COMPARISON OF LOSS TO FOLLOW-UP AMONGST HIV AND AIDS PATIENTS IN CARE AND TREATMENT IN KISUMU, KENYA

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A mini-thesis submitted in partial fulfilment of the requirements for the degree of Masters in Public Health at the School of Public Health, University of the Western Cape

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August 2012
Declaration

I declare that “Comparison of loss to follow up amongst HIV and AIDS patients in care and treatment in Kisumu, Kenya”, is my own independent work that has not been submitted before any degree or examination in any other university and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Fredrick O. Miruka
August 2012
Keywords
Loss to follow-up
Retention
Antiretroviral Therapy
Cotrimoxazole Preventive Therapy
HIV treatment
HIV care
HIV/AIDS
Mortality
Outcomes of treatment
ABSTRACT

Background
Even though there have been marked increases in the number of patients accessing HIV care and treatment in sub-Saharan Africa, challenges in patient retention remain. Most health systems in sub-Saharan Africa routinely report on loss to follow up of patients, but only a limited number of factors associated with loss to follow up are measured. In Kenya there is limited research on loss to follow up in HIV care and treatment programs. This study reports on rates of loss to follow up and factors associated with loss to follow up at the New Nyanza Provincial General Hospital (NNPGH) in Kisumu, Kenya.

Methods
A retrospective cohort study of 4,740 adult patients that was registered for HIV and AIDS care and treatment between 2003 and 2008 was conducted. Data was analysed using SAS 9.2 and STATA 10. Cox proportional hazard ratio was calculated to describe the association between risk factors and loss to follow up.

Results
Of the total 4740 patients, 64.6% were female, males [median age of 36 (IQR 30-44) years vs. 32 (IQR 26-39) years for females] were older than females, more males (68.3%) were married, more females (6.2%) had no education and 68% of all patients enrolled had been lost to follow up over 6 years. Risk for lost to follow up was greater amongst males (Adjusted Hazard Ratio (AHR) =1.12; 95% Confidence Interval (CI) = 1.02-1.22); younger patients (15-30 vs. >40 years: AHR=1.37, 95%CI = 1.23 – 1.53; and 31-40 vs. >40 years: AHR=1.15, 95%CI=1.03-1.28); those who were unemployed (AHR=1.14, 95%CI=1.05-1.25); and having advanced HIV disease (WHO stage 4 vs. WHO stage 1: AHR=1.53, 95%CI=1.29-1.81). Patients on ART (AHR=0.64, 95%CI=0.52-0.78) at enrollment were less likely to be lost to follow-up compared to those in HIV care.

Conclusion
More attention is needed in developing retention strategies for patients with much focus on patients on care. Targeted intervention is required to improve retention amongst males, unemployed patients, patients with advanced HIV disease and younger patients. Additionally, targeted follow up in the community for patients on care is required.
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Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>HIV</td>
<td>Human Immuno-Deficiency Virus</td>
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<td>AIDS</td>
<td>Acquired Immuno-Deficiency Syndrome</td>
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<td>KAIS</td>
<td>Kenya AIDS Indicator Survey</td>
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<td>PLHIV</td>
<td>People living with HIV</td>
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<td>KDHS</td>
<td>Kenya Demographic Health Survey</td>
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<td>ARVS</td>
<td>Antiretroviral</td>
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<td>ART</td>
<td>Antiretroviral therapy</td>
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<td>NNPGH</td>
<td>New Nyanza Provincial General Hospital</td>
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<td>CCC</td>
<td>Comprehensive Care Centre</td>
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<tr>
<td>CPT</td>
<td>Cotrimoxazole preventive Therapy</td>
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<td>CD4</td>
<td>Cluster designated 4</td>
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<td>CBC</td>
<td>Complete Blood Count</td>
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<td>LFT</td>
<td>Liver function tests</td>
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<td>WHO</td>
<td>World Health Education</td>
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<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<td>CDC</td>
<td>Center for Disease Control and Prevention</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>LTFU</td>
<td>Loss to Follow Up</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>ERC</td>
<td>Ethics Review Committee</td>
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Definition of terms

**Loss to follow up** - Patient who has missed clinic visit for a period more than 3 months (90 days) (Ministry of Health, 2007) and there are no records indicating that the patient has been transferred to other clinic or dead.

**Retention** – ability of a program to follow up patients in care and treatment with minimal dropout or loss to follow-up rates.

**Care** – provision of Cotrimoxazole and other supportive services to HIV infected patients to assist in preventing preventable illnesses.

**ART** – Provision a package of services that includes but not limited to antiretroviral drugs and care and support services.
1.1 Background
Since the identification of Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV/AIDS) in 1981 (WHO, 2003b), this pandemic has continued to rob countries of the resources and capacities for human security and development (UNAIDS and WHO, 2002). The HIV/AIDS pandemic has continued to be a heavy public health Achilles heel and more so in sub-Saharan Africa (UNAIDS, 2004; UNAIDS, 2008; UNAIDS and WHO, 2001; UNAIDS and WHO, 2002; UNAIDS and WHO, 2006; UNAIDS and WHO, 2009; WHO, 2008). In 2010, an estimated 34 million people were living with HIV/AIDS including 3.4 million children under the age of 15 years. It is further estimated that there were 2.7 million incident infections and that approximately 1.8 million people died of HIV related illnesses (WHO, UNAIDS and UNICEF, 2010).

Sub-Saharan Africa which contributes to only 10% of world’s population, disproportionately contributes to an estimated 23.1 million (68%) of the total worldwide population of People living with Human Immuno-deficiency Virus (PLHIV) in 2010 (WHO, UNAIDS and UNICEF, 2010). Additionally, 59% of PLHIV in Sub-Saharan Africa were women (WHO, UNAIDS and UNICEF, 2010). The region also accounted for 70% of all new HIV infections among adults. In addition, 67% of all deaths due to HIV/AIDS in the world occurred in sub-Saharan Africa. HIV/AIDS has impacted negatively on communities due to loss of productivity from mortality and morbidity in 30 to 50 years age group. It is projected that an additional 6 million households will be in poverty by 2015 due to either loss of productivity or the burden of disease in this age group unless national responses such as increased access to Antiretroviral Therapy (ART) and support to PLHIV are strengthened (UNAIDS, 2008).

HIV/AIDS in Kenya
The Kenya AIDS Indicator Survey (KAIS) of 2007 conducted by the National AIDS and STI program estimated the national adult (15 – 64 years) HIV prevalence at 7.1% with an estimated 1.4 million PLHIV (National AIDS and STI Control Program and Kenya Ministry of Health, 2009). The report further estimated that the HIV prevalence among adults in the 15 to 49 years age group to be 7.4% (National AIDS and STI Control Program and Kenya Ministry of Health, 2009). The HIV prevalence in the 15-49 years age group was not very different from those reported in the Kenya Demographic and Health Survey (KDHS) of 2003 (Central Bureau of Statistics, Ministry of Health Kenya and ORC Macro, 2003). KAIS also
estimated that of the 1.4 million PLHIV, 138,000 (9.7%) were on antiretroviral therapy (ART) at the time of the survey in 2007. The report further indicates that the HIV prevalence is higher in the urban areas (8.4%) compared to rural areas (6.7%) (National AIDS and STI Control Program and Kenya Ministry of Health, 2009).

Nyanza province has the highest HIV prevalence at 14.9% compared to the other seven provinces in Kenya. HIV prevalence in Nyanza is double the national prevalence and is home to an estimated 417,000 PLHIV (National AIDS and STI Control Program and Kenya Ministry of Health, 2009). In Nyanza, of the 56,000 patients that are eligible for ART, 44,000 are on ART (National AIDS and STI Control Program and Kenya Ministry of Health, 2009). The HIV prevalence in the rural areas at 14.9% in the province is slightly higher than the prevalence in the urban areas at 13.9% which is reverse of the national trend (National AIDS and STI Control Program and Kenya Ministry of Health, 2009).

**Impact of support towards HIV program on mortality and morbidity**

Since the introduction of ART in 1996, there has been substantial reduction in mortality and morbidity (Montaner et al., 1998). In countries with adequate resources, ART has greatly improved the outcome of treatment such as quality of life for patients with HIV/AIDS (Egger et al., 2002; Schneider et al., 2005; Walensky et al., 2006). Additionally, use of Cotrimoxazole Preventive Therapy (CPT) in sub-Saharan has also been shown to prolong life (Mwaungulu et al., 2004; Nunn et al., 2008) resulting in improved outcomes for patients started on CPT (Nunn et al., 2008) including those in successfully integrated TB and HIV services (Friedland, Harries and Coetzee, 2007).

Due to the heavy burden and negative impact of HIV/AIDS and more so to sub-Saharan Africa, joint efforts and resources have been mobilized globally and geared towards ameliorating the effects to these populations. Joint efforts such as the “3 by 5” initiative in 2003 which aimed at improving access to ART to 3 million people by the year 2005 (WHO, 2003c) whose target was later achieved in the year 2007 (WHO, 2009). In addition to political commitment (WHO, 2009), other substantial effort and support by multiple partners has led to expansion of HIV/AIDS HIV care and treatment programs (WHO, 2009). These efforts have resulted in expanded access to HIV care and treatment services evidenced by improved ART coverage and access with an estimated 4,030,000 in 2008 up from only
400,000 in 2003 worldwide; 2,925,000 in 2008 up from only 100,000 in 2003 in sub-Saharan Africa and an increase from 177,000 in 2007 to 242,881 in 2008 in Kenya. This improvement has resulted in an overall coverage of 31% globally and 30% in sub-Saharan Africa (UNAIDS and WHO, 2009). Despite the success in Sub-Sahara Africa, there are still gaps such as shortage of human resources that need to be addressed (Muula et al., 2007), sufficiently trained healthcare personnel, inadequate facilities, complexity of drug regimens and formulations and compartmentalization of ART program that have negative impact on referral and linkages (Meyers et al., 2007).

**Influence of retention on patient treatment outcomes**
Long term retention is important in achieving adherence in treatment HIV care and treatment programs even though most HIV care and treatment programs have paid less attention to patients lost due to attrition (Rosen, Fox and Gill, 2007). Initiation of care (opportunistic infections preventive care) and ART to HIV infected persons reduces morbidity and mortality hence the need for patient to continue with care and treatment without dropping out (National AIDS and STI Control Program and Kenya Ministry of Health, 2007; National AIDS and STI Control Program and Kenya Ministry of Health, 2008). Optimal adherence to ART (taking 95% or more of medication) is important in preventing treatment failure and development of drug resistance (National AIDS and STI Control Program and Kenya Ministry of Health, 2007). Non-adherence to treatment results in severe consequences such as poor clinical outcomes (WHO, 2003a), worsening of the condition being treated, death and increased health care costs, deaths, and hospitalizations (Frost and Sullivan, 2010; Osterberg and Blaschke, 2005). Additionally, poor adherence can lead to development of viral resistance and treatment failure amongst HIV infected patients on ART posing a great public health problem (WHO, 2003a).

**1.2 Problem statement**
New Nyanza Provincial General Hospital (NNPGH) HIV Comprehensive Care Clinic (CCC) has been providing care and ART to PLHIV since 2003. As of December 2011 an estimated 21,000 HIV infected adults and children had ever been enrolled for care and ART at the CCC. However, an estimated 15-20% of patients initially enrolled for HIV care and ART, are no longer receiving care at the clinic (Omollo, 2009). There is however limited information on the actual proportion of patients lost to follow-up and the associated factors thus the need
to determine the rates and factors associated with loss to follow-up among adult HIV-infected patients enrolled at the CCC between 2003 and 2008. Determination of rates of loss to follow-up and factors associated to loss to follow up may provide insight for future interventions and resources needed to maximize retention.

1.3 Study aim and objectives

The aim of this study was to describe and compare loss to follow-up between the patients on care and those on Cotrimoxazole Preventive Therapy (CPT) and ART; and to determine the factors associated with loss to follow up among adult HIV- patients enrolled in New Nyanza Provincial General Hospital HIV Comprehensive Care Clinic between January 2003 and December 2008.

The objectives were:

- To describe the demographic and clinical characteristics of HIV infected adults enrolled for HIV/AIDS care and treatment.
- To calculate loss to follow-up of HIV infected adults.
- To determine factors associated with loss to follow up among HIV infected adults.
- To compare the rates of loss to follow up and associated factors between HIV/AIDS care and ART groups.

1.4 Study setting

This study was set within the NNPGH CCC 2003 – 2008 evaluation which has approval from Kenya Medical Research Institute (KEMRI) Ethical Review Committee (ERC). NNPGH is the regional referral hospital for Nyanza province with a population of 5.4 million in 2009 (Kenya National Bureau of Statistics, 2010). NNPGH mainly serves the population in Nyanza province though patients from neighbouring provinces (Rift Valley and Western province) may also be referred to the hospital for specialised treatment. It offers a variety of services including out-patient care with general and special cases clinics such as Medical, Paediatric, Surgical, Obstetrics and Gynaecology out-patient clinics, both in-patient and out-patient pharmacies, in-patient care with a capacity of 442 beds, CCC and a laboratory with capability to offer several tests including specialised tests such as CD4 cell count for PLHIV as recommended by Ministry of health (MoH) (Ministry of Health, 2006).
In NNPGH, HIV specific programmatic efforts began in May 2001, with the introduction of Prevention of Mother to Child Transmission (PMTCT-Plus) Programme which aimed at reducing the transmission of HIV from the mother to the child (Ministry of Health, 2006). The CCC was started in January 2003 and provides both HIV care and ART to patients. The patients on care benefit from CPT, psychosocial support, nutritional supplementation, laboratory monitoring and treatment and prevention of other opportunistic infections (OI). Additionally, patients who are eligible for ART are initiated on ART as per the Ministry of Health guidelines (National AIDS and STI Control Program and Kenya Ministry of Health, 2007). As part of these guidelines, patients are required to enroll into the CCC and are then provided with CPT, Multivitamin, regular monthly or quarterly follow-up, supportive counselling, baseline laboratory testing, including but not limited to CD4 count testing, Complete Blood Count (CBC) and Liver Function Tests (LFTs), assessment and possible initiation of ART accompanied by monthly clinical and six-monthly laboratory monitoring or as deemed necessary by the clinician.
2. Literature review

“Loss to follow-up” has been defined by several authors as patients missing two or more consecutive clinic appointments (Wester et al., 2005) or when a patient had not been seen at the clinic for at least 2 or 3 months (Calmy et al., 2006; Wools-Kalaustian et al., 2006; Laurent et al., 2005). In Kenya, the National AIDS and STI which co-ordinates all HIV care and treatment programs considers a patient as “loss to follow up” when the patient had missed their scheduled appointment for a period of more than three months (Ministry of Health, 2007).

Globally, it is estimated that more than 20% of patients on ART are not retained in ART programmes after 12 months and retention is even worse with less than three quarters retained at 4 years (WHO, 2009). On the other hand, in sub-Saharan Africa, of the total 74,289 patients included in the analysis, 22.5% (16,715) had dropped from care and treatment. Amongst those that dropped from care and treatment, 56% (9,360) were due to loss to follow up (Rosen, Fox and Gill, 2007). Additionally, in sub-Saharan Africa retention on ART HIV care and treatment programs is estimated to be 75% at 12 months and 67% at 24 months of treatment and stabilizes afterwards (WHO, 2009). However, several HIV care and treatment programs recorded high retention rates between 67% and 84% (Barth et al., 2008; Bekker et al., 2006; Dalal et al., 2008; Lawn et al., 2006; Makombe et al., 2008; Orrell et al., 2007; Severe et al., 2005). In a recent systematic review of retention in Sub-Saharan Africa, Rosen and Fox assessed retention at various stages from testing to treatment initiation. The pre-ART retention rate was lowest at 46% in a Cape Town township public clinic in South Africa and highest at 70% in Arba Minch hospital in Ethiopia (Rosen and Fox, 2011).

Mortality among patients on ART and those not on ART were comparable. Mortality amongst patients on ART were from proportions as low as 6.6% to as high as 19% while that among patients not on ART were estimated at between 5% and 19% (Barth et al., 2008; Bekker et al., 2006; Karcher et al., 2007; Laurent et al., 2005; Lawn et al., 2006; Makombe et al., 2008; Orrell et al., 2007; Severe et al., 2005; Sow et al., 2007; Wools-Kalaustian et al., 2006).

Loss to follow up is contributed to by reasons such as complex therapeutic regimen (Osterberg and Blaschke, 2005), loss of hope in medication, belief in spiritual healing, excessive alcohol consumption, being bed ridden, lack of disclosure, no money for transport...
and some transfer out without informing the clinic (Deribe et al., 2008). Loss to follow up among patients on ART has been estimated by several studies and HIV care and treatment programs to be between 3% and 29% with the highest being in Kibera Kenya (Barth et al., 2008; Bekker et al., 2006; Dalal et al., 2008; Karcher et al., 2007; Laurent et al., 2005; Lawn et al., 2006; Makombe et al., 2008; Orrell et al., 2007; Severe et al., 2005; Sow et al., 2007; Unge et al., 2009; Wools-Kalaustian et al., 2006; Yu et al., 2007).

2.1 Characteristics of patients at enrollment

Patients in majority of the studies and HIV care and treatment programs had a median age less or equal to 35 years at enrolment with 45% of them being in the 30-39 years age group (Barth et al., 2008; Lawn et al., 2006; Lawn et al., 2005; Stringer et al., 2006; Brinkhoft et al., 2008). In contrast, HIV care and treatment programs in Kenya and Uganda had older patients with a median age of more than 35 years (Kamya et al., 2007; Marston et al., 2007; Wools-Kalaustian et al., 2006).

Females were dominant in most HIV care and treatment programs and comprised from as low as 46% to 74% of patients of enrolled patients (Amuron et al., 2009; Brinkhoft et al., 2008; Kamya et al., 2007; Lawn et al., 2006; Lawn et al., 2005; Marston et al., 2007; Orrell et al., 2007; Stringer et al., 2006; Wools-Kalaustian et al., 2006). In contrast, a clinical cohort in France and an ART program in the Malawi police force had more men comprising 78% and 75% respectively (Lebouche et al., 2006; Makombe et al., 2008).

An estimated 51% in a cohort of patients in South Africa at enrolment had no education (Barth et al., 2008) compared to an ART program in western Kenya and Haiti which had only 8% and 17% of patients enrolled with no education respectively (Severe et al., 2005; Wools-Kalaustian et al., 2006). In Kenya, of the proportion that attended school, the median years of school attendance was 9 (Wools-Kalaustian et al., 2006).

Patients in most HIV care and treatment programs had a median CD4 cell count less than 250 cells/\mu l^3 (Barth et al., 2008; Kamya et al., 2007; Lawn et al., 2006; Lawn et al., 2005; Orrell et al., 2007; Wools-Kalaustian et al., 2006; Brinkhoft et al., 2008; Marston et al., 2007; Stringer et al., 2006). Most patients initiating ART in sub-Saharan Africa were enrolled with advanced clinical disease with most HIV care and treatment programs having more than 70% of patients in WHO stage 3 and 4 (Barth et al., 2008; Kamya et al., 2007; Lawn et al., 2006;
Lawn et al., 2005; Makombe et al., 2008; Marston et al., 2007; Stringer et al., 2006). Other HIV care and treatment programs however still registered proportion of patients in WHO stage III and IV lower than 70% (Amuron et al., 2009; Brinkhoff et al., 2008; Wools-Kalaustian et al., 2006). In Guguletu, South Africa, Bekker and others showed changes in WHO clinical staging trends and that there was a decrease in the proportion of patients enrolled in stage IV over the years from 44% in 2002/3, 25% in 2003/4 and 21% in 2004/5 (Bekker et al., 2006).

Only 23.9% of patients enrolled in a South Africa program were employed (Barth et al., 2008) compared to 30.5% of patients having employment outside home in western Kenya (Wools-Kalaustian et al., 2006). Of patients enrolled, 49.2% were living with a partner in South Africa (Barth et al., 2008) compared to 64% who were married in western Kenya (Wools-Kalaustian et al., 2006).

2.2 Factors contributing to loss to follow up

2.2.1 Period of patient’s time on care and treatment

ART is a lifelong treatment and patients once initiated on it will continue on treatment. Period of treatment has been shown to influence patient outcomes. In an urban clinic in Cameroon, ART eligible patients who were older than 14 years were initiated on ART and prospectively followed for a period of 18 months. Findings from this study showed that patients were most likely to be lost to follow during the first 6 months of ART initiation (Tsague et al., 2009). Additionally, Patients lost to follow up at 12 months had significantly high CD4 cell count compared to those retained in the program. Those patients with CD4 cell counts above 50 cells/μl and without Tuberculosis (TB) infection were more likely to remain in care (Tsague et al., 2009).

In a study at a Hospital in Yaounde Central Hospital in Cameroon where 312 patients initiated on ART were followed up for 6 months, results showed that most losses to follow up occurred during the initial months of ART initiation (Rougemont et al., 2009). In a study by Wools Kalaustian et al. (2006), it was demonstrated that the risk of a patient being lost to follow up was associated with the length of time on treatment. The study also indicated that losses to follow up after two and three years of treatment were 24.5% and 29.7% respectively.
2.2.2 Age of the patient

In a review of ART programmes in 13 low income countries in Northern Africa, Southern Africa, Eastern Africa, Central and Western Africa, South America and Asia, data for 5,491 patients were reviewed and included in the analysis. Results indicated that patients who were old were more likely not to return to the clinic after the first visit (Brinkhoft et al., 2008). In contrast, a study looking at 253 patients from hospitals in Malawi, results indicated that the patients who had defaulted were at a much young age of 35 years (Yu et al., 2007).

Similar findings to those in the Malawi study by Yu et al. were noted in an urban clinic in France where a cohort of 1,756 patients was followed up for about 13 years. Results indicated that the younger the patients were, the more likely they were to be lost to follow up and that patients who were younger than 30 years of age (52%) were more likely to be lost to follow up followed by those who were 30-40 years old (37%) and lastly by those who were older than 40 years of age (11%) (Lebouche et al., 2006). Similar results were documented in a study in Migori Kenya which followed up PMTCT patients together with their partners and children enrolled in the HIV clinic for a period of about 20 months. Results indicated that young age was associated with more clinic drop outs (Karcher et al., 2007).

2.2.3 Gender of the patient

In a Uganda study looking at loss to follow up of patients screened for ART eligibility before ART initiation, males were more likely not to complete the three required pre-ART screening visits compared to females (Amuron et al., 2009). Similar findings in a large ART program in western Kenya where data of 2,059 patients were reviewed indicated that males were significantly more likely to be lost to follow up compared to females (Wools-Kalaustian et al., 2006). Males were also associated with early mortality and reduced chances of survival which may have contributed to early loss to follow up (Lawn et al., 2006; Nachega et al., 2006).

Of contrast are the results of a study comparing outcomes of patients in a central hospital compared to those in three peripheral hospitals in Malawi. Results showed that 60% of patients lost to follow up were females (Yu et al., 2007). In an urban clinic cohort in France which had more males (78%) than females, the proportion of loss to follow up between males and females were not significantly different (Lebouche et al., 2006).
2.2.4 Economic status of the patient

Patient’s economic status was associated with probability of loss to follow up as demonstrated in Kibera Kenya and France. In Kibera which is largely an informal settlement, an ART program based in Kibera provided services to both Kibera and non-Kibera residents. Results from Kibera showed that patients who were Kibera residents and lived under hard conditions were 11 times more likely to drop out from treatment programmes compared to non-Kibera residents (Unge et al., 2009). In an urban clinic in France, unemployment was associated with loss to follow up of patients (Lebouche et al., 2006). In contrast, Rougemont and others (2009) in a study in Yaunde Central Hospital in Cameroon found that income was not associated with adherence.

In an ethnographic study done in both Tanzania and Nigeria by Ware and others, participants indicated that most adherence obstacles were due to resource constraints. The participants in the study indicated that obtaining money for transportation to clinic appointments was a challenge. Most patients had to borrow or “beg” for money to raise money for transportation to the clinic (Ware et al., 2009).

2.2.5 Clinical status of the patient

Clinical status of the patients has also been shown to influence patient outcomes and loss to follow up. Yiannoustos and others in review of a HIV treatment program in western Kenya with 8,977 enrolled patients showed that patients with advanced WHO stage (stage 3 or 4) were more likely to be lost to follow up compared to those in stage 1 or 2 (Yiannoutsos et al., 2008). Similar results were found in a study in a hospital in Yaounde Cameroon. A cohort of patients starting ART was followed up for a period of 6 months to determine outcomes. Patients who had CDC stage B and C disease were more likely to be lost to follow up compared to those who were asymptomatic and CDC stage A (Rougemont et al., 2009).

Stringer and others in their study in Zambia showed that patients in WHO stage 4 were more likely not to adhere to ART in the first 6 months of therapy and in effect impacting negatively on CD4 and outcome (Stringer et al., 2006). In a Malawi study comparing outcomes of patients enrolled in a central hospital compared to those in three peripheral hospitals, patients in WHO stage 3 and 4 contributed to 91% and 99% of patients lost to follow in the central hospital and three rural hospitals respectively (Yu et al., 2007).
Contrasting results were documented in a review of HIV treatment programs across selected 15 countries across Africa, Asia and South America by Brinkhoff et al. and Lawn et al. where records of 5,419 patients who had been followed up for more than 12 months were analyzed. Advanced clinical disease of patient was not associated with loss to follow up (Brinkhoff et al., 2008). Similar results were also indicated by Lawn and others in a study looking at determinants of mortality and non-death losses from an ART service in South Africa (Lawn et al., 2006).

2.2.6 Immunological status of the patient

Immunological status of the patients has been shown to influence patient outcomes. Patients with low CD4 cell count at enrollment were shown to be more likely to be lost to follow up (Amuron et al., 2009; Lawn et al., 2006; Yiannoutsos et al., 2008). Other studies also indicated that low CD4 cell count was associated with high likelihood of mortality and decreased survival amongst patients (Barth et al., 2008; Lawn et al., 2006; Nachega et al., 2006; Stringer et al., 2006). Additionally, in correlating CD4 cell count and likelihood of mortality, results indicated that the lower the CD4 cell count the higher the likelihood of death (Barth et al., 2008). Contrasting results were recorded by Lebouche and others in their review of a clinical cohort of patients enrolled in an urban clinic in France indicated that patients who had a CD4 cell count above 350 were more likely to be lost to follow up (Lebouche et al., 2006).

2.2.7 Size and structure of the HIV care and treatment program

Size of the ART program in terms of patient load and the level of patient tracing have also been shown to influence outcomes. Larger HIV care and treatment programs with high patient loads were less likely to trace patients lost to follow up resulting in high proportions of patients lost to follow up (Brinkhoff et al., 2008). HIV care and treatment programs with active follow up systems had lower lost to follow up rate (12%) with a median loss to follow up time of 5.8 months compared to 19% of patients lost to follow up in HIV care and treatment programs with passive follow up system with a median lost to follow up time of 3.4 months (Brainstein et al., 2006). The level of health facility also influences patient outcomes as shown by a study in Malawi indicating that the rates of loss to follow up were far much higher in hospitals compared to that of health centres due to geographical access (Massaquoi et al., 2009).
2.2.8 Cost of care and treatment

Cost has been shown to be an influence continuity of treatment amongst PLHIV and adherence to ART. HIV care and treatment programs that required partial or full payment for services had lower chances of retaining patients compared to those providing services for free in most cases (Rosen, Fox and Gill, 2007; Laurent et al., 2005; Mills et al., 2006). However a study of 15 treatment HIV care and treatment programs in Africa, Asia, and south America showed that free-for-service program was associated with increased probability of no follow up and death (Brinkhoft et al., 2008).

2.2.9 Other factors

Other factors contributing to loss to follow up and lack of adherence include lack of disclosure for fear of being stigmatized; patients movement out of catchment area and problems with transportation access; distance to the clinic related to the inconvenience of travel and transfer to another ART programme (Brinkhoft et al., 2008; Mills et al., 2006; Roura et al., 2009; Severe et al., 2005; Wools-Kalastian et al., 2006). In a Gambia study, a significant 40% of patients were lost to follow up due to lack of disclosure of their HIV status to their family member of a friend before ART initiation (Togun et al., 2011). Underlying causes to drop out include premature death, competing causes of disease, alcohol or substance abuse, poverty and high mobility (Unge et al., 2009).
CHAPTER THREE

METHODOLOGY

WESTERN CAPE
3.1 Study design
This was a retrospective cohort study based on a retrospective review of patient clinical care and treatment data in NNPGH from January 2003 to December 2008. The study design was selected based on its strengths that include ability to determine cause of the problem - which in this study is loss to follow-up (LTFU); enable longitudinal follow up of patients; ability to estimate incidence and risk of an event which in this study is LTFU and allows for accurate measurement of exposure variables.

3.2 Study population
This study was set within A Retrospective Clinical Record Review: Nyanza Provincial General Hospital HIV Comprehensive Care Clinic: 2003 – 2008 study which was a retrospective study to review NNPGH program data and determine outcomes of adults and children enrolled in NNPGH between January 2003 and December 2008. In this study, data of adult patients (15 years and above) enrolled between 2003 and 2008 was reviewed to determine LTFU amongst patients on care and ART.

3.3 Inclusion and exclusion criteria
Inclusion criteria: - To be included in this study, patients must have been enrolled in NNPGH CCC between 8th January 2003 and 30th September 2008; been older than 14 years of age at enrollment and have complete records.
Exclusion criteria: - All patients that have been discontinued due to death or transfer out to other facilities were excluded from this study.

3.4 Sampling
Data used for this study were from the intake, enrollment and follow up databases which were for the same patients. A total of 9100 records were in the intake database and 9298 in the enrollment database. The intake and enrollment databases were merged into one database and only 6108 (3190 records were excluded from analysis due to missing intake information for 198 records and 2,992 records did not successfully link) which represented 78% of all patients were successfully linked. An additional 1,368 records were excluded from analysis due to missing key variables of analysis such as age, WHO clinical staging, marital status, employment status and type of treatment. A total of 4740 records were finally included in the analysis and successfully linked to the follow up database as indicated in figure 3.1 below.
3.5 Data collection

Data for this study was collected as part of routine patient care and treatment by health care providers who as part of clinical care completed standardized intake, enrolment, follow-up and discontinuation forms among others designed using Teleform® version 10.0 Software. Information from the intake form provided social and demographic information such as age, gender, marital status, employment and level of education while enrolment and follow-up forms provided clinical information such CD4 level, WHO clinical staging and type of treatment the patient was on at baseline and at each follow-up visits respectively. These
forms once filled were then scanned into a password protected computer, verified, cleaned and finally stored into access based database. The data sheet shown in the appendix I indicate the variables of interest abstracted from the electronic medical database to create dataset for analyses. This database was then cleaned and the final variables picked for analysis.

3.6 Validity and Reliability

Automation of data entry through scanning of forms eliminated the need for manual data entry and as a result minimizing errors. Information bias was minimized by using a designed standard data tool for data extraction to ensure that similar information was extracted from the database for all records included in the analysis. I additionally relied on accurate record keeping using the electronic database. Integrity of data was ensured through data cleaning by checking for outliers and errors, eliminating duplicates and identifying and filling in missing data that was abstracted by trained data abstractors.

Selection bias was minimized by providing all patients who were enrolled within the study period with equal opportunity of being included in the study and those excluded were due to incomplete records. Lastly, confounding was minimized by ensuring that possible confounding factors such as age, employment, marital status, treatment group, education and gender were included in the multivariate analysis to deal with interaction of one variable on another that may have otherwise resulted in a wrong conclusion on the effect of the variable on the outcome variable, loss to follow-up.

3.7 Generalizability

Findings from this study are therefore generalizable to the general adult population accessing HIV care and treatment in NNPGH CCC.

3.8 Data analysis

Data analysis was done using statistical analysis software (SAS) for windows version 9.2 (SAS Institute, Cary, North Carolina, USA) and STATA version 10 (STATA Corp LP). Additionally, Microsoft office Excel 2007 was used in creating graphs. Loss to follow up was calculated by getting the difference in terms of days between the date the patient was last
seen in the clinic and the study censor date i.e. 31/12/2008. The difference was then
dichotomized into equal or less than 90 days and more than 90 days. A patient was
considered to be lost to follow up if he/she was absent from the clinic for a duration of more
than 90 days, otherwise the patient was active as indicated in the MOH 257 Comprehensive
Care Clinic Patient Card (Ministry of Health, 2007).

To describe the baseline demographic characteristics of adult patients, frequencies and
proportions of patient characteristics such as age, gender, education, employment, marital
status, baseline CD4 cell count, clinical status (WHO clinical stage), type of treatment (either
care or ART) and HIV status disclosure were done. Median was also computed for
continuous variables like age because median is not much affected when variables are not
normally distributed. Additionally, trends of patients at enrollment over the years (2003 –
2008) were also analyzed by clinical status (WHO stage), gender, age and baseline CD4.

Rates of loss to follow up of HIV infected adults, incidence and prevalence of loss to follow
up were calculated by year, period of follow up, gender and clinical WHO staging. The
incidence of loss to follow up was also be calculated at month 6, 12, 24, 36, 48 and 60 of
follow up by year of enrollment and by period of treatment looking at type of treatment (Care
or ART) at time of loss to follow up.

To determine factors associated with loss to follow up, relative risk were calculated to
explore the risks associated with loss to follow-up across different categories in each
variable; Cox proportional hazard model was used to explore the association between various
risk factors and loss to follow up. Hazard ratios and 95% confidence intervals were calculated
to select the variables to be included in the final model. Associations (hazard ratio) and test of
significance (Chi-square) were done. Cox proportion hazards model was done and all the
presumed risk factors found to have p values of <0.25 from the bivariate analysis were then
included in the multivariate analysis. The cut off p value of <0.25 was chosen based on the
works of Bendel and Afifi (Bendel and Afifi, 1977) and Mickey and Greenland (Mickey and
Greenland, 1989) which showed that this cut off point allows for the inclusion of all
important variables even though it also has the disadvantage of including variables with
questionable importance (Hosmer and Lemeshow, 2000).

Risk factors analyzed included age, gender, level of education, employment, marital status,
baseline CD4 cell count counts dichotomized into two groups (less than or equals 250 µl3 and
above 250 μl³), clinical status (WHO clinical stage) and HIV status disclosure. Bivariate analyses of the presumed risk factors (age, gender, education, employment, marital status, baseline CD4 cell count, clinical status (WHO clinical stage), type of treatment and HIV status disclosure) and patient status (active versus lost to follow up) were done. Kaplan Meier survival curves were drawn for variables that change with time.

3.9. Ethical considerations

Human Subjects: The main study SSC No. 1525 from which data for this study was abstracted had been approved by the Kenya Medical Research (KEMRI) Ethical Review Committee (ERC) and US Centers for Disease Control and Prevention (CDC) Institutional review Board (IRB). This study proposal was submitted and received ethical clearance by the University of the Western Cape.

Study Procedures & Risks: Data used in patient cohort reporting routinely collected to support medical services. Chances of inadvertent release of patient information were very remote because identifiers such as patient names were not in the electronic database. Additionally, patient-level information such as patient CCC identification number were stripped of personal identifiers and coded with a unique, database-specific number.

Benefits: No direct benefit was gained by the patients but the results will help improve care and treatment for future clients at the CCC.

Informed Consent: Informed consent was not sought to review the data that had already been collected for the following reasons: Patients were not put at risk by this study because data had already been collected and entered into a database. The data analysis process required no contact with the patients and patients continued to receive care and treatment services in accordance with the standards of care in Kenya regardless of this study or its outcomes; rights of patients was not adversely affected; the information being analyzed during this study had already been collected and seeking patient’s informed consent before reviewing the data was not done because some patients included in the database may have already defaulted during and could not be traced. However, permission of the hospital to use the data was sought.
**Confidentiality:** Access to the database used in this study was limited to authorized project staff; the database remained in a secured location and in a password protected computer at KEMRI/CDC and no individual patient(s) will be identified when the results of this study are presented. All results will be reported in an aggregate form.
4.1. Patient enrollment at baseline

4.1.1 Patient enrollment by year

The number of patients enrolled slightly increased from 1108 in 2003 to 1447 in 2004 followed by a slight reduction in 2005; sharp decline to 248 in 2006; slight decline to 75 in 2007 and then a sharp increase to 516 in 2008.

Figure 4.1: Patient enrollment by year

4.1.2 Patient enrollment by age group

Enrollment of patients in 15-30 and 31-40 age groups were high in the first three years, and then declined in the following two years from 526 and 486 to 104 and 89 respectively. The >40 years age group had a decline from the second to fifth year from 414 to 9. Enrollment in all age groups had a sharp increase in 2008.
4.1.3 Patient enrollment by WHO clinical stage

Enrollment of patients in WHO clinical stage 1 and 2 increased steadily from 2003 to 2005, dropped sharply between 2005 and 2006; stabilized between 2006 and 2007; and finally sharply increased between 2007 and 2008. Enrollment of patients in WHO stage 3 and 4 were initially very high over the first 3 years, then declined dramatically from 191 and 268 to 16 and 13 respectively over the next 2 years. There was however a sharp increase in enrollments across all WHO clinical stages in the last year.

Figure 4.2 – Patient enrollment by age group and year
4.1.4 Patient enrollment by type of treatment

Enrollment of patients on ART were consistent over the period; whereas enrollment of patients on care only were initially very high over the first 3 years, then declined dramatically from 1273 to 69 over the next 2 years. There was however a sharp increase in the last year.

Figure 4.4 – Patient enrollment by type of treatment and year
4.2. Baseline Socio-demographic and Clinical Characteristics

The median age of patients was 33 (IQR 27 - 41) years, 35.6% (1691/4740) were in the 31-40 years age category, 25.2% (1195/4740) had no education, 50.1% (2377/4740) were single, and 42.2% (2000/4740) had employment. Only 1,547 (32.6%) records that had documented baseline CD4 results were included in the analysis for baseline CD4 patient characteristic (Refer to appendix 2). Of the total 4,740 patients 65% were female. Males were slightly older with the median age of 36 years compared to females who had a median age of 32 (15-80) years. The difference between males and females was significant across age groups \( p <.0001 \). Most females (46.5%) were in the 15-30 age groups while males (40.1%) were in the 31-40 years age group. Most females (47.7%) had primary education while males (53.7%) had secondary education. Majority of females (64.9%) were unemployed compared to males (44.9%). Most males (60.3%) had disclosed their HIV status compared to 56.3% of females. The proportion of males who enrolled with advanced HIV status (WHO stage 4) was higher than that in females. There was no difference between males and females in the highest level of education attained, marital status and WHO clinical staging.
Table 4.1 - Baseline Socio-Demographic and Clinical Characteristics of patients enrolled in NNPGH CCC, 2003-2008 (N=4740)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Female (%)</th>
<th>Male (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled patients</td>
<td>3064 (64.6)</td>
<td>1676 (35.4)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Median age (IQR) in years</td>
<td>32 (26-39)</td>
<td>36 (30-44)&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Age in years at enrolment</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>&gt; 40</td>
<td>621 (20.3)</td>
<td>574 (34.3)</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>1019 (33.3)</td>
<td>672 (40.1)</td>
<td></td>
</tr>
<tr>
<td>15-30</td>
<td>1424 (46.5)</td>
<td>430 (25.7)</td>
<td></td>
</tr>
<tr>
<td>Highest level of education</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>None</td>
<td>189 (6.2)</td>
<td>47 (2.8)</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>1462 (47.7)</td>
<td>605 (36.1)</td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>1297 (42.3)</td>
<td>900 (53.7)</td>
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</tr>
<tr>
<td>Post-secondary</td>
<td>116 (3.8)</td>
<td>124 (5.1)</td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td></td>
<td></td>
<td>0.249</td>
</tr>
<tr>
<td>Care</td>
<td>2882 (94.1)</td>
<td>1590 (94.9)</td>
<td></td>
</tr>
<tr>
<td>ART</td>
<td>182 (5.9)</td>
<td>86 (5.1)</td>
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</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Married</td>
<td>1232 (40.2)</td>
<td>1145 (68.3)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>602 (19.7)</td>
<td>262 (15.6)</td>
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</tr>
<tr>
<td>Widowed/Divorced/Separated</td>
<td>1230 (40.1)</td>
<td>269 (16.1)</td>
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<td></td>
<td>0.007</td>
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<tr>
<td>Disclosed</td>
<td>1725 (56.3)</td>
<td>1011 (60.3)</td>
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<tr>
<td>No disclosure</td>
<td>1339 (43.7)</td>
<td>665 (39.7)</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
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</tr>
<tr>
<td>Employed</td>
<td>1076 (35.1)</td>
<td>924 (55.1)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>1988 (64.9)</td>
<td>752 (44.9)</td>
<td></td>
</tr>
<tr>
<td>WHO Clinical Staging</td>
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<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>1</td>
<td>547 (17.9)</td>
<td>189 (11.3)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>505 (16.5)</td>
<td>258 (15.4)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1740 (56.8)</td>
<td>1006 (60.0)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>272 (8.9)</td>
<td>223 (13.3)</td>
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</tr>
<tr>
<td>Baseline CD4</td>
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</tr>
<tr>
<td>≤ 250 cells/μl³</td>
<td>544 (53.7)</td>
<td>287 (53.8)</td>
<td></td>
</tr>
<tr>
<td>&gt; 250 cells/μl³</td>
<td>469 (46.3)</td>
<td>247 (46.3)</td>
<td></td>
</tr>
</tbody>
</table>
4.3 Loss to follow-up of enrolled patients

4.3.1 - Risk of loss to follow up of enrolled patients in NNPGH CCC

The relative risk (RR) of loss to follow-up (LTFU) in the 15-30 years age group was 1.6 (95%CI=0.89-1.19) times more than that in the >40 years age group. Patients who had no education, primary and secondary education were 2.9 (95%CI=1.88-4.44), 2.6(95%CI=1.94-3.43) and 1.8 (95%CI=1.39-2.43) times respectively more like to be LTFU compared to those who had post-secondary education. Those in the ART group (RR=0.5, 95%CI=0.37-0.62) were less likely to be lost to follow up compared to Care group. Patients who had not disclosed their HIV status were 1.5 (95%CI=1.33-1.77) times more likely to be LTFU compared to those who had disclosed their HIV status. Only patients in WHO stage 4 (RR=1.8, 95%CI=1.33-2.44) had a significant LTFU compared to those in WHO stage 1 while those in WHO stage 2 and 3 were not significant. The differences in the rates of LTFU in the gender, marital status, employment status and baseline CD4 were not significant.
Table 4.2 - Risk of loss to follow up of enrolled patients in NNPGH CCC, 2003-2008
(N=4740)

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>patients enrolled</th>
<th>patients LTFU</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Female</td>
<td>3064</td>
<td>2382 (77.7)</td>
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</tr>
<tr>
<td>Male</td>
<td>1676</td>
<td>1312 (78.3)</td>
<td>1.0 (0.89-1.19)</td>
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<tr>
<td><strong>Age-group at enrolment</strong></td>
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<tr>
<td>&gt; 40</td>
<td>1195</td>
<td>882 (73.8)</td>
<td>ref</td>
</tr>
<tr>
<td>31-40</td>
<td>1691</td>
<td>1301 (76.9)</td>
<td>1.2 (1.00-1.41)</td>
</tr>
<tr>
<td>15-30</td>
<td>1854</td>
<td>1511 (81.5)</td>
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<tr>
<td>None</td>
<td>236</td>
<td>196 (83.1)</td>
<td>2.9 (1.88-4.44)</td>
</tr>
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<td>Primary</td>
<td>2067</td>
<td>1683 (81.4)</td>
<td>2.6 (1.94-3.43)</td>
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<td>Secondary</td>
<td>2197</td>
<td>1664 (75.7)</td>
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<td>Care</td>
<td>4472</td>
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<tr>
<td>ART</td>
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<tr>
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</tr>
<tr>
<td>Disclosed</td>
<td>2736</td>
<td>2049 (74.9)</td>
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<tr>
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<td>1645 (82.1)</td>
<td>1.5 (1.33-1.77)</td>
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<tr>
<td>Employed</td>
<td>2000</td>
<td>1532 (76.6)</td>
<td>0.9 (0.76-1.01)</td>
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<tr>
<td>Unemployed</td>
<td>2740</td>
<td>2162 (78.9)</td>
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<td><strong>WHO Clinical Staging</strong></td>
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<tr>
<td>1</td>
<td>736</td>
<td>561 (76.2)</td>
<td>ref</td>
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<td>2</td>
<td>763</td>
<td>595 (78.0)</td>
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<td>3</td>
<td>2746</td>
<td>2116 (77.1)</td>
<td>1.0 (0.87-1.27)</td>
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<td>4</td>
<td>495</td>
<td>422 (85.3)</td>
<td>1.8 (0.76-1.24)</td>
</tr>
<tr>
<td><strong>Baseline CD4</strong></td>
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<td></td>
</tr>
<tr>
<td>≤ 250 cells/ μl³</td>
<td>831</td>
<td>658 (79.2)</td>
<td>ref</td>
</tr>
<tr>
<td>&gt; 250 cells/ μl³</td>
<td>716</td>
<td>563 (78.6)</td>
<td>1.0 (0.76-1.24)</td>
</tr>
</tbody>
</table>
4.3.2 Proportion of enrolled patients lost to follow up of at different time points in NNPGH CCC, 2003-2008 (N=3694)

The proportion of patients enrolled into care and LTFU was higher that those on ART in the in the 0-6 (12.5%), 7-12 (35.0%), 13-24 (2.0%) and 37-48 (9.2%) months after enrollment. There were however period where loss to follow-up in the ART group was higher than in the Care group was 12.5% higher than those on ART. This included 25-36 (7.9%), 49-60 (19.3%) and 61-72 (12.0%) months after enrollment.

![Figure 4.5 – Proportion of patients LTFU at different time points (months of follow-up) and treatment groups](image)

4.3.3. Rates of loss to follow up by year of enrollment of enrolled patients in NNPGH CCC

The proportion of patients on both care and ART LTFU reduced over the years with 2003 having the highest and 2008 the lowest. Rates of LTFU were however higher in the care group compared to ART group. Rates of LTFU were comparable in both groups in 2007 though different in 2008 where the loss to follow up in the care group was much higher at 46.6% of enrolled patients compared to that in the ART group at 18.8%.
4.3.4 Rates of loss to follow up of enrolled patients by gender in NNPGH CCC

The difference in proportion of males and females enrolled into care and ART had minimal differences ranging from 0 – 1.3%. Rates were initially low though increased sharply in the following one year from 14.3% for males and 13% for females to 29% and 29.5% respectively, stabilized in 2005 followed by a sharp declined over the following 2 years from 28.8% and 30.3% to 4.8% and 5 % respectively and finally a sharp increase in 2008.
4.3.5 Rates of loss to follow up of enrolled patients by age in NNPGH CCC

The proportions of patients LTFU in the 15-30 years and 31-40 years age groups over the years was minimal. The >40 years age group compared to 15-30 years and 31-40 years age groups was higher in 2004 compared to 2003 followed by a sharp decline in 2005 while trends were similar in all age groups over the last 3 years.

![Figure 4.8 – Rates of LTFU by age and year](image)

4.3.6 Rates of loss to follow up of enrolled patients by WHO stage in NNPGH CCC

The rates of LTFU were high in 2004 across all WHO stages. There was however a difference in the next 1 year where rates for patients in WHO stage 1 and 3 stabilized while that in WHO stage 4 had a sharp decline and that of WHO stage 2 continued to increase. All WHO stages had a sharp decline in the following two years and finally a sharp increase in 2008. Loss to follow up was highest in the WHO stage 4 in 2003 (20.9%) and in 2004 (31.8%), in WHO stage 2 in 2005 (34.8%) and 2006 (8.7%), in WHO stage 3 (5.2%) and in WHO stage 1 in 2008 (18%).
4.4 Factors associated with loss to follow up

The third objective of this study is to determine the factors which at enrolment are predictive of loss to follow up.

4.4.1 Risk of loss to follow up

Bivariate Hazard Ratio

The risk of LTFU amongst patients with primary (HR=0.76, 95%CI=0.63-0.91) and secondary education (HR=0.67, 95%CI=0.52-0.87) were significantly lower compared to tertiary education. Patients who had no education (HR=0.83, 95%CI=0.76-1.11) had risk of LTFU that was not significantly different to that of patients with tertiary education.

Hazards of patients who had not disclosed their HIV status (HR=1.10, 95%CI=1.0-1.18) higher than in those who disclosed their HIV status. As for employment status, hazards of patients who had no employment (HR=1.20, 95%CI=1.11-1.31) were higher than those who were employed. Hazards of patients who had WHO clinical stage 4 was 1.43 (95%CI=1.20-1.69) higher than that of patients in WHO clinical stage 1 while those of patients in WHO clinical stage 2 (HR=1.05, 95%CI=0.90-1.22) and stage 3 (HR=1.03, 95%CI=0.91-1.17) had no significant difference. Hazards of LTFU in patients in 31-40 years and 15-30 years groups.
were 1.12 (95%CI=1.01-1.24) and 1.36 (95%CI=1.22-1.51) higher than that of patients in the >40 years category.

As for the type of treatment, the patients who were on ART at enrolment (HR=0.62, 95%CI=0.51-0.76) were lower than that of patients in care. The hazards of patients who had a baseline CD4 >250 cells/μl³ (HR=0.67, 95%CI=0.51-0.87) were lower compared to that in patients who had a baseline CD4 ≤250 cells/μl³. On the other hand, the hazards of males (HR=1.01, 95%CI=0.93-1.10) compared to females and patients who were divorced/separated/widowed (HR=0.99, 95%CI=0.88-1.12) and married/cohabiting (HR=0.94, 95%CI=0.84-1.05) compared to those who were single had no statistically significant difference.

**Multivariate analysis**

All factors with P-value of <0.25 in the bivariate HR and gender with a p value >0.25 were included in the multivariate analysis. Gender was included because it is a demographic characteristic of importance to LTFU. Variables included were gender; 31-40 years age-group; 15-30 years age-group; unemployment; WHO stage 4; primary and secondary education; no disclosure of HIV status and ART group. CD4 group was not included in the multivariate analysis due to the limited number of patients who had their baseline CD4 cell count records available in the database hence WHO clinical staging was used as a proxy to CD4 cells count in indicating level of disease progression.

After adjusting for other variables, the hazards of males being LTFU were 1.12 (95%CI=1.02-1.22) higher than that of females. Patients with Primary (AHR=0.73, 95%CI=0.61-0.90) and secondary (AHR=0.69, 95%CI=0.53-0.91) level of education had lower hazards to LTFU than those with tertiary education while patients who had no education (AHR=0.92, 95%CI=0.76-1.11) had hazards that were not significantly different from that of patients with tertiary education after controlling for other factors. As for employment status, hazards (AHR=1.14, 95%CI=1.05-1.25) of patients who had no employment was higher than that those who were employed after controlling for other factors. Controlling for other factors, hazards of patients who had WHO clinical stage 4 was 1.53 (CI=1.29-1.81) higher than that of patients in WHO clinical stage 1 while those of patients in WHO clinical stage 2 (AHR=1.07, 95%CI=0.92-1.25) and 3 (AHR=1.05,
95% CI=0.93-1.20) had no significant difference. Controlling for other factors, the hazards of LTFU in patients in 31-40 years and 15-30 years groups were 1.15 (95% CI=1.03-1.28) and 1.37 (95% CI=1.23-1.53) higher than that of patients in the >40 years category. As for the type of treatment the patient was on at enrollment, the hazards of patients on ART (AHR=0.64, 95% CI=0.52-0.78) were lower than that of patients in care after controlling for other factors. Controlling for other factors, the hazards of patients who had not disclosed their HIV status (AHR=1.05, 95% CI=0.97-1.14) were not significantly different to those who had disclosed their HIV status.
Table 4.3 – Factors associated with loss to follow up in NNPGH CCC, 2003 – 2008

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<td>AHR (95% CI)</td>
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<tr>
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<td>Stage 3</td>
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<td>Stage 4</td>
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<tr>
<td>&gt; 250 cells/µl³</td>
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</table>
4.5 Kaplan-Meier survival analysis

In this section, comparison of loss to follow up by treatment type, age group and WHO clinical staging through-out follow up period is presented.

4.5.1 Loss to follow up by treatment type

Patients on care had a faster loss to follow-up rate especially in the first 500 days of follow up and then the rate has steady decline. The drop out rate in the ART group but is higher after 1500 days of follow up though still lower with better survival than that of care group. There was a significant difference in the survival rates for the two groups ($p<0.0001$).

![Kaplan-Meier survival estimates, by treatment type](image)

Figure 4.10 – Survival curve of patients in care and ART at enrollment
4.5.2 Loss to follow up by age group

Patients in the 15-30 years age group were lost to follow-up at a faster rate and had lowest survival rates compared to 31-40 and > 40 years age groups while the > 40 years had the slowest rate of loss to follow up and highest survival rates and there was a significant difference between the groups ($p=<0.0001$).

Figure 4.11 – Survival curve of patients by age group at enrollment
4.5.3 Loss to follow up by WHO stage

Patients with WHO stage 4 were lost to follow-up at a higher rate than those in WHO 1, 2 and 3 with least survival. On the other hand, Patients in WHO stage 1, 2 and 3 had similar dropout rates though patients in WHO stage 1 had highest survival rates compared to WHO stage 2 and 3 with similar survival. Log rank test showed that there was a significant difference in the different groups of WHO disease clinical staging.

Figure 4.12 – Survival curves of patients by WHO clinical staging
4.5.4 Loss to follow up by CD4 group

The loss to follow-up rate are similar for both groups except at the end of follow up period where the ≤ 250 cells/μl have better retention compared to the > 250 cell/μl group. The survival rates for the two categories of baseline CD4 were the same.

Figure 4.13 – Survival curves of patients by CD4 count
5.1 Characteristics of patients at enrollment

The median age of patients was 33 (IQR 27 - 41) years and was consistent with most studies and HIV care and treatment programs in Sub Sahara Africa (Barth et al., 2008; Lawn et al., 2006; Stringer et al., 2006; Brinkhoff et al., 2008). The result was however not consistent with studies in Kibera, Western Kenya program in and study in Uganda which had patients with a median age of more than 35 years (Kamya et al., 2007; Marston et al., 2007; Wools-Kalaustian et al., 2006).

Females were dominant (65%) amongst enrolled patients with similar results noted in most HIV care and treatment programs (Lawn et al., 2006; Amuron et al., 2009; Brinkhoff et al., 2008; Kamya et al., 2007; Marston et al., 2007; Orrell et al., 2007; Stringer et al., 2006; Wools-Kalaustian et al., 2006). This was expected since the prevalence rate of HIV for females in the province is much higher than males (National AIDS and STI Control Program and Kenya Ministry of Health, 2009). The results were however inconsistent with findings in France which may could have been because the clinic in France was mainly male population (Lebouche et al., 2006) and Malawi (Makombe et al., 2008) HIV care and treatment programs where males were 75% and 78% respectively of patients enrolled.

Of the total number of the enrolled patients, (25%) of patients enrolled had no education and the proportion was much higher compared to cohorts in Kenya which had 8% (Wools-Kalaustian et al., 2006) and 17% in Haiti (Severe et al., 2005) though was much lower compared to the South African cohort which had 51% with no education (Barth et al., 2008). The high proportions of patients with no education may be attributed to the pockets of informal settlements in the hospital’s catchment area.

Patients in this study had a median CD4 cell count of 226 cells/μl. This was consistent with some HIV care and treatment programs that had median CD4 cell count of ≤250 cells/μl (Barth et al., 2008; Kamya et al., 2007; Lawn et al., 2006; Lawn et al., 2005; Orrell et al., 2007; Wools-Kalaustian et al., 2006; Brinkhoff et al., 2008; Marston et al., 2007; Stringer et al., 2006). The proportion (68%) of patients enrolled in this study had WHO clinical stage 3 and 4 was consistent with findings of some with less than 70% of patients in WHO clinical stage 3 and 4 at enrollment (Amuron et al., 2009; Brinkhoff et al., 2008; Wools-Kalaustian et al., 2006). However, the results were not consistent with some HIV care and treatment
programs which showed that more than 70% of patients initiating ART in Sub Sahara Africa were in WHO clinical stage 3 and 4 at enrollment (Barth et al., 2008; Kamya et al., 2007; Lawn et al., 2006; Lawn et al., 2005; Makombe et al., 2008; Marston et al., 2007; Stringer et al., 2006). Most of the patients enrolled in the study at advanced stage of the disease could be attributed to attempts to seek care from other alternative methods like traditional medicine, religion (holy water) or belief on other issues like breaking of taboos as source of the ailment and belief in witch craft.

Proportion of patients (42%) enrolled in this study had employment and was higher compared to 23.9% in South Africa (Barth et al., 2008) and 30.5% in the western Kenya program (Wools-Kalaustian et al., 2006). Of the patients enrolled, 50% were married at enrollment. This was consistent to the cohort in South Africa (Barth et al., 2008) though not consistent with to results of the Western Kenya cohort which was 64% (Wools-Kalaustian et al., 2006).

5.2 Overall loss to follow-up rates
The overall LTFU for both patients on care and ART from 2003 to 2008 was 78%. LTFU at 12 months was 74% (26% retention) while that of patients on care and ART were 76% (24% retention) and 41% (57% retention). At 24 months of follow up, rates of LTFU was 96% (4% retention) for both care and ART, 97% (3% retention) for patients on care and 94% (6% retention) for patients on ART. At 12 months of follow-up, LTFU rate of 41% (59% retention) was not consistent with results of 25% (retention 75%) in Sub-Sahara Africa HIV care and treatment programs (WHO, 2009). This could be attributed to patients choosing to self-transfer to new sites that were established in other districts after NNPGH. Similarly at 24 months of follow-up, 94% LTFU rates of patients on ART was not consistent with 33% shown in Sub-Sahara Africa (WHO, 2009). Generally, rates of LTFU amongst patients on ART were 41% and 94% at 12 and 24 months of follow-up which was inconsistent with 3%-29% in most HIV care and treatment programs in Sub-Sahara Africa (Barth et al., 2008; Bekker et al., 2006; Dalal et al., 2008; Laurent et al., 2005; Lawn et al., 2006; Makombe et al., 2008; Orrell et al., 2007; Severe et al., 2005; Sow et al., 2007; Wools-Kalaustian et al., 2006; Yu et al., 2007). The high rates of LTFU could be attributed to limited options of HIV clinics in the initial years of the program and patients travelled long distances for services hence may have been unable to keep clinic appointments. The second attributable reason could have been due to rapid decentralization (establishment of new clinics) leading to patients who had initially enrolled in the program opted to be enrolled in other clinics near
their homes without informing NNPGH program. The post-election violence that occurred in Kenya with Kisumu amongst hard hit areas may have also contributed to LTFU in 2007 and 2008.

5.3 Factors contributing to loss to follow up
Males were more likely to be LTFU (AHR=1.12, P=0.018) and was consistent with results in France and Sub-Sahara Africa (Amuron et al., 2009; Lebouche et al., 2006; Wools-Kalaustian et al., 2006). These results were not consistent with those of the study in Malawi showed that females were more likely to be LTFU in the peripheral hospitals more than in the central hospital. (Yu et al., 2007). This may have been due to the reason that the women in the peripheral hospitals which may have been in the rural areas were very busy with farming activities. Additionally, the decision on whether women continued with care may have been made by other persons such as spouses.

Patients who had primary education were less likely to be LTFU compared to those who had post-secondary education (AHR=0.73, P=0.002). This was also evident in secondary level of education where those who had secondary level of education were less likely to be LTFU compared to those who had post-secondary education (AHR=0.69, P=0.008). There was however no significant difference between patients who had no education (AHR=0.98, P=0.379) and those who had post-secondary education.

The difference between patients who had disclosed their HIV status and those who had not disclosed was not significant (AHR=1.05, P=0.244). This was not consistent with a review done by Mills and others indicated that lack of disclosing HIV status was associated with dropping out of treatment (Mills et al., 2006). Though the difference was not significant, lack of disclosure for fear of discrimination could have also contributed to LTFU in this study.

Unemployed (AHR=1.14, P=0.003) patients were more likely to be LTFU. This was consistent with results found in Kibera (Unge et al., 2009) and France (Lebouche et al., 2006) though not consistent with those in Yaunde Cameroon which showed no association (Rougemont et al., 2009). This could be inability of the patients to afford transportation cost to attend clinic for follow up as required, poor nutrition status and not able to afford prescription drugs leading to mortality.
Patients with advanced HIV disease (WHO clinical stage 4) were more likely to be LTFU (AHR=1.15, P=<0.0001) compared to those in WHO clinical stage 1. These findings are similar to those recorded in other studies (Rougemont et al., 2009; Stringer et al., 2006; Yiannoutsos et al., 2008; Yu et al., 2007). There was no significant difference when patients in WHO stage 2 (AHR=1.07, P=0.372) and WHO stage 3 (AHR=1.05, P=0.402). Finding of this study were however contrary to those by Brinkhoft and others and Lawn and others which indicated that advanced HIV clinical disease was not associated with loss to follow-up (Brinkhoft et al., 2008; Lawn et al., 2006). This could be attributed to the reason that patients with advance disease are more likely to remain active in treatment as they really need it or because they have seen the benefit of treatment.

Younger patients in the age-group 15-30 years were more likely to be LTFU compared to the older age-group and this showed significant results (AHR=1.30, P=<0.0001) and those patients in the age-group 31-40 years were more likely to be LTFU compared to older (> 40 years) patients (AHR=1.15, P=0.011). These findings were consistent with studies in Migori (Karcher et al., 2007) and France (Lebouche et al., 2006) though not consistent with a study done by Brinkhoft and others in 2008 in Yaunde Cameroon which showed that older patients (>50 years) were more likely not to return for follow-up. The younger age-group could be highly migratory to other urban centres for employment or studies which may have resulted in self transfers to other treatment clinic closer to their new residences. The older population may have had less frequent movements as they may not have been actively searching for employment or going to colleges for studies.

Patients who were on ART (AHR=1.37, P=<0.0001) at enrollment were less likely to be LTFU compared to those who were on care although studies reviewed did not compare the two groups. The patients who are enrolled in ART may have already known the benefits of adherence through knowledge on HIV treatment and dangers of non-adherence the drug gained from adherence counselling classes.

It was worth noting that a patient may have been LTFU at NNPGH but accessing care and treatment in other facilities that were being established, therefore LTFU in this study may not mean that a patient has stopped treatment or has completely defaulted the HIV care and
treatment services. The true LTFU were the ones that died and the facility has a proper documentation on the same.

5.4 Limitations
Since the study did not include variables like user fee (amount of money a patient was required to pay for services); holy water, religious factors, distance from the hospital; amount of time spent to travel to hospital; accessibility of the hospital; alcohol and substance abuse; place of work in relation to the hospital, type of work in relation to travel requirements, it was not possible to test the effects that this variable had on LTFU. Data was also incomplete for some patients and there could have been errors during data entry by the clinicians and during data verification process.
CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

UNIVERSITY of the
WESTERN CAPE
6.1 Conclusions

The overall LTFU was 78% over the six years of patients follow up. Rates of loss to follow up of patients on care and ART at 12 months of follow up was 76% and 41% respectively while LTFU at 24 months of follow up was 97% for patients on care and 94% for patients on ART. This presents retention of patients in the program as a problem that need to be addressed more so for patients on care.

Several records were excluded from analysis due to incompleteness and failure to link patient information in the different databases which may have been due to wrong data entry or improper filing of patient forms and could lead to lack of continuity of patient care. This presents documentation as a problem that needs to be addressed.

Factors including male gender, unemployment, advance HIV disease, younger patients, patients on care were significantly associated with LTFU hence present as a problem that need to be addressed.

6.2 Recommendations

Based on the determination of rates of loss to follow up and factors associated with loss to follow up amongst HIV and AIDS patients in care and treatment in Kisumu, Kenya; the following recommendations are made to the program:

1. More attention is needed in developing retention strategies for patients with much focus on patients on care and those who have been follow-up for prolonged period of time.
2. Data quality need to be strengthened by ensuring completeness of information at point of entry and proper filing practices put in place including regular cleaning of data in the electronic databases to facilitate accurate reporting.
3. Need to develop tailored HIV care and treatment programs with much focus on identifying and addressing problems predisposing males, unemployed patients, and enrollment of patients with HIV disease at an advanced stage, younger patients and patients on care to loss to follow-up. This will contribute in reducing LTFU with improved treatment outcomes.
References


Appendices

Appendix 1- PATIENT DATA TOOL

Patient information at enrollment

Patient CCC No -

Enrollment date / / 

Date of Birth / / 

Patient age at enrollment years

Patient’s sex O Male O Female

Marital status O Single O Married monogamous
O Married polygamous O Divorced/Separated O Widowed

No. of years of schooling 

Employment status O Employed outside home O Unemployed

Has the patient disclosed their HIV status to anyone? O Yes O No
If yes, specify
O Spouse O Other family member O Friends
O other specify

**WHO stage at enrollment**  
- O Stage 1  
- O Stage 2  
- O Stage 3  
- O Stage 4  
- O Missing

**WHO stage when last seen in CCC**  
- O Stage 1  
- O Stage 2  
- O Stage 3  
- O Stage 4  
- O Missing

**Type of care at time of data collection**  
- O CPT  
- O ARVs

**Duration on Care only or ART**  
[ ] __________ months

**Baseline CD4 count**  
[ ] __________

**CD 4 when last seen in the clinic**  
[ ] __________

**Date of ART initiation**  
[ ] __________ / [ ] __________ / [ ] __________

**Date patient last seen in the clinic**  
[ ] __________ / [ ] __________ / [ ] __________

**Date of expected next clinic visit**  
[ ] __________ / [ ] __________ / [ ] __________

**What is the current status of patient outcome?**  
- O Defaulter  
- O Loss to follow-up  
- O Transfer out  
- O Death
Appendix 2: Baseline Socio-Demographic and clinical Characteristics of Patients enrolled in NNPGH CCC, 2003 – 2008 (N=4740)

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<th>Characteristic</th>
<th>Frequency</th>
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</tr>
<tr>
<td>&gt; 250 cells/mm³</td>
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*3193 records were missing