, you may do so freely without consequences against you.

Utafiti

Kushiriki katika utafiti huu ni wa hiari. Uamuzi wako kushiriki au kutoshiriki katika utafiti huu hautaatathiri huushiano wako.
Risks and/or discomforts

We do not anticipate any risks or discomforts to you during this study. You will be requested to avail yourself for an interview at a place that you are most comfortable. You may become worried or anxious about discussing matters of the study. We will make every effort to protect your privacy and confidentiality while you are participating in the study. The interview will take place in private.

Madhara ya kushiriki kwa utafiti

Utafiti huu hauna madhara yanayo fahamika utahitajika kuuliza maswali bila mtu mwingine kusikia. Hakuna mtu mwingine yeyote atakaye pata ruhusa kuona/kusikiaila wale wanaohusika kwa utafiti huu.

Benefits

Your participation in this study is voluntary and you have the right to refuse to participate or to answer to any question that you feel uncomfortable with. If you change your mind, you have the right to withdraw at any time. If anything is not clear or if you need further information, we shall provide it to you.

Manufaa

Kwa kushiriki Kwa utafiti huu Na kujibu maswali yetu, utatusaidia kufahamu mahitaji ya jamii kuhusu huduma za wagonjwa wanaougua ugonjwa wa ukimwi. Kusihiriki kwako katika utafiti huu ni kwa hiari na unahaki ya kukataa kushiriki au kujibu swali lolote. Kama utabidili fikira zako, unaweza, unahaki kuacha wakati wowote Kama kuna jambo halieleweki au unataka habari zaidi tutakupa

Your records will be private

Every effort will be made to keep the information you provide confidential. You will be identified only by a code and personal information from the interview will not be
released without your written permission. You will not be personally identified in any publication about this study. However absolute confidentiality cannot be guaranteed. Your records may be reviewed by: Study Investigator or Ethics Committee at (ITROMID, KEMRI)

Kubaniwa kwa utafiti


Harm involved participating in this study

It is unlikely that any form of harm could happen to you as a result of being in this study

Kudhurika kwa utafiti huu

Hakuna madhara yeyote ambayo inatarajiwa kwenye utafiti huu

If you ever have questions about this study contact:

Principal Investigator, Serah Njoki Gathu,

Telephone number: 0720926049,

Email address: njoki_sg@yahoo.com

Watakao jiibu maswali
Mtafiti anayefanya utafiti huu ni Serah Gathu, Unaweza kuuliza maswali yeyote uliyonayo sasa ama ikiwa utakuwa nayo baadaye, unahimiza umjulishe kwa nambari yasimu: 0720926049 barua pepe njoki_sg@yahoo.com.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher, you are encouraged to contact the following:

The Director, Institute of tropical medicine and infectious diseases (ITROMID),
Jomo Kenyatta University of Agriculture and Technology,
P. O. Box 62000 00200, Nairobi.

Tel. 067 – 52711,

E-mail: info@jkuat.ac.ke

Mkurugenzi (ITROMID) JOMO KENYATTA, S.L.P 62000-00200, NRB

Simu; 067-52711 Barua Pepe: info@jkuat.ac.keAU,

Mkurugenzi, ITROMID-KEMRI OFFICE, Kenya Medical Research Institute
S.L.P 54840-00200 Nairobi.

Simu: 020-2722541/4

OR

The Chairman KEMRI National Ethical Review Committee

P.O BOX 54840 – 00200 NAIROBI, KENYA.

TEL: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003;

E-mail: info@kemri.org
PART B: CONSENT FORM / FOMU YA KUPEANA HIARI

Please read the information sheet (PART A) or have the information read to you carefully before completing and signing this consent form. If there are any questions you have about the study, please feel free to ask them to the investigator prior to signing your consent form.

Declaration of the volunteer / Arifa yamhojiwa wahiari

I Mr, Miss, Mrs………………hereby give consent to Miss Serah N. Gathu to include me in the proposed study entitled risk factors and outcomes of loss to follow up adults patients on antiretroviral therapy, Mbagathi District Hospital, Comprehensive care Clinic, Nairobi, Kenya. I have read the information sheet concerning this study, I understand the aim of the study and what will be required of me if I take part in the study. The risks and benefits if any have been explained to me. Any questions I have concerning the study have been adequately answered. I understand that at any time that I may wish to withdraw from this study I can do so without giving any reason and without affecting my access to normal health care and management. I realize that I will be interviewed once. I consent voluntarily to participate in this study.

Subject’s Name,/ Jina la mhijiwa

Signature or left thumb print ______________ Date____________

Name of person taking consent…………………………………………

Signature/Sahihi ……………Date/Tarehe …………………

Name of Investigator / Jina la mtafiti

Signature of Investigator / Sahihi ya mtafiti _____Date/Tarehe…………..
Appendix 4: Ethical Approval

KENYA MEDICAL RESEARCH INSTITUTE

TO: SERAH NOOKI GATHU,
PRINCIPAL INVESTIGATOR

THRU: DR. YERI KOMBE,
THE DIRECTOR, CPHR,
NAIROBI

RE: SSC PROTOCOL NO. 1804 (RE-SUBMISSION): RISK FACTORS AND OUTCOMES ASSOCIATED WITH LOSS-TO FOLLOW-UP ADULT PATIENTS AT THE MBAGATHI DISTRICT HOSPITAL COMPREHENSIVE CARE CLINIC, NAIROBI KENYA

October 27, 2010

Make reference to your letter dated October 11, 2010 received on October 13, 2010. Thank you for your response to the issues raised by the Committee. This is to inform you that the issues raised during the 183rd meeting of the KEMRI/ERC meeting held on 6th September 2010, have been adequately addressed.

Due consideration has been given to ethical issues and the study is hereby granted approval for implementation effective this 27th day of October 2010, for a period of twelve (12) months.

Please note that authorization to conduct this study will automatically expire on 26th October 2011. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by 2nd September 2011.

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study.

Yours sincerely,

R. C. KITENJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE