Viral Load Suppression and Retention in Care Rate Amongst Adult HIV-Positive Patients at 12 Months on Antiretroviral Treatment Initiated Through the Universal Test and Treat Programme in Ekurhuleni North Sub-District, Gauteng Province

by

PATRICIA CHAUKE

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Supervisor: Mrs M Huma
Co-supervisor: Prof. S Madiba

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DECLARATION

I, Patricia Chauke, Student number 201709926 declare that this thesis is my own work. It is submitted for the degree of Master of Public Health at the Sefako Makgatho Health Sciences University. It has not been submitted before for any degree or examination at this or any other university. All references contained herein have been duly acknowledged by means of complete references.

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Patricia Chauke

19 April 2019
Date
DEDICATION

I dedicate this dissertation to my late father, Fannie Silinda, and my mother, Joyce Silinda, who instilled a culture of learning, a spirit of perseverance and a sense of responsibility in me and my siblings. Without their prayers, tireless efforts, gentle pressure and encouragement I would not have reached my current position in life and my academic milestones.
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I am eternally grateful to God for His unwavering love towards me, for strengthening and carrying me and being a guiding light throughout this challenging journey. All glory and honour belongs to Him.

I would like to acknowledge and thank the following for their contributions towards the completion of this thesis:

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ABSTRACT

Introduction
South Africa adopted and integrated universal test and treat (UTT) into the existing antiretroviral therapy (ART) programme. However, one of the main concerns about UTT is that individuals with a high CD4 count who are healthier than others might have lower ART adherence and retention in care. Since UTT was implemented in 2016, no empirical studies have been conducted in this regard to ascertain their viral load suppression (VLS) and retention in care rate.

Study aim
The aim of the study was to determine the retention in care rate, attrition factors, and the VLS rate of patients initiated on ART through the UTT.

Methods and materials
This was a retrospective review of 372 records in a cohort of adult patients initiated on ART through UTT in November 2016 at health facilities in Ekurhuleni North sub-district. STATA 13 was used to calculate the rates of retention in care and viral load suppression at 12 months. Logistic regression was used to determine attrition factors.

Results
More women 64% (n=237) were initiated on ART than males 36% (n=135); the mean age was 36 years (range 18-72 years). Over half (55%; n=203) were initiated through UTT. The mean CD4 count was 342 cells/mm$^3$, and 23% (n=86) had CD4 less than 100 cells/mm$^3$; 26% (n=97) had CD4 above 500 cells/mm$^3$, and 50.8% (n=189) had CD4 between 101 and 499 cells/mm$^3$. The viral load (VL) suppression rate (undetectable VL below 400 copies/ml) at 12 months was 77% (n=169) and 51% (n=118) at 6 months. The rate of retention in care rate was as low as two-thirds (n=219; 59%) at 12 months. The two main attrition factors were lost to follow-up and transfer out. Males were less likely to be retained (OR=0.61; p=0.035; CI: 0.39-0.96) as well as those with CD4 above 500 cells/mm$^3$ (OR=0.59; p=0.036; CI: 0.37-0.97). Lost to follow-up (LTFU) was the major attrition factor; of the 153 patients that were not retained, 28% (n=103) were LTFU at 12 months. Patients were LTFU regardless of the CD4 count. LTFU was significantly associated with UTT, as those initiated through
UTT were twice more likely to be LTFU (OR=1.75; p= 0.022; CI: 1.08-2.83) than those initiated from the pre-ART list.

**Conclusions**
The expectations were that with UTT there should be higher proportions of viral load suppression than what was previously observed. However, VLS rate was lower than the triple 90 targets, which requires that 90% of people on ART have viral suppression. Furthermore, the retention in care rate falls short of the rate of 94% set by National Strategic Plan (NSP) as well as the triple 90 targets. Gender and CD4 count above 500cells/mm3 were associated with less chance of retention in care. The results suggest that retention in care under the UTT could be negatively affected by initiation with high CD4 count. The association between LTFU and UTT explains the high proportion of those with high CD4 count being LTFU.

**Recommendations**
It is imperative that studies evaluate the adherence patterns of those who do not suppress after 12 months. The low retention rate calls for thorough investigation through empirical studies to identify other barriers to high retention rate.
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<tr>
<th>Abbreviation</th>
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<td>ART</td>
<td>anti-retroviral treatment</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HSRC</td>
<td>Human Sciences Research Council</td>
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<td>LTFU</td>
<td>lost to follow-up</td>
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<td>NSP</td>
<td>National Strategic Plan</td>
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<td>Ols</td>
<td>opportunistic infections</td>
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<td>PLWHIV</td>
<td>people living with HIV</td>
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<td>RIC</td>
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<td>Rest in Peace</td>
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<td>TFO</td>
<td>transfer out</td>
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<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UTT</td>
<td>universal test and treat</td>
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<td>VL</td>
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DEFINITION OF TERMS

**CD4 count** is a laboratory test that measures the number of CD4 T lymphocytes (CD4 cells) in a sample of blood. The CD4 count is the most important laboratory indicator of immune function and the strongest predictor of HIV progression. The CD4 count is also used to monitor a patient’s response to antiretroviral therapy (Aids info; 2018).

**Lost to follow-up** is defined as a patient who has not visited the clinic and has not received drugs for more than 90 days after their last clinic visit (ART SOP).

**Opportunistic infections** are those infections that occur recurrently and are severe in people with deteriorated immune systems, including people with HIV. They take advantage of the weakness in the immune defence in HIV-positive patients and are thus called opportunistic. In HIV they are classified in line with the WHO staging (WHO, 2015).

**Viral load** is a measure of the number of viral particles present in a human being, especially the number of HIV viruses in the bloodstream. The term ‘viral load’ refers to the number of copies of HIV per ml of blood. In other words, it is the amount of virus in the blood.

**Viral suppression** is defined as suppressing or reducing the function and replication of a virus. This means the amount of HIV in the blood is reduced to levels that are undetectable by standard laboratory tests and the set standard is below 400 copies/ml.

**WHO** staging sorts patients into one of four hierarchical clinical stages ranging from Stage 1 (asymptomatic) to Stage 4 (AIDS). Patients are categorized to a particular stage when they demonstrate at least one clinical condition in that stage’s criteria. Patients remain at a higher stage after they recover from the clinical condition which placed them in that stage (WHO; 2017).
CHAPTER ONE
INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION
The Joint United Nations Programme on HIV/AIDS (UNAIDS) data reported that 36.9 million people were living with HIV globally in 2017, which is inclusive of about 1.8 million children (UNAIDS, 2017). The report further indicated that approximately 21.7 million people were accessing antiretroviral therapy (ART) in 2017 globally. The great majority of people living with HIV (PLHIV) are in low and middle-income countries and an estimated 19.6 million PLHIV live in eastern and southern Africa. Approximately 12.9 million were accessing ART in 2017 (UNAIDS, 2017).

South Africa carried the greatest number, accounting for 20% of PLHIV who are on ART globally. The HIV impact assessment survey conducted by the Human Sciences Research Council (HSRC) documented that approximately 7.9 million people of all ages were living with HIV in South Africa in 2017. Amongst all PLHIV aged 15 to 64 years who knew their HIV status, 70.6% were on ART, which is the largest treatment programme in the world (HSRC, 2018).

There is substantive evidence that ART has reduced AIDS-related morbidity and mortality (Holtzman et al, 2015). Ware et al (2013) mentioned that the rollout of ART in sub-Saharan Africa has brought lifesaving treatment to millions of HIV-infected persons. Furthermore, data from numerous sources show that ART drastically improves the prognosis of individuals with HIV infection (Brown et al., 2016). In South Africa the 2002 World Health Organization (WHO) ART guidelines were implemented in 2004, although the initiation was limited to HIV-infected patients who had moderate and advanced stages of infection at a CD4 count of 250 cells/mm³, aiming to limit the disease progression and mortality (Plazy et al, 2015).

Notwithstanding substantial progress in HIV prevention, in sub-Saharan Africa 1.8 million people were recorded to be newly infected with HIV in 2017 (UNAIDS, 2018). The report estimated that South Africa had 199 700 newly infected people (HSRC, 2018). With efforts to further scale up and expand access to ART globally to end the
AIDS epidemic by 2030, UNAIDS then established the 90-90-90 targets for 2020 that would prevent new HIV infections worldwide (UNAIDS, 2018). These targets require that 90% of all PLHIV know their status, that 90% of all people diagnosed with HIV receive sustained ART and that 90% of all people receiving ART are retained and have durable viral suppression (UNAIDS, 2017).

Achieving these targets would require countries to align their national guidelines and programmes with the latest scientific evidence that demonstrates the benefits of immediate ART in reducing the risk of HIV-related morbidity, mortality and transmission (Gupta & Granich, 2016). In 2015 the WHO published guidelines which recommended that adult patients that test HIV-positive should be offered ART regardless of their CD4 count. As mentioned, there is evidence that immediate ART reduces the mortality and HIV infectivity (WHO, 2015). This is referred to as universal test and treat (UTT), which was implemented as of 2016.

However, to reduce mortality and infectivity, patients need to remain in care. Therefore, retention in care is a key indicator of programme quality and critical determinant of adherence. Patients must actively attend and participate in an ART care programme to receive medication and to have their HIV clinical indicators monitored at proper frequencies (Koole et al, 2014).

One of the clinical indicators that should be monitored for patients enrolled in the ART programme is viral load suppression because it contributes to reducing HIV infectivity and to controlling the HIV epidemic (Eholié et al, 2016). Viral suppression suppresses or reduces the function and replication of a virus. When a patient is initiated on ART, the purpose of the medication is to reduce the patient's viral load to undetectable levels. The term ‘viral load’ refers to the number of copies of HIV per ml of blood. Therefore, the viral load for all patients on ART should be measured at the following intervals: 6 months, 12 months, and then annually (WHO, 2015). The WHO guidelines indicate that the main goal of therapy is to obtain and maintain viral load undetectability, which is defined as a plasma VL below the limit of detection of routine VL essays at <400 copies/ml (WHO, 2015).
According to Mugavero et al. (2012), failure to achieve and sustain viral load suppression poses increased risk of HIV transmissibility. Poor early retention in HIV care is a barrier to timely viral load suppression and a factor associated with a greater cumulative viral load burden over the first two years. Mugavero et al. (2012) found that about 63% of the 676 patients achieved viral load suppression (<50 copies/ml) in a median 308 days from entry into care. These findings seem worrying in that the viral load suppression rate should be at 90% at 12 months on ART (UNAIDS, 2014).

1.2 PROBLEM STATEMENT
As countries adopt and integrate UTT into their existing treatment frameworks, the main concern is that individuals with a high CD4 count who are healthy and often asymptomatic will have lower ART adherence and retention in care (Jain et al., 2014). The District Health Information System (DHIS) 2016 report for Ekurhuleni health district showed a three-month retention of 75% in the care rate. This rate was for patients that had been initiated the previous year when the guidelines still recommended that patients were to be initiated with a CD4 of <500 cell/mm$^3$.

In a study conducted in three countries in sub-Saharan Africa, 80% of patients started on ART were still in care after one year. Current estimates of retention in care in sub-Saharan Africa are widely variable and the estimated regional average 12-month retention of 76% (range 65%-89%) is insufficient to achieve the 90-90-90 targets. Furthermore, patient retention worsened over time especially among males and younger persons (Koole et al. 2014).

Margins of attrition guidelines are set globally. Naturally South Africa has followed suit and set up its own targets aligned to each time frame throughout the lifespan of ART care. The set targets are as follows: 12 months, 94%; 24 months, 88%; 36 months, 82%; 48 months, 76%; and 60 months, 70% (ART SOP). Since UTT no studies have been done in South Africa to show what retention in care is under these conditions.

Although in sub-Saharan Africa a great deal of research on daily adherence to ART has been published, the long-term retention of patients on treatment programmes has received comparatively less attention (Fox, 2010). This suggests that there is a need for further studies to be conducted especially in the context of the UTT implementation.
1.3 AIM
The aim of the study was to determine the viral load suppression and retention in care rate amongst adult patients at 12 months on ART, initiated through the UTT programme in Ekurhuleni North sub-district.

1.4 RESEARCH QUESTIONS
The research questions were as follows:

(i) What is the rate of viral load suppression amongst adult patients, at 12 months on ART, initiated through the UTT?

(ii) What is the retention in care rate of adult patients, at 12 months on ART, initiated through UTT?

(iii) What are the attrition factors amongst adult patients, at 12 months on ART, initiated through UTT?

1.5 STUDY OBJECTIVES
The study objectives were as follows:

(i) To determine the rate of viral load suppression amongst adult patients at 12 months on ART, initiated through the UTT;

(ii) To determine the retention in care rate of adult patients at 12 months on ART initiated through UTT;

(iii) To determine the attrition factors amongst adult patients at 12 months on ART initiated through UTT.

1.6 JUSTIFICATION OF THE STUDY
The results of the study may provide guidance on the identification of prominent attrition factors and which population group is mostly affected. The findings might add a new body of knowledge regarding the stage at which patients are leaving care and the viral load suppression. In addition, with this information policy makers and planners in the Department of Health may be able to calculate the retention in care strategies within acceptable margins. Further studies might provide in-depth understanding of the patients’ perspective.
1.7 CONCLUSION
This chapter provided an explanation of the background, the focus and rationale behind the study. The literature review pertaining to the research topic will be discussed in the next chapter.
CHAPTER TWO
LITERATURE REVIEW

2.1 INTRODUCTION
This chapter presents the literature review conducted in keeping with the aim of this study. Relevant literature was reviewed from previous studies done on a similar topic in sub-Saharan Africa, including Uganda, Botswana, Nigeria and South Africa. The scope of the review synthesized evidence from scientific reports and other credible sources of scientific work done globally. The focus was mainly on retention in care of ART patients, viral load suppression, and the attrition factors that affect retention. Several sources were consulted, including medical and research textbooks, the latest journals, district reports, the internet, Department of Health (DOH) publications and several WHO publications.

2.2 BENEFITS OF ANTIRETROVIRAL TREATMENT ON HIV
An HIV diagnosis was once considered an acute and life-threatening disease but nowadays it can be chronic and manageable. This change was primarily brought about by the developments in ART because ART has meaningfully reduced AIDS-related morbidity and mortality (Holtzman et al, 2015). Data from numerous sources show that ART drastically improves the prognosis of individuals with HIV infection (Brown et al, 2016).

McCreesh et al (2017) mentioned that the key component of the UNAIDS strategy seemed to suggest that the natural progression in ART care and treatment is to use the treatment as prevention to reduce further HIV incidence. This transformation is primarily due to advancements of ART, which have significantly reduced AIDS-related co-morbidities such as tuberculosis and mortality and is now being used to prevent new HIV infection (Plazy et al, 2015). In addition to the ART being proven to reduce morbidity and mortality in patients with all CD4 count levels, it also decreases the probability of HIV transmission to uninfected partners (Brown et al, 2016).

Wide-scale provision of ART is now recognised as a key preventive intervention for HIV control (Hayes et al, 2017). Consequently, by treating HIV-infected individuals,
HIV infections are prevented and transmission decreases. The concept of treatment as prevention is based on evidence showing that HIV transmission is strongly correlated with viral load and that the risk of transmission is very low if the virus is undetectable at 400 copies/ml (Hayes et al, 2017). This is the rationale for the recommendation of the UTT approach as a prevention strategy to control HIV epidemics (Wagner et al, 2012).

Global trends in HIV infection demonstrate an overall increase in HIV prevalence and a substantial decline in AIDS-related deaths largely attributable to the survival benefits of ART (Brown et al, 2016). Furthermore, sub-Saharan Africa carries a disproportionate burden of HIV, accounting for more than 70% of the global burden of infection (UNAIDS, 2015). Success in Africa has the potential to impact on the global burden of HIV (Brown et al, 2016).

2.3 EVOLUTION OF ART GUIDELINES

The rollout of ART to the millions of persons with HIV/AIDS in resource-limited settings represents one of the largest public health interventions ever undertaken (Geng et al, 2010). The evolution of the WHO Guidelines has assisted countries to keep and initiate large-scale populations on ART. The WHO recommendations on when to initiate eligible patients on ART have dramatically evolved over the past decade (Plazy et al, 2015).

Starting in 2002, ART was recommended for HIV-infected patients in moderate and advanced stages of infection at a CD4 count of 250 cells/mm³ and aimed at limiting disease progression and mortality. It was then strongly suggested following evidence of fewer side effects that ART might be more effective if initiated earlier rather than deferring to start at a CD4 count of 250 cells/mm³ and in any case before advanced HIV disease (Hontelez et al, 2013).

This brought about the 2010 national guidelines’ adjustment to start patients on ART when they were still asymptomatic at the CD4 threshold of 350 cells/mm³. In 2013 the CD4 count threshold was revised to 500/mm³ to reduce the risk of disease progression (Plazy et al, 2015). In 2015 WHO issued an early release to its guidelines to recommend immediate ART at all CD4 counts and this was informed by results from...
the HPTN 052,5 the INSIGHT-START6 and the TEMPRANO trial (Hontelez et al, 2013). These recommendations were aimed to significantly increase individuals initiated on ART; thereafter ART eligibility criteria were expanded to initiate all people who test HIV-positive regardless of the CD4 count (Plazy et al, 2015).

Data have demonstrated correlations between ART coverage at the population level and reductions in HIV incidence. Based on this evidence, the UNAIDS promulgated a set of targets aimed at ensuring that a high proportion of the HIV-infected population is diagnosed, initiated on ART and virally suppressed. The promulgation aimed to reduce HIV incidence as well as to protect the health of HIV-infected individuals (Hontelez et al, 2013).

The 90-90-90 targets are to be achieved by 2020, and require that 90% of all PLHIV know their status, that 90% of all people diagnosed with HIV receive sustained ART and 90% of all people receiving ART are retained and have durable viral suppression (UNAIDS, 2017). Meeting these targets would imply that approximately 73% of HIV-infected individuals would be virally suppressed. An even more ambitious set of 95-95-95 targets is to be achieved by 2030, with the aim of substantially reducing HIV incidence and prevalence by then. This could lead to steep reductions in HIV incidence and potentially to the long-term elimination of HIV as a public health problem (Bigna et al, 2016).

In order to realize these individual and public health benefits and to achieve these targets patients must remain in care. Ensuring long-term retention in care and treatment for HIV/AIDS has proven challenging in resource-scarce settings, whereby there is a concern that individuals with a high CD4 count who are healthier and often asymptomatic will have lower ART adherence, retention in care and viral suppression (Ware et al, 2013, Jain et al, 2014).

2.4 RETENTION IN CARE
Retention in care is a key indicator of programme quality and a critical determinant of adherence as patients must actively attend and participate in ART care programmes in order to receive medication and have their HIV clinical indicators monitored at proper frequencies (Koole et al, 2014). Retention in care will also be essential to
realizing the UNAIDS target of 90-90-90, particularly the final goal that requires that 90% of the population on ART is virally suppressed (Fox et al, 2014). Patient retention is associated with public health benefits (Assefa et al, 2011).

A major barrier to the success of ART programmes in Africa may be low rates of long-term retention in care as overall numbers on treatment increase. Retaining patients in lifelong HIV care is a major challenge in many countries in sub-Saharan Africa, where ART has been rapidly scaled up. Recent data in South Africa show that an increasing proportion of patients on ART are being lost to follow-up (LTFU). Although up to a third of adult patients lost to care are estimated to have died, the majority are alive and the main concern is that without treatment they are at increased risk of morbidity and mortality (Luque-Fernandez et al, 2013).

While increasing the treatment thresholds will have a benefit for patients on ART as well as a reduction in transmission (Fox et al, 2014), to reduce mortality and infectivity, patients need to remain in care (Koole et al, 2014). If patients cannot be retained in HIV care continuously from the time of testing positive through long-term adherence to ART then the 90-90-90 strategies may fail to achieve the anticipated benefits (Fox et al, 2014).

As large-scale programmes to provide ART are expanding and maturing in sub-Saharan Africa, attention has shifted from a single-minded focus on treatment access and initiation to the broader set of long-term challenges of sustenance (Miller et al, 2010). One of these concerns is retention of patients in care since ART is regarded as a lifelong commitment that requires patients to adhere diligently to medication and make frequent clinic visits for care (Miller et al, 2010). Moreover, ART is effective in reducing mortality among those who remain in treatment and adhere to therapy; however, not all patients remain in treatment. Bigna et al (2016) also reiterate that by adopting UTT, treatment programmes will be challenged to extend ART to newly eligible patients while supporting retention in care in an expanded patient population.

The South African National Department of Health’s adoption and implementation of UTT faces many challenges. Switching from treating people infected with HIV at 500 CD4/mm^3 to treating everyone requires more resources such as laboratories, medical
staff, family members or people to support patients and help them remain in care once they start treatment (Eholié et al, 2016). Patient retention is a vital measure of the effectiveness of ART services and in long-term care is complex, especially in low- and middle-income countries (Wubshet et al, 2012).

A study done of ART programmes in sub-Saharan Africa found that on average only 64% of patients who were initiated on ART remain in care after three years. A recent analysis of 44 177 patients attending public sector ART services in South Africa found that 71% of patients remained in care after 24 months and 59.6% after 48 months with the proportion of these being lost to follow-up increasing over that time (Holtzman et al, 2015). While in a study by Boyles et al (2011), lower retention rates of 71.5% were found at 12 months. These rates might be attributed to the fact that their population included pregnant women, hospitalized patients, TB patients and those that were on pre-ART. This finding was contrary to the study done in Uganda which showed relatively higher retention of 97% at week 48 (Jain et al, 2014).

Significant questions remain about whether high retention in a UTT system is possible, given the increasing proportion of asymptomatic patients and the known barriers to retention. Current estimates of retention in sub-Saharan Africa are widely variable and the estimated regional average 12-month retention of 76% (range 65% to 89%) is insufficient to achieve the 90-90-90-targets. The main concern is that the current retention estimates are in all likelihood biased due to incomplete ascertainment of outcomes (Brown et al, 2016).

Retention data from studies conducted in sub-Saharan Africa varies, nevertheless Brown et al (2016) recently found the patient retention in care rate of (61.4%) which is comparable to the findings of other sub-Saharan countries in studies conducted earlier (Wubshet et al, 2012; Assefa et al, 2011). In a study conducted in Ethiopia, Wubshet et al (2012) found that ART programmes were able to retain on average 68% of their patients over two years. Likewise, Fox and Rosen (2010) reported that ART programmes were able to retain about 60% of their patients at the end of two years.
2.5 ATTRITION FACTORS

Patients who discontinue treatment are at a high risk of illness and death because of Aids-related conditions. Consequently, many studies have attempted to quantify and ascertain the status of patients reported as lost to follow-up, including several in South Africa (Miller et al, 2010). Individual factors such as younger age, male gender, lower education, occupation, feeling healthy, and mobility have been associated with lower levels of retention in ART care and could affect retention under the UTT programme. In addition, clinical factors contributing to non-retention in care have also been identified (Brown et al, 2016).

The major causes of attrition are lost to follow-up (LTFU), death and transfer out (TFO) to other facilities. However, the greatest threat to the success of many African ART programmes is the high levels of LTFU, which is the outcome that reflects patients who have truly left care. LTFU increases throughout the follow-up period resulting in decline in retention of care (Cornell et al, 2015).

2.5.1 Lost to follow-up

The adoption of 180 days since the last clinic visit has been recommended and adopted as a standard LTFU definition (Chi et al, 2011). However, the South African context of LTFU is defined as patients who have not visited the clinic and have not received drugs for more than 90 days after their last clinic visit. The date of LTFU is then recorded as the date of their last clinic visit (ART SOP, 2012). The size and pace of ART scale-up may have contributed to the observed LTFU. Patients who are truly LTFU are likely to be non-adherent to treatment and at higher risk of death. In addition, they face increased risk of drug resistance to ART, undermining the long-term effectiveness of treatment programmes (Wubshet et al, 2012).

Studies done in sub-Saharan Africa showed that the major cause of non-retention is LTFU, which ranges from 11.1% to 31.4% at 6 months (Charurat et al, 2010; Boyles et al, 2011; Mugavero et al, 2012). In another study by Wubshet et al (2012) at the end of the 66 months of the programme initiation, 61.4% of patients were retained on treatment and 31.4% were lost to follow-up. Almost half (46%) of the LTFU had occurred in the first year of treatment (Wubshet et al, 2012). In a systematic review of patients who initiated ART across sub-Saharan Africa, approximately 25% were no
longer in care one year after initiation, and 40% were no longer in care after two years. A minority of the patients had died, while the rest were classified as LTFU (Miller et al, 2010). In study conducted by Nglazi et al (2013) in Gugulethu Township, Western Cape Province, South Africa, about 13% of the patients were LTFU.

Tracking studies in which LTFU patients are sought in the community to ascertain outcomes suggest that 20–80% of patients ‘lost’ but alive are no longer in care. Research, using tracking data to estimate outcomes for a large clinic population, indicated that approximately one in six patients taking ART were not in care after two years (Geng et al, 2010). Among this group of patients, a minority had died, while the majority was classified as LTFU (Rosen et al, 2007).

Demographic characteristics found to be associated with LTFU include being male, race, younger age, heterosexual orientation, less education, lack of health insurance and lower household income (Charurat et al, 2010; Hontelez et al, 2013). Clinical characteristics associated with LTFU or non-retention in care have included a higher CD4 cell count, absence of an Aids diagnosis, and detectable viral load or Aids-defining CD4 cell count (Hontelez et al, 2013). In other studies, patients in the highest CD4 cells count category and those in the lowest category, e.g.100 cells/mm³ at ART initiation, have higher risk of LTFU (Charurat et al, 2010).

In contrast, Jain et al (2014) found that LTFU was insignificantly low in their study where the median CD4 count was 569. However, the findings by Jain et al (2014) might be attributed to the design of the study. The design was an intervention prospective cohort where the patients were enrolled at initiation and followed up or monitored until 12 months. The follow-up visits were short and conducted by a specifically allocated nurse. Secondly, the patients also had direct access to a physician for any queries relating to care and treatment.

CD4 count <200 cells/ml was significantly associated with LTFU (Brown et al, 2016). Compared with those retained, the median CD4 count was lower in patients LTFU (Hontelez et al, 2013). The explanation may be that patients may not attend their appointments because they do not feel sick or they also may not attend because they feel too unwell to do so. Which condition comes first and causes the other, the missed
appointment or the poor health, is not clear (Assefa et al, 2011). LTFU patients had nearly three times the risk of death compared with retained patients (Cornell et al, 2015). LTFU is increasing by calendar year as ART programmes scale-up enrolment (Nglazi et al, 2013). The study conducted by Nglazi et al (2013) also found that half of the LTFU patients had died, and mostly within three months of being LTFU.

2.5.2 Mortality
Mortality is not regarded as a major reason for patient attrition in large ART programmes in developing countries. LTFU is the commonest cause of attrition, followed by death, which is often underestimated. Wubshet et al (2012) argue that some LTFU patients might have died at home and the death had not been documented on the patient’s card. This may be so because there is no system to ascertain the death of patients that have fallen out of care even if it is self-reported by a relative or next of kin (Fox et al, 2010). Sites have limited capacity to keep track of large numbers of patients enrolled for ongoing care, while also continuing to increase enrolment onto ART; keeping an accurate record of mortality within and outside ART programmes presents major challenges. As a programme expands, its ability to accurately ascertain patient deaths deteriorates and high observed LTFU may be associated with poor mortality ascertainment (Wubshet et al, 2012).

In a study conducted in Ethiopia by Wubshet et al (2012) 3 012 AIDS patients were enrolled in the ART programme between March 2005 and August 2010. At the end of the 66 months since the programme’s initiation, 61.4% of the patients were retained on treatment and 10.4% had died; 56% of the deaths occurred in the first year of treatment (Wubshet et al, 2012). Death as a factor of attrition is documented in several studies as ranging from 6.5 to 16% at 12 months (Giordano et al, 2007; Charurat et al, 2010; Boyles et al, 2011; Wubshet et al, 2012).

At Madwaleni Hospital in the Eastern Cape Province of South Africa, 31% of LTFU patients had died soon after ART initiation (Boyles et al, 2011). Another public sector clinic in South Africa obtained similar results after tracing patients who were at least one month late for their last clinic visit 6 months after starting ART and found that 41% had died. Studies from other countries report similar outcomes after actively tracing those initially reported as LTFU. Nglazi et al (2011) found that 6% of a sample of 19
481 had died. At one and two years after ART initiation, 5.5% and 7.0% patients had died (Fox & Rosen, 2010).

Mortality was associated with being a male of a particular age, i.e. 16-24 years and with a baseline median CD4 cell of less than 200 cells/mm$^3$ and having been TFO or LTFU. Men were more likely than women to die, and the risk of death increased with age. Mortality was inversely associated with the baseline CD4 count, meaning the higher the CD4 at baseline the lower the mortality rate and vice versa (Nglazi et al, 2011). Missed appointments during the initial year of clinic enrolment lead to higher mortality rates, compared with not missing any appointments (Miller et al, 2010).

2.5.3 Transfer-out
Many studies have reported on mortality and LFTU rate outcomes. However, few have characterised those who transfer-out to other ART services. An increasing proportion of patients enrolling for ART subsequently transfer-out (Nglazi et al, 2013). As patient numbers increase, particularly in countries like South Africa with highly mobile populations, health systems need to transfer patients efficiently to ensure uninterrupted linkage to care for optimal outcomes (Cornell et al, 2015). Although many programmes report the proportion of patients who are transferred out to other services, little is known about how patients transition between services and their outcomes after TFO. Sites have limited capacity to keep track of large numbers of patients enrolled for ongoing care, while also continuing to increase enrolment onto ART (Nglazi et al, 2013).

Wubshet et al (2012) reported a transfer rate of 10.9% while Giordano et al (2007) reported it at 14.3%. However, Wubshet et al. (2012) argue that the assumption that those transferred out were retained in other health facilities may not hold true, as these patients may not be in care. This suggests that the picture on the retention in care on the broad level is worse than that documented. In South Africa, about 10% of patients who had started ART five years earlier were TFO. In addition, the probability of being TFO increased with each calendar year of ART initiation (Charurat et al, 2010). In another study, at one and two years after ART initiation TFO was 3.6% and 6.0% (Cornell et al, 2015).
In South Africa TFO increased the cumulative programme lost by 24 months from 22% to 28% (Nglazi et al, 2013). Of the 4 511 patients who received ART during the study period, 13.2% transferred out. The probability of transferring out by one year of ART steadily increased from 1.4% in the 2002/2004 cohort to 8.9% for the 2009 cohort (Cornell et al, 2015). However, a study from Botswana reported a transfer out rate of 5.2% after one year (Nglazi et al, 2013).

In a study conducted by Cornell et al (2015) the risk factors for TFO were a more recent calendar year of enrolment, younger age (25 years) and being female. There was also an association with baseline CD4 cell count and viral load. The median duration on ART at the time of transfer out was 29.0 months among patients who were ART naive at baseline. The CD4 count of 200 cells/ml was 20.1% and the viral load of 1000 copies/ml was 20.7%. A high proportion of patients (20%) did not have a suppressed viral load just prior to transfer and there was evidence that discontinuity of ART was common around the time of transfer (Nglazi et al, 2013).

2.6 VIRAL LOAD SUPPRESSION

Reducing viral load increases survival, but also decreases the infectivity of the individual (Wagner et al, 2012). It was further illustrated that ART could lower the viral load in HIV-positive individuals and very significantly decrease the risk of HIV transmission within sero-discordant couples (Plazy et al, 2015). Because the risk of HIV transmission is substantially reduced with a decreasing viral load, the hope is that increasing treatment thresholds could have an important impact on reducing HIV incidence (Fox et al, 2014).

VLS is an important clinical indicator that needs to be monitored for patients enrolled in an ART programme because it contributes to reducing HIV infectivity and controlling the HIV epidemic (Eholié et al, 2016). The WHO guidelines indicate that the main goal of therapy is to obtain and maintain viral load undetectability, which is defined as a plasma VL below the limit of detection of routine VL essays, <400 copies/ml (WHO, 2013). Failure to achieve and sustain VLS poses an increased risk of HIV transmissibility.
Although VLS is an important indicator, it is difficult to compare the suppression rates in studies due to the different periods under review. For example, in a study conducted by Gerretti et al (2008) among 10,053 patients, 8,235 (82%) had 12-month VL measures with 6,304 (77%) achieving suppression (VL<400 copies/ml). In another study VLS occurred in 674 (60%) of 1,125 patients. Additionally in a south-western Ugandan clinic, virologic suppression was 80% in individuals with CD4+ 250-350 and 90% in individuals with CD4+ <250, suggesting lower adherence in the higher CD4+ count patients (Jain et al., 2014). In a South African study, VLS was highest among older adults, 74.6% females aged 45 to 49 years and 76.4% males aged 50 years or older (HSRC survey, 2018). In contrast, VLS prevalence was lower in younger adults aged 15-24 years and 25-34 years (HSRC survey, 2018).

Poor early retention in HIV care is a barrier to timely VLS and a factor associated with a greater cumulative viral load burden over the first two years. Mugavero et al (2012) found that about 63% of the sample achieved VLS within the first year of entry into care. The survey recorded that the VLS rate amongst PLHIV aged 15-49 years in South Africa was 61% (HSRC survey, 2018). Higher rates of early retention in HIV care are associated with achieving VLS, whereas sub-optimal early retention in care represents a challenging obstacle to achieving HIV VLS. These findings are useful for a test-and-treat approach to HIV prevention (Nglazi et al, 2013).

2.7 CONCLUSION

Studies show that retention in care plays an important role in the ART programme. It also influences VLS because for patients to achieve suppression they have to remain on ART and adhere to treatment. The three attrition factors are death, TFO and LTFU, with LTFU being the greatest threat to the success of many African ART programmes. This might worsen during the UTT as more patients that are asymptomatic are put on ART when they still feel healthy. Achieving and sustaining VLS is the key to the delivery of long-term ART. The findings seem worrying in that the VLS rate should reach 90% at 12 months on ART (UNAIDS, 2014).

Considering these guidelines and what has already been presented in the previous paragraphs of this chapter, it is a matter of great concern that the retention in care and VLS rate are already looking dire. Of note is that these studies did not measure
retention in care using UTT, but focused on retention on ART before the implementation of the UTT. Treatment withdrawal increases some of the concern about drug resistance, which incomplete adherence does, and nullifies much of the benefit sought by those implementing treatment programmes (Wubshet et al; 2012).
CHAPTER THREE
METHODS AND MATERIALS

3.1 INTRODUCTION
In this chapter, the study design, setting, population and sample size, inclusion criteria and sampling, data collection, reliability and validity of the data collection instruments, data analysis and ethical considerations are presented.

3.2 STUDY DESIGN
This is a retrospective cohort study design. Retrospective cohort studies are a type of observational research in which the investigator looks back in time at archived or self-report data to examine whether the risk of disease was different between exposed and non-exposed patients. The researcher needed to extract data by reviewing the records of a cohort of patients that were initiated on ART through UTT in November 2016 and this made this study design the most suitable choice.

3.3 STUDY SETTING
The study was conducted in Ekurhuleni North sub-district in Gauteng Province. The sub-district comprises 28 primary health care (PHC) facilities. The services that are generally rendered by the PHC facilities include management of acute conditions, minor ailments and emergencies, mother and child health services, which include immunization of children, family planning, antenatal care, and chronic condition care, e.g. HIV and TB. The facilities operate from 07h30 to 16h30 on weekdays with a few facilities that are open on Saturdays from 08h00 to 14h00; community health centres are open 24 hours. Regarding ART services, the facilities provide care and support to PLHIV free of charge using the National Department of Health and WHO guidelines. The facilities are using the Tier.net to capture the details of visits of all patients that are on ART. This database has been used to provide aggregate data on key indicators and monitoring. Patients that are on ART are managed by the counsellors for adherence counselling, and by nurses/doctors for medical management.

3.4 STUDY POPULATION
The study population consisted of the records/files of adult patients that were initiated on ART through UTT in Ekurhuleni North PHC facilities, since the beginning of
September 2016. According to the DHIS data, 1412 patients were initiated in September 2016 at the introduction of UTT in Ekurhuleni North facilities. The Tier.net database is used to capture all the files of patients that are initiated on ART at each facility. The database further updates each visit when patients visit the facility for follow-up. According to the DHIS report, at the onset of UTT the number of patients initiated per facility ranged from 13 to 119.

3.4.1 Inclusion criteria
Files of male and female patients aged 15 years and above, were ART naïve, and started on ART through UTT were included in the study.

3.4.2 Exclusion criteria
The files of pregnant women, children below the age of 15 years, patients that were not naïve and those that were reinitiated, were excluded.

3.5 SAMPLING SIZE AND PROCEDURE
A sample size of 303 records was calculated using the Raosoft sample size calculator (Raosoft Inc., 2004). The sample was selected from a population size of 1412 records, with a confidence level of 95%, margin of error of 5% and response distribution of 50%. The researcher oversampled files by an extra 50 files to 372 files to compensate for records with missing information or incomplete data. Because the data extraction was limited to a cohort of patients initiated during a specified period, the number of files in the facility was disregarded. All files that were eligible for the same cohort month, i.e. November 2016, were used in the study. At each facility all files of patients initiated during this period were reviewed, and this was repeated from one facility to the next until the total of 372 files was reviewed. The researcher used the Tier.net database to filter through the cohort of patients initiated in the relevant month. This was used for ease of access to the list with file numbers and take out the files from the filing cabinets. In each selected facility, all eligible files were included in the review.

3.6 DATA EXTRACTION
Data extraction commenced after the researcher had received ethical clearance from the Sefako Makgatho University Research Ethics Committee (SMUREC), and
permission from authorities of the Gauteng provincial department of health, Ekurhuleni health district and the managers of the selected facilities. The researcher requested permission to conduct the study from the selected facilities by email. The facilities that responded first were prioritized as the first to have initiated data extraction.

3.6.1 Data collection tool
The researcher extracted data from the patients’ files using a self-developed data extraction tool. The data extraction tool was developed using the data elements commonly captured in the patients’ files. The tool extracted patient’s demographic data, clinical information, which also covered baseline data elements and monitoring bloods data elements, and attrition factors.

3.6.2 Data extraction procedure
Following approval to conduct the study, the researcher arranged with the facility manager for an area for data extraction. This was usually the boardroom/tea/staff room. In facilities that did not have these areas or in instances where they were already in use, the researcher used the data capturing room or an empty consulting room. In all the facilities, the researcher was accorded space to extract data and adhere to the principle of ensuring confidentiality.

The records were kept in the bulk filing room or in the capturing room during the capturing periods. Files were pulled from the filing room in batches of 10 and when the researcher had finished with each batch, these were returned to the filing cabinet before pulling out the next batch of 10 files. This procedure was followed to avoid overloading the clerks who were assisting the researcher. To minimize interrupting the capturers during important capturing and reporting periods the researcher arranged per facility in advance for the use of Tier.net to run the cohort list of patients that had been initiated in November 2016.

During data extraction, the identity of the patients was not on the data extraction tool, only the file numbers. All files were kept within the area of data collection at all times and no files were removed from the area or from the facility by the researcher to ensure that confidentiality of patients’ information was observed. The researcher had set 10 weeks for data extraction but this period had to be increased The files of clients that were still in care were easy to find as they had been filed in the bulk filing area.
However, files of patients that were no longer in care had been filed haphazardly with no logical system. Hence finding these files was really challenging and the researcher needed extra time to access them. The process for extracting data was repeated until the representative sample had been reached and the data extraction was completed. This took about 14 weeks to complete.

3.6.3 Data management
The researcher crosschecked each data collection before leaving a facility. Data were extracted from the files of 372 patients. All completed data extraction tools were stored in a locked cabinet and only the researcher had access to the cabinet. All data were entered in a password-protected computer where access was restricted to the researcher only. The collected information was used for the purposes set out in this proposal and nowhere else.

3.7 DATA ANALYSIS
The researcher used a Microsoft Excel 2010 spreadsheet to capture the data from the data extraction tool. The data were captured, cleaned, coded, imported, and analyzed using STATA software version 13.0. The univariate analysis included both summary and descriptive statistics. Summary statistics were used to analyze and interpret the mean, median and ratio of numeric variables such as age, CD4 count, and viral load. Categorical data were analyzed by use of descriptive statistics and presented as a frequency distribution in the form of percentages or proportions. In terms of bivariate analysis, cross tabulation in the form of two-by-two tables was used to determine any association between variables. The Pearson chi-square test was used to test for associations between categorical variables and the outcome variables. Variables that showed significance at bivariate analysis were used in the logistic regression to determine association with the outcome variables. A p-value of less than 0.05 was considered statistically significant. The results were reported as an odds ratio with 95% confidence interval. Graphs and tables were used to illustrate the findings. The retention in care rate and VLS rate were calculated following the ART data management guidelines.
3.8 VALIDITY, RELIABILITY AND BIAS

The data extraction tool was in English because the researcher was to implement it to collect data. The tool was comprehensive enough to collect all the information needed to address the objectives of the study. The extraction tool included brief, non-ambiguous and to-the-point questions that were relevant to the study.

To ensure reliability the researcher pre-tested the tool in one facility on 20 files to assess whether the tool captured all the relevant elements from the patients’ files. The tool was tested during a pilot study to determine the feasibility of the study in relation to the ability to access files and extract the data. The results of the pre-test were used to adjust the tool and processes accordingly where there were areas with gaps in information. Several gaps were identified, for instance, under clinical section the CD4 count at 12 months was missing from the extraction tool, weight at 12 months, adherence sessions and whether the patients disclosed information to anybody. These were included in the final tool. To ensure reliability, the data extraction was standardized as well as the conditions under which data was conducted and extracted, for example, the researcher was the only person who extracted data and followed the same steps. Patients’ files that had missing data above 10% were excluded from the extraction and extra files that were oversampled were used to buffer these kinds of files.

In a retrospective record review, missing values cause information bias that could lead to the variables being under- or over-reported during data analysis. Missing data can also lead to hidden or non-response bias. To minimize this bias the researcher conducted pre-testing of the tool and oversampled files to be reviewed. Furthermore, to avoid inter-observer variability when multiple individuals are gathering and entering data, the researcher collected data independently.

3.9 ETHICAL CONSIDERATIONS

The proposal was submitted to the School of Health Care Sciences Research Committee. Ethical clearance was obtained from the Ethics and Research Committee of Sefako Makgatho Health Sciences University (SMUREC/H/290/2017/PG) before the research was conducted. Permission was also requested from Ekurhuleni Health
District (Ref GP_ 201802_011) and from the managers of the sampled facilities to conduct the study in that setting. To ensure confidentiality, only the file numbers were recorded on the data extraction tool. The researcher ensured that no patients’ names were documented in the data extraction tools. The files were not removed from the demarcation area where they were naturally kept, which was the bulk filing room, the data capturing room or boardroom, nor did the researcher take any files out of the facility.

3.10 CONCLUSION
This chapter provided feedback on the methods and materials employed to extract data from the patient folder. Furthermore clarification of the ethical considerations observed ensured that the study adhered to good practice. The results will be presented in the next chapter.
CHAPTER FOUR
RESULTS OF THE STUDY

4.1 INTRODUCTION
This chapter presents and describes the results of the study. The format of the chapter is that first the socio-demographic characteristics of the patients that were initiated on ART through UTT are presented using graphs and frequency tables. This is followed by clinical data of patients as extracted from their files. Then the attrition factors are presented and finally factors associated with attrition are presented.

4.2 DEMOGRAPHIC DATA
The socio-demographic data of the patients were extracted from 372 files. The socio-demographic data extracted included the age, gender, employment status, and marital status of patients on ART. These are presented in Figures 4.1 to 4.4.

![Figure 4.1: Gender distribution of patients on UTT](image)

This diagram illustrates that 64% (n=237) of the patients were females, while only 36% (n=135) were males.
The graph in Figure 4.2 shows that the largest proportion of patients (38%; n=142) were in the age group 26-35 years, and patients aged 56 and above constituted 1%. The mean age was 36.3 years (SD 9.6; range, 18-72 years).

The results highlighted that 62% (n=230) of the patients were single, while 38% (n=142) were married.
The results highlight that over half (n=195; 52%) of the patients were employed; 45% (n=168) were unemployed; and less than 1% (n=7) were pensioners. This corresponds with and is linked to the total number of people that were aged 56 years and above.

Table 4.1: Distribution of demographic variables by gender

<table>
<thead>
<tr>
<th>Variables</th>
<th>Female 236</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td><strong>Age category</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-25 years</td>
<td>39</td>
<td>16.1</td>
<td>5</td>
<td>3.9</td>
</tr>
<tr>
<td>26-35 years</td>
<td>115</td>
<td>47.3</td>
<td>32</td>
<td>24.8</td>
</tr>
<tr>
<td>36-45 years</td>
<td>55</td>
<td>22.6</td>
<td>60</td>
<td>46.5</td>
</tr>
<tr>
<td>46-55 years</td>
<td>26</td>
<td>10.7</td>
<td>25</td>
<td>19.4</td>
</tr>
<tr>
<td>Above 56 years</td>
<td>8</td>
<td>3.3</td>
<td>7</td>
<td>5.4</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>149</td>
<td>64</td>
<td>81</td>
<td>58.3</td>
</tr>
<tr>
<td>Married</td>
<td>84</td>
<td>36</td>
<td>58</td>
<td>41.7</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>117</td>
<td>50.2</td>
<td>78</td>
<td>57.8</td>
</tr>
<tr>
<td>Unemployed</td>
<td>113</td>
<td>48.5</td>
<td>55</td>
<td>40.7</td>
</tr>
<tr>
<td>Pension</td>
<td>4</td>
<td>0.4</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Grant</td>
<td>2</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4.1 illustrates the variables by gender distribution. It shows that all age categories are dominated by females except for those that were aged between 36 and 45 years. There were slightly more males than females. The majority of the patients were single and female. The majority (69%) of females were employed, whereas only 31% of the males had employment. Three (0.8%) of the patients were pensioners.
Recipients of social grants were mainly those that were receiving child grants and only two mentioned this in their record.

4.3 CLINICAL DATA OF PATIENTS
To determine the attrition factors, the clinical data of the patients were also extracted from the files. These included the weight, CD4 count, BMI, WHO staging, opportunistic diseases, ART regimen, and viral load copies.

4.3.1 Weight at baseline and 12 months
All patients enrolled in the ART programme were weighed at baseline and on all subsequent visits. The weight is one of the measures of the WHO clinical staging and assists clinicians to manage the nutritional status of patients. It is also a very important indicator for recovery especially for those patients who start treatment when they have already lost substantial weight.

<table>
<thead>
<tr>
<th>Patients’ weight at baseline and 12 months interval</th>
<th>Observation</th>
<th>Mean</th>
<th>Std. dev.</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight at baseline</td>
<td>369</td>
<td>67.8</td>
<td>13.4</td>
<td>43</td>
<td>115</td>
</tr>
<tr>
<td>Weight at 12 months</td>
<td>113</td>
<td>68.4</td>
<td>13.5</td>
<td>41</td>
<td>98</td>
</tr>
</tbody>
</table>

Table 4.2 presents the weight distribution of the patients; 369 of the 372 records showed that patients were weighed at baseline, and the mean weight was 67.8 kg, and the range was 43 to 115 kg. In addition, the records showed that at 12 months, only 113 of the 372 patients had been weighed, and the mean weight was 68 kg with a range from 41 to 98 kg. Fewer patients were weighed at 12 months because some had already left care before reaching 12 months on ART. The mean weight is similar at baseline and 12 months interval, however, the upper point of the range might be due to the patients that left care early or some of the patients that were obese at baseline might have lost weight through the course of treatment.
4.3.2 Universal test and treat

UTT requires that patients be initiated on ART on diagnosis, regardless of CD4 count unless there are any contra-indications to same-day initiation. This means that patients should be initiated on ART within 14 days after HIV diagnosis. The study established the rate at which UTT is implemented as per guidelines.

![Image of Universal Test and Treat](image)

**Figure 4.5: Proportion of patients initiated on UTT (n=372)**

The graph in Figure 4.5 illustrates that out of the 372 patients’ records reviewed, over half (55%; n=203) of the patients were initiated through the UTT. The remaining 45% (n=169) were initiated after being on pre-ART.

4.3.3 CD4 count

The CD4 count is the most important laboratory indicator of immune function and the strongest indicator of HIV progression. The CD4 count is also used to monitor the patient’s response to ART; thus it is done at baseline and once again at 12 months. The researcher also needed to determine at what level of disease patients presented to care.

<table>
<thead>
<tr>
<th>Table 4.3: CD4 count data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean CD4 count</strong></td>
</tr>
<tr>
<td>342 cells/mm³</td>
</tr>
</tbody>
</table>

Table 4.3 illustrates that the mean CD4 count was 342 cells/mm³, the lowest CD4 count on baseline was four (4) cells/mm³ and the highest was 1411 cells/mm³.
Table 4.4: Distribution of CD4 count at baseline

<table>
<thead>
<tr>
<th>CD4 count levels</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 below 100 cells/mm³,</td>
<td>86</td>
<td>23.12</td>
</tr>
<tr>
<td>CD4 above 500 cells/mm³,</td>
<td>97</td>
<td>26.08</td>
</tr>
<tr>
<td>CD4 between 101-499 cells/mm³,</td>
<td>189</td>
<td>50.8</td>
</tr>
</tbody>
</table>

The results show that of the 372 patient records reviewed, less than a quarter (23%; n=86) of the patients had CD4 less than 100 cells/mm³; slightly over a quarter (26%; n=97) had CD4 above 500 cells/mm³, leaving the other half (50.8% n=189;) of the patients in the CD4 count ranging between 101 and 499 cells/mm³. The results revealed that the lowest CD4 count was four (4) cells/mm³ and the highest was 1411 cells/mm³. These data illustrate that patients still present late for care and treatment as the proportion of patients with baseline CD4 count less than 100 cells/mm³ were (n=86) 23% and those with CD4 count more 500 cells/mm³ were (n=97) 26% and these are very similar.

Table 4.5: Comparison of CD4 count categories by patient’s gender

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th></th>
<th>Males</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freq.</td>
<td>Percent</td>
<td>Freq.</td>
<td>Percent</td>
</tr>
<tr>
<td>CD4 count below 100 cells/mm³</td>
<td>44</td>
<td>51%</td>
<td>82</td>
<td>49%</td>
</tr>
<tr>
<td>CD4 count above 500 cells/mm³</td>
<td>75</td>
<td>77%</td>
<td>22</td>
<td>23%</td>
</tr>
</tbody>
</table>

Table 4.5 shows that of the 126 patients that had CD4 less than 100 cells/mm³, 51% (n=44) were females and 49% (n=82) were males. Of the 97 that had a CD4 above 500 cells/mm³, 77% (n=75) were females and 23% (n=22) were males.

4.3.4 WHO staging

The WHO system for adults sorts patients into one of four hierarchical clinical stages ranging from Stage 1 (asymptomatic) to Stage 4 (AIDS). It is done to determine or confirm the HIV infection and its progression by presumption. All patients are categorized to a particular stage when they demonstrate at least one clinical condition in that stage’s criteria. WHO staging at baseline helps guide ART and care-related decisions. On each follow-up visit it is used to determine if the patient’s condition is worsening or stabilising so that management can be adjusted accordingly. Patients
remain at a higher stage after they recover from the clinical condition which placed them at that stage.

The graph in Figure 4.6 shows that a high proportion 78% (n=292) of the patients were asymptomatic and only 3% (n=11) were at an advanced stage of HIV/AIDS at baseline. Opportunistic diseases were scantily distributed amongst the remaining number and the most prominent was the weight loss of <10% body weight, which is aligned to WHO Stage II.

**4.3.5 Opportunistic disease at baseline**

Opportunistic infections are also used to categorize patients using the WHO staging. The researcher needed to learn which opportunistic infections (OIs) were more prominent amongst the patients that were initiated on ART through UTT at baseline. These infections take advantage of the weakness in the immune defence in HIV-positive patients. These OIs are classified in line with the WHO staging.
Table 4.6: Opportunistic diseases at baseline

<table>
<thead>
<tr>
<th>Opportunistic Diseases</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>292</td>
<td>78.5</td>
</tr>
<tr>
<td>Weight loss of &lt;10% body weight</td>
<td>20</td>
<td>5.4</td>
</tr>
<tr>
<td>Minor mucocutanous</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Uncomplicated herpes zoster</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Pulmonary TB</td>
<td>9</td>
<td>2.4</td>
</tr>
<tr>
<td>Meningitis</td>
<td>5</td>
<td>1.3</td>
</tr>
<tr>
<td>Weight loss of &gt;10% body weight</td>
<td>5</td>
<td>1.3</td>
</tr>
<tr>
<td>Oesophageal candidiasis</td>
<td>4</td>
<td>1.1</td>
</tr>
<tr>
<td>Herpes simplex zoster virus lesion</td>
<td>3</td>
<td>0.8</td>
</tr>
<tr>
<td>Recurrent URTI</td>
<td>3</td>
<td>0.8</td>
</tr>
<tr>
<td>Previous PTB</td>
<td>1</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 4.6 demonstrate that a high proportion (78.5%; n=292) of the patients were asymptomatic, which is consistent with the results from the WHO staging. This seems to be in line with the requirement of UTT where ART is to be initiated early while the clients are asymptomatic. Furthermore, only 3% (n=11) were at an advanced stage of HIV/AIDS with OIs like extra-pulmonary TB. The OIs were scantily distributed amongst the remaining number and the other most prominent was the weight loss of <10% body weight which is aligned to WHO stage II.

4.3.6 ART regimen

Data on the ART were extracted to determine the line of treatment. The results showed that all the patients were initiated on first-line ART, which is a fixed dose combination of Tenofovir (TDF), Emtricitabine (FTC) and Efavirenz (EFV) (1TFE). Only one patient was switched to second line of treatment at month 10 after initiation and was put on Abacavir and Lamivudine and Efavirenz (ABC+3TC+Alluvia). The patient’s VL results at 6 months were 165000 copies while the expected was fewer than 400 copies/ml.

4.3.7 Viral load suppression

Viral suppression means suppressing or reducing the function and replication of a virus. When a patient is initiated on ART, the purpose of the medication is to reduce the patient’s viral load to undetectable levels. The term ‘viral load’ refers to the number
of copies of HIV per millilitre (ml) of blood. Therefore all patients that are on ART need to have their viral load taken at 6 months, 12 months, and then annually.

Table 4.7: Viral load suppression rate

<table>
<thead>
<tr>
<th></th>
<th>Less than 400 copies/ml (undetectable viral load)</th>
<th>More than 400 copies/ml (detectable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percent</td>
</tr>
<tr>
<td>Viral load at 6 months</td>
<td>118</td>
<td>51%</td>
</tr>
<tr>
<td>Viral load at 12 months</td>
<td>169</td>
<td>77%</td>
</tr>
</tbody>
</table>

Table 4.7 presents the viral load suppression rate, and the results showed that of the 231 patients who had their bloods taken for viral load analysis, almost half (49%; n=113) had detectable viral load (above 400 copies/ml) and slightly over half (51%; n=118) had undetectable viral load at 6 months. However, the results illustrate that viral load suppression was improving because at 12 months, of the 219 patients who had their viral load analysed, over three quarters (77%; n=169) had a viral load less than 400 copies/ml, while 23% (n=50) had viral load results that were above 400 copies/ml.
Table 4.8: Distribution of clinical data segregated by gender

<table>
<thead>
<tr>
<th>Variables</th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>WHO staging</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO Stage I</td>
<td>193</td>
<td>81.4</td>
<td>99</td>
<td>75</td>
</tr>
<tr>
<td>WHO Stage II</td>
<td>27</td>
<td>11.4</td>
<td>22</td>
<td>16.3</td>
</tr>
<tr>
<td>WHO Stage III</td>
<td>12</td>
<td>5.1</td>
<td>8</td>
<td>5.9</td>
</tr>
<tr>
<td>WHO Stage IV</td>
<td>5</td>
<td>2.1</td>
<td>6</td>
<td>4.4</td>
</tr>
<tr>
<td>CD4 count</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 count less than 100</td>
<td>44</td>
<td>18.6</td>
<td>42</td>
<td>31.8</td>
</tr>
<tr>
<td>CD4 count above 500</td>
<td>75</td>
<td>31.6</td>
<td>22</td>
<td>16.3</td>
</tr>
<tr>
<td>CD4 count between 101-499</td>
<td>118</td>
<td>49.8</td>
<td>71</td>
<td>52.6</td>
</tr>
<tr>
<td>Viral load copies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral load &gt; 400copies/ml at 6 months</td>
<td>67</td>
<td>25.2</td>
<td>52</td>
<td>28</td>
</tr>
<tr>
<td>Viral load &lt; 400copies/ml at 6 months</td>
<td>67</td>
<td>25.2</td>
<td>42</td>
<td>22.6</td>
</tr>
<tr>
<td>Viral load &gt; 400copies/ml at 12 months</td>
<td>117</td>
<td>44</td>
<td>79</td>
<td>42.5</td>
</tr>
<tr>
<td>Viral load &lt;400copies/ml at 12 months</td>
<td>15</td>
<td>5.6</td>
<td>13</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 4.8 illustrates that WHO staging by gender distribution was dominated by females in Stages I, II and III, however, most females (81.4%; n=193) were initiated at baseline WHO Stage I which was the same as males with 75% (n=99). In addition, fewer patients presented at an advance baseline WHO stage at initiation. The dominance of females was the trend in all the other variables illustrating that females were in the majority and this is reflective of the gender distribution of this cohort which had 64% of all patients initiated being females.

The majority of both females (49.8%; n=118) and males (52.6%; n=71) presented to care on baseline CD4 between 101 and 499 cell/mm$^3$. In addition, fewer females (18.6%; n=44) were initiated with baseline CD4 count less than 100 cell/mm$^3$ and males were initiated at baseline CD4 count more than 500 cell/mm$^3$ (16.3%; n=22).

Furthermore, on VLS at 6 and 12 months more females were suppressing than males.
Table 4.9: Comparison of outcome period and death by baseline CD4 count

<table>
<thead>
<tr>
<th></th>
<th>CD4 count above 500 cells/mm</th>
<th>CD4 count below 100 cells/mm</th>
<th>CD4 count between 101 and 499 cells/mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freq.</td>
<td>Percent</td>
<td>Freq.</td>
</tr>
<tr>
<td>LTFU at 12 months</td>
<td>31</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>Immediately</td>
<td>13</td>
<td>39.4</td>
<td>7</td>
</tr>
<tr>
<td>At three months</td>
<td>22</td>
<td>33</td>
<td>15</td>
</tr>
<tr>
<td>Death</td>
<td>1</td>
<td>17</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 4.9 demonstrates the LTFU at different time frames. What is prominent is that almost 40% (n=13) of the patients left care immediately after initiation and these patients had a baseline CD4 count above 500 cell/mm$^3$; equally those that had a CD4 count below 100 cell/mm$^3$ at 40% (n=13) also left care immediately.

4.4 ATTRITION FACTORS

The attrition factors were found to be LTFU, TFO and death.

![Attrition factors](image)

Figure 4.7: Distribution of attrition factors

Figure 4.7 shows that a high proportion (59%; n=219) of the 372 patients were retained on ART at 12 months after initiation. While 28% (n=103) of the patients were LTFU, 11% (n=42) were transferred out, only 2% (n=6) had died and two patients were referred to the hospital for further management.
4.4.1 Lost to follow-up at 12 months

Of the 372, 28% (n=103) of the patients were lost to follow-up at 12 months.

![Lost to follow up at 12 months](image)

Figure 4.8: Lost to follow-up at 12 months

The graph in Figure 4.8 illustrates the breakdown of baseline CD4 count of the patients that were LTFU at 12 months. Of the 103 patients that were lost to follow-up throughout the 12-month period, 30% (n=31) had a CD4 that was above 500 cells/mm$^3$ while 19% (n=20) had a CD4 below 100 cells/mm$^3$. The remaining 51% (n=30) had a baseline CD4 count ranging from 101 to 499 cells/mm$^3$.

Of the 67 patients that were lost to follow-up at 3 months after ART initiation 33% (n=22) had baseline CD4 above 500 cells/mm$^3$ and 22% (n=15) had CD4 below 100 cells/mm$^3$ and the remaining 48% (n=30) had a baseline CD4 count ranging from 101 to 499 cells/mm$^3$.

4.4.2 Reported deaths

A total of six (6) patients were reported to have died which constitutes 1.5%. The period of death ranged between months 1 and 10 after ART initiation. Five (5) patients that died had a baseline CD4 count of less than 100 cells/mm$^3$ and only one had CD4 above 500 cells/mm$^3$ at baseline.
4.4.3 Transfer out
From the cohort of 372, 11% (n=42) patients were transferred out at 12 months. Seventy-six percent (n=32) of these patients that were transferred out were females and only 24% (n=10) were males. The majority (64%; n=27) of these patients were initiated from the pre-ART.

4.5 FACTORS ASSOCIATED WITH LOST TO FOLLOW-UP
Logistic regression was performed with retention in care and the three attrition factors, which are LTFU, TFO and death as the dependent variables. Two-by-two tables were first conducted between these dependent variables and other independent variables (gender, age, marital status, weight at baseline, BMI, CD4 above 500cell/mm3 and below 100 cells/mm3 and WHO staging).

Bivariate analysis, using the chi-square tests, was then performed with each independent variable in order to determine the variables to include in the logistic regression model. From the chi-square tests, independent variables, which yielded p-values less than 0.05, were included in the initial logistic regression model. The results from this logistic regression showed no association between the independent variables and retention in care.

| Table 4.10: Factors associated with retention in care |
|---------------------------------|-------|-------|-------|-------|-------|-------|
| Retention in care | Coef. | Std. Err. | t | P>t | [95% Conf. Interval] |
| Age | .005 | .003 | 1.69 | 0.091 | -.000 | .0107 |
| Gender | -.073 | .06 | -1.22 | 0.222 | -.190 | .044 |
| UTT | -.088 | .053 | -1.67 | 0.097 | -.193 | .016 |
| BMI | -.004 | .005 | -0.75 | 0.456 | -.013 | .006 |
| CD4 results | -.000 | .000 | -0.20 | 0.843 | -.000 | .000 |
| CD4 below 500 | -.160 | .075 | -2.14 | 0.033 | -.308 | -.013 |
| CD4 above 500 | -.142 | .096 | -1.48 | 0.139 | -.330 | .046 |
| WHO stage | .030 | .038 | 0.80 | 0.426 | -.044 | .105 |
| Counselling session | .024 | .036 | 0.66 | 0.507 | -.048 | .096 |
| Marital status | -.033 | .055 | -0.60 | 0.548 | -.142 | .075 |
| _cons | .589 | .201 | 2.94 | 0.004 | .194 | .984 |
Table 4.11: Distribution of attrition factors by gender

<table>
<thead>
<tr>
<th>Variables</th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td><strong>Attrition factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retention in care</td>
<td>128</td>
<td>58%</td>
<td>91</td>
<td>42%</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>71</td>
<td>68%</td>
<td>32</td>
<td>32%</td>
</tr>
<tr>
<td>Transfer out</td>
<td>33</td>
<td>79%</td>
<td>9</td>
<td>21%</td>
</tr>
<tr>
<td>Death</td>
<td>4</td>
<td>67%</td>
<td>2</td>
<td>33%</td>
</tr>
</tbody>
</table>

Table 11b and 11b illustrates the distribution of attrition factors extracted from the patients’ records segregated by gender. A high proportion of females were retained 58% (n=128) compared to 44% (n=91) males. This illustrative that there were more females than males in this cohort because in all the attrition factors the females are leading in proportion.

Table 4.12: Factors associated with retention in care

| Retention in care               | Odds ratio | P>|z | [95% Conf. ] Interval |
|---------------------------------|------------|-----|----------------------|
| Gender                          | 0.61       | 0.035 | 0.39 | 0.96 |
| Marital status                  | 0.95       | 0.837 | 0.618 | 1.48 |
| UTT                             | 0.69       | 0.092 | 0.45 | 1.06 |
| CD4 count above 500             | 0.59       | 0.036 | 0.37 | 0.97 |

Table 4.12 presents the factors associated with retention in care, and there was significant association between gender, and CD4 count and retention in care. Patients that had a CD4 above 500 cells/mm3 were less likely to be retained in care (OR=0.59; p=0.036; 95% CI: 0.37-0.97) compared to those with CD4 counts less than 500 cells/mm3. Males were less likely to be retained in care (OR=0.61, p=0.035, 95% CI: 0.39-0.96) than females.
Table 4.13: Factors associated with transfer out.

<table>
<thead>
<tr>
<th>Transfer Out</th>
<th>Odds ratio</th>
<th>P value</th>
<th>[95% Conf. Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>UTT</td>
<td>9.87</td>
<td>0.695</td>
<td>0.45</td>
</tr>
<tr>
<td>CD4 below 100 cells/mm3</td>
<td>0.44</td>
<td>0.002</td>
<td>1.58</td>
</tr>
<tr>
<td>CD4 above 500 cells/mm3</td>
<td>3.17</td>
<td>0.003</td>
<td>1.46</td>
</tr>
</tbody>
</table>

Table 4.13 presents the factors associated with transfer out, and there was significant association between CD4 count and transfer out. Patients with CD4 below 100 cells/mm³ were less likely to transfer out (OR=0.44, p=0.002, 95% CI: 1.58-7.51), whereas those with CD4 above 500 cells/mm³ were 3 times more likely to transfer out (OR=3.17; p=0.003; 95% CI: 1.46-6.87).

Table 4.14: Factors associated with lost to follow-up

<table>
<thead>
<tr>
<th>Lost to follow-up</th>
<th>Odds ratio</th>
<th>P&gt;z</th>
<th>[95% Conf. Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>1.20</td>
<td>0.468</td>
<td>0.72</td>
</tr>
<tr>
<td>Marital status</td>
<td>1.10</td>
<td>0.686</td>
<td>0.68</td>
</tr>
<tr>
<td>UTT</td>
<td>1.75</td>
<td>0.022</td>
<td>1.08</td>
</tr>
<tr>
<td>CD4 below 100 cells/mm³</td>
<td>0.84</td>
<td>0.576</td>
<td>0.45</td>
</tr>
<tr>
<td>CD4 above 500 cells/mm³</td>
<td>1.24</td>
<td>0.440</td>
<td>0.71</td>
</tr>
<tr>
<td>WHO staging</td>
<td>0.69</td>
<td>0.072</td>
<td>0.46</td>
</tr>
</tbody>
</table>

Table 4.14 presents factors associated with lost to follow-up. The results showed significant association between lost to follow-up and UTT. Patients that were initiated through UTT were twice more likely to be lost to follow-up than those initiated through the pre-ART (OR=1.75; p 0.022; 95% CI: 1.08-2.83). There was no significant association between lost to follow-up and gender, marital status, CD4 count, and WHO staging.
Table 4.1: Linear regression between VLS and clinical variables at 12 months

<table>
<thead>
<tr>
<th>Viral load at 12 months</th>
<th>Coef.</th>
<th>P&gt;t</th>
<th>[95% Conf. Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>364.99</td>
<td>0.196</td>
<td>-189.32</td>
</tr>
<tr>
<td>Weight at baseline</td>
<td>-234.21</td>
<td>0.473</td>
<td>-876.32</td>
</tr>
<tr>
<td>CD4 count</td>
<td>-5.14</td>
<td>0.612</td>
<td>-25.09</td>
</tr>
<tr>
<td>Viral load copies at 6 months</td>
<td>0.50</td>
<td>0.000</td>
<td>.41</td>
</tr>
</tbody>
</table>

Table 4.15 presents the relationship between VLS at 12 months and age, weight at baseline, and viral load at 6 months. There was significant positive linear relationship between viral load copies 6 months and viral load copies at 12 months.

4.6 CONCLUSION

This chapter provided the results through tables and graphs to illustrate the findings. The chapter presented an analysis of the variable in line with the objectives of the study and the research questions. The discussion, conclusion and recommendations are recorded in the next chapter.
CHAPTER FIVE
DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION
This chapter presents the discussion, conclusions, and recommendations from the interpretation of the study results. The main objectives of the study were to determine the rate of viral load suppression, retention in care, and the attrition factors amongst adult patients who were initiated ART through UTT. In this chapter, the results will be discussed and possible reasons for findings will be given.

5.2 DEMOGRAPHIC CHARACTERISTICS OF ART PATIENTS
The sample consisted of 372 records of patients initiated on ART through the UTT. The extracted data showed that most patients were female (64%), single (62%) and (52%) employed. Their age ranged from 18-72 years and the mean age was 36 years. The mean age at the time of enrolment to ART was consistent with a study that was done in Nigeria where the findings showed that out of a population of 5760, 59% were female and the median age at time of enrolment was 35 years (Charurat et al., 2010). The current study results are further consistent with a South African study conducted in four health facilities where females comprised 68% (Cornell et al., 2015). The findings that a higher proportion of women were initiated on ART and remained in care in the current study cohort mimic findings from other cohorts in sub-Saharan Africa and may reflect gender differences in health-seeking behaviours which have been shown to affect retention in care (Cornell et al, 2015).

5.3 BASELINE CLINICAL PROFILE
The main objective of the study was to establish the rate at which UTT is implemented and determine its association with attrition or retention in care. Over half (55%) of the patients were initiated through UTT and about 45% were initiated after being on pre-ART. A high proportion (78%) of the patients was asymptomatic at baseline and categorized into WHO Stage I. Only a small proportion of patients (3%) was at an advanced stage of HIV/AIDS, classified as WHO Stage IV. Data were also extracted on the presence of opportunistic infections at baseline. The opportunistic infections are classified in line with or define the WHO staging. The results showed that the opportunistic infections were scantily distributed and the most commonly identified
among patients was the weight loss of <10% body weight, which is aligned to WHO Stage II.

The results of the current study are not consistent with the study that was done in Cape Town, South Africa where 73.1% of patients in the cohort that were put on ART between 2002 and 2009 were mostly categorized as WHO clinical Stage III or IV (Nglaizi et al., 2013). The study cohort was initiated on ART during the era when ART was recommended for HIV-infected patients in moderate and advanced stages of infection at a CD4 count of 250 cells/mm3 with the aim of limiting disease progression and mortality (Hontelez et al., 2013).

The asymptomatic status of the patients is expected since clients initiated through UTT are initiated immediately after testing regardless of the CD4 count. In the current study the mean CD4 count was 342 cells/mm³, the lowest CD4 count on baseline was 4 cells/mm³ and the highest was 1411 cells/mm³. The CD4 count is used to monitor the patient’s response to ART thus it is done at baseline and once again at 12 months.

Furthermore, the results showed that about a quarter (23%) of the patients had a baseline CD4 less than 100 cells/mm³, slightly over a quarter (26%) had a CD4 above 500 cells/mm³, and half (50.8%) of the sample had CD4 ranging between 101 and 499 cells/mm³. The mean CD4 count in the current study is higher than that of earlier studies in which the median CD4 absolute count at ART initiation was 121 cells/mm³ with 76% of the patients having had CD4 of 200 cells/mm³ in a study conducted in Nigeria (Charurat et al., 2010). Similar to the differences in WHO clinical staging, the inconsistency in the mean CD4 count can be attributed to the 2002 WHO ART guidelines that recommended that HIV-infected patients should be initiated on ART at a CD4 count of 250 cells/mm³ (Hontelez et al., 2013). On the other hand, the current study was conducted during the UTT era where patients are initiated immediately after testing regardless of the CD4 count. Often this happens while the patients are still asymptomatic and thus the majority were presenting at WHO Stage I and at a higher baseline CD4 count.

The evolution for the WHO guidelines on ART through the years makes it difficult to compare the baseline clinical data of CD4 count and staging with previous studies. As
stated, in the past patients were eligible for ART when they presented at health facilities with symptoms and CD4 count below a certain threshold. However, with UTT patients are initiated regardless of CD4 count. Since there is a dearth of data or evaluation of recent studies on CD4 count at baseline, the current study findings could serve as baseline data for other studies.

However, it is a matter of concern that the current study found that patients still present for care at an advanced stage of the disease. Even though the proportion was small, the results revealed that almost a quarter (23%) of the patients presented for care with a CD4 count below 100 cells/mm³. The lowest CD4 count was 4 cells/mm³. Of those who presented with a CD4 count of less than 100 cells/mm³, 49% were males and 51% were females.

5.4 ART REGIMEN
All the patients were initiated on first-line ART, which is a fixed dose combination of Tenofovir (TDF), Emtricitabine (FTC) and Efavirenz (EFV) (1TFE). The study also showed that the transition to second-line treatment remained very low and progressed slowly because only one patient was switched to second line at month 10 after initiation. The patient’s VL result at 6 months was 165000 copies/ml. The study conducted by Assefa et al. (2011) in Ethiopia also found that the transition to second-line treatment also remained very low and progressed slowly, from 0.33% at sixth month to 2.13% after 24 months on ART.

5.5 VIRAL LOAD SUPPRESSION
At 6 months, 231 patients had their bloods taken for viral load analysis. Almost half (49%) of these patients had a detectable viral load (above 400 copies/ml) and slightly more than half (51%) had an undetectable viral load (below 400 copies/ml). Whereas at 12 months, over three quarters (77%) of the 219 patients still remaining in care had an undetectable viral load less than 400 copies/ml, while about a quarter (23%) had a viral load that was detectable (viral load above 400 copies/ml). The results illustrate that the viral load suppression rate improved at 12 months, which is indicative that patients do not suppress earlier on care.

The profile of the patients that had a detectable viral load at 12 months showed that there were more females (54%) who were suppressed than males (46%), and the
results further showed that there was no difference in the age category of those who had suppressed in the study cohort. The viral load suppression rate was consistent with those reported in a study done by Gerretti et al (2008) where 77% of the sample achieved suppression (VL<400 copies/ml). To note is that similarly, this study was conducted during the era when patients were initiated with a baseline CD4 of <250 cells/mm3. This suggests that with good adherence, a high proportion of patients will have an undetectable viral load. With UTT, there should be higher proportions of viral load suppression than what has been observed in the current study. It is important to evaluate the adherence patterns of the almost 25% of the patients that did not suppress. Nevertheless, the viral load suppression in the current study is substantially higher than that of previous studies, e.g. in a study conducted by Moore et al. (2006) the viral load suppression occurred in 60% of the cohort. It might be challenging to compare the resource-limited settings of areas of Europe and those of African countries as the context and conditions might be very different. As stated the suppression rate seem to be even lower than the current study.

In the current study viral load suppression was lower than in a Ugandan study which reported a higher virologic suppression rate of 80% in individuals with CD4+ 250-350 and 90% in individuals with CD4+ <250 (Jain et al; 2014). As already stated, the study was an intervention prospective cohort study design with short follow-up visits conducted by a specifically allocated nurse.

The study findings are far off the mark of the triple 90 targets promulgated by the UNAIDS (2017) to be achieved by 2020. It requires that 90% of all PLHIV know their status, and that 90% of all people diagnosed with HIV receive sustained ART and that 90% of all people receiving ART have durable viral suppression and are retained on care (UNAIDS, 2017). An even more ambitious set of 95-95-95 targets is to be achieved by 2030, with the aim of substantially reducing HIV incidence and prevalence by then. The implications of the lower-than-target suppression rate jeopardise the attainment of the concept of treatment as prevention based on evidence showing that HIV transmission is strongly correlated with the viral load and that the risk of transmission is very low if the virus is undetectable (Hayes et al., 2017). This is the rationale for the recommendation of UTT approach as a preventive strategy to control HIV epidemics (Wagner et al, 2012).
On analysis the study found a negative linear relationship between viral load copies at 6 months and viral load copies/ml at 12 months ($p=0.022$). For every increase in number of months on treatment, the viral load copies decrease by 0.49 copies. Patients who remain in care after 6 months are more likely to be suppressed at month 12. This suggests that patients should remain in care and adhere to treatment for that length of time to achieve viral suppression. The viral load suppression could be attributed to the continuous adherence support provided to patients to understand the treatment, the side effects, and improve adherence to treatment. The main objective is to assure retention in care, thereby minimising treatment interruption.

### 5.6 RETENTION IN CARE
The study found that about two-thirds (59%) of the patients were retained on ART at 12 months. On further analyses, the results showed that similar to the CD4 count level, more females (58%) were retained in care as compared to males (42%). The mean CD4 count at baseline was 5-1129 cells/ml for the patients who were retained in care. Over a quarter (26%) of the patients initiated ART when their CD4 was very high (500-1411 cells/mm$^3$) and 78% were asymptomatic when they initiated ART.

Despite the fact that patients were much healthier, the current study retention in care rate is consistent with an earlier South African study conducted in the Eastern Cape. The study reported a retention rate of 71.5% at 12 months (Boyles et al, 2011). The estimates of retention in sub-Saharan Africa are varied and the estimated regional average at 12-month retention is 76% with range of 65-89% (Fox and Rosen 2010; Assefa et al, 2011; Wubshet et al; 2012, Brown et al, 2016). The current study’s rate of retention in care falls below the regional rate, despite the fact that the study cohort was initiated through UTT with patients with much higher CD4 counts, but could not outperform earlier studies conducted under different initiation protocols. For most studies the eligibility criteria was a CD4 count that is below 350 and 500. It is imperative that a thorough investigation be undertaken to identify the barriers to a high retention rate. Of great concern is that the current study retention in care rate also falls far short of the retention rate of 94% set by the South African National Strategic Plan (NSP) as a target for 12 months.
As mentioned, the current retention in care rate is relatively low and the concern is that when the retention rate is so low at 12 months during the era of UTT, then one queries what it will look like at 36 and 48 months. There is evidence that the retention in care rate naturally worsens with time rather improves. Thus the NSP target requires that retention in care should be the following: at 12 months – 94%; 24 months – 88%; 36 months – 82%; 48 months – 76%; and 60 months – 70%. This suggests that the retention in care has an allowance for patients to leave care along the way.

The results showed that CD4 count and gender were associated with retention in care. Patients with CD4 above 500 cells/mm3 had a 59% less chance of being retained in care as compared to those with CD4 count less than 500 cells/mm3 (OR=0.59; p 0.036; 95% CI: 0.37-0.97). Men had a 61% less chance of being retained in care than females (OR=0.61; p 0.003; 95% CI: 0.39-0.96). The results are consistent with findings by Brown et al. (2016) from a cluster-randomized controlled trial conducted in East Africa between 2013 and 2014. The study found that being male, having a higher CD4 count, and feeling healthier were associated with lower levels of retention in ART care. The implications of the results are that the patients who are initiated with a high CD4 count could affect retention in care under the UTT programme. The findings of the current study show that the levels of retention have worsened for patients initiated through UTT. Brown et al (2016) also found that a younger age, lower level of education, and occupation were associated with a lower retention rate. In the current study, due to the design where data was abstracted from files, the level of education and occupation status was not captured. As a result, we could not assess the association of educational level with retention in care.

5.7 LOST TO FOLLOW-UP

In the process of establishing retention in care, the study also determined those patients who were no longer in care. During analysis it was established that 153 of the patients were no longer in care and of those 103 (28%) patients were LTFU. The result further indicated that overall more women (68%) than males (31.7%) were lost to follow-up, although the difference was not statistically significant. This does not reflect the health-seeking behaviour of men and women, which suggests that men have poor health-seeking behaviour and do not necessarily adhere to treatment. The study evaluated the CD4 count levels of the patients who were LTFU and found that 30% of
patients that were lost to follow-up throughout the 12-month period had a CD4 that was above 500 cells/mm$^3$; and 19% had CD4 below 100 cells/mm$^3$. Of those that were lost to follow-up at 3 months after ART initiation, 33% had baseline CD4 above 500 cells/mm$^3$ and 22% had CD4 below 100 cells/mm$^3$. These findings are aligned to other studies where the patients in the highest CD4 cells count and those in the lowest CD4 100 cells/mm$^3$ were at higher risk of LTFU (Charurat et al, 2010). The results showed that a higher proportion of patients were lost to follow-up at three months after ART initiation than at 12 months.

The proportion of patients LTFU seems to be consistent with the findings of other studies that were done in sub-Saharan Africa. Miller et al (2010) found that 25% of the patients were no longer in care one year after initiation. This then implies that the rate that we found in the current study is slightly higher. In the analysis, increased risk of LTFU was associated with initiation through UTT. There was a significant association between LTFU and UTT. Patients that were initiated through UTT were twice more likely to be lost to follow-up than those initiated through the pre-ART (OR=1.75; p 0.022; 95% CI: 1.08-2.83).

A higher CD4 count seems to be a risk for both LTFU and retention in care. While patients with a higher CD4 count were less likely to be retained in ART care, the high proportion of patients with high CD4 were LTFU. The bimodal findings suggest that the risk associated with a higher CD4 group may be due to patients who considered themselves as healthy and not ready for lifelong ART, while those with lower CD4 might be suggestive of patients who were too sick to present for follow-up as directed by clinicians or had even died unbeknown to anyone (Assefa et al, 2011). The current study’s findings suggest that individuals with a high CD4 count lack motivation for ART and are at high risk of LFTU.

### 5.8 DEATH

Reported death in the current study cohort was very low; the death of only six patients was recorded officially in the files. The time of death ranged between months one and 10 after ART initiation. Five of the patients that died had a baseline CD4 count of less than 100 cells/mm3 while the other patient had a CD4 that was above 500 cells/mm3. Death as an attrition factor was reported in several studies as ranging from 6.5% to
16% at 12 months (Giordano et al, 2007; Charurat et al, 2010; Boyles et al, 2011; Wubshet et al, 2012). Our study recorded a much lower rate. However, similar to the current study, mortality was not regarded as a major reason for patient attrition in large ART programmes in developing countries (Fox et al 2010). This could be because it is difficult to ascertain death especially when it occurs at home. Moreover, the patients that were classified as LTFU might actually have died.

5.9 TRANSFER OUT
Transfer out is one of the attrition factors observed in the study. The study found that of the 153 patients who were no longer in care, 11% were transferred out during the 12 months. The current study result is almost triple those of other studies in sub-Saharan Africa with regard to the TFO rate. The reported rate of TFO at one and two years after ART initiation, ranges from 3.6 to 6.0% (Cornell et al, 2015; Nglazi et al, 2013). On the other hand, the study conducted in Malawi by Yu et al (2018) found that the transfer out rate was 19%, which exceeds the rate in the current study.

The result further indicated that overall more females (78%) than males (21.4%) transferred out; this could be attributed to the gender distribution of the study cohort as more women were initiated on ART than men were. However, the majority of the TFO are self- or silent-transfer out, as no reasons for TFO were documented in the patients’ files. The results imply that there is insufficient information about how patients transition between services and their outcomes after TFO. This is compounded by a limited capacity to keep track of and trace large numbers of patients enrolled for ongoing care. Wubshet et al (2012) argue that the assumption that those transferred out were retained in other health facilities may not hold true, as these patients may not be in care. If their argument is true this may suggest that retention in care on a global level could be worse than the figures documented. The current study shows a picture worse than that of other studies. Moreover, Ekurhuleni metropolitan where the study was conducted bears a highly mobile population and is situated on the borders of similar metros. This is likely to further compromise retention in care of patients on ART.

The risk factor for TFO was CD4 count; the study found a significant association between CD4 count and TFO. Patients with CD4 below 100 cells/mm$^3$ were less likely to transfer out (OR=0.44; p=0.002; 95% CI: 1.58-7.511), whereas those with CD4
above 500 cells/mm³ were three times more likely to transfer out (OR=3.17; p=0.003; 95% CI: 1.46-6.87). Once again, CD4 count has been identified as a risk factor for retention in care similar to other attrition factors that found an association between CD4 count and retention in care.

5.10 CONCLUSIONS

Over half of the patients were initiated ART through UTT and the majority were asymptomatic as expected since they were initiated immediately after testing regardless of the CD4 count. The study showed that patients still present for care very late with low CD4 count despite the evolution of ART guidelines that recommend patients are diagnosed and treated earlier before the disease is at an advanced stage.

The gender distribution of patients initiated on ART in this cohort was skewed. More women than men were initiated on ART at a higher proportion (64%) in this cohort. This appears to mimic findings from other cohorts in sub-Saharan Africa and may reflect gender differences in health-seeking behaviours that have been shown to affect most indicators like retention in care and viral load suppression rate.

The study found that viral load suppression improved between 6 and 12 months. The viral load suppression rate (undetectable viral load below 400 copies/ml) at 12 months was 77% compared to 51% at 6 months. Most patients do not suppress within the first six months but the viral load suppression rate improves with the duration of the patient in care. Patients who remain in care after 6 months were more likely to be suppressed at month 12. Therefore, with good adherence, a high proportion of patients could have an undetectable viral load if they remain in care. However, the viral load suppression rate was lower than the triple 90 targets which stipulate that 90% of people on ART should have viral suppression. With UTT, there should be higher proportions of viral load suppression than those observed in the current study because patients were initiated with higher CD4 counts.

The study found that the rate of retention in care rate was low as only two thirds (59%) of the patients were retained at 12 months. The retention in care rate is significantly below the NSP set target of 94% at 12 months. The two main attrition factors that led to the low retention in care rate were LTFU and TFO and to a lesser extent, death, as
only six patients were officially reported dead. The retention in care rate falls far short of the retention rate of 94% set by NSP as a target for 12 months as well as the triple 90 targets. Gender and a high CD4 count were significantly associated with lower chances of retention in care. The implication of the results is that retention in care under the UTT programme could be affected by patients who are initiated with a high CD4 count.

Lost to follow-up was the major attrition factor among patients in the study. This was attributed to the gender distribution in the study cohort. A higher proportion of patients were LFTU within three months after ART initiation, with more leaving immediately after initiation, than at 12 months. Furthermore, patients were LTFU regardless of the CD4 count. Patients with high CD4 were LTFU so were those with low CD4. Lost to follow-up was significantly associated with UTT; patients that were initiated through UTT were twice more likely to be LTFU. This explains the higher proportion of patients with high CD4 count being LTFU.

5.11 RECOMMENDATIONS
As mentioned, the expectations are that with UTT there should be higher proportions of viral load suppression than what has been observed when patients were initiated through previous protocols of lower CD4 counts. Therefore the low viral load suppression is a cause for concern and it is imperative that larger sample studies evaluate the adherence patterns of patients who do not suppress after being on ART for 12 months.

The retention in care rate falls far short of the set targets for South Africa and globally. It is crucial that a thorough investigation through empirical studies is undertaken to identify the barriers to a high retention rate. This could be by means of qualitative and quantitative studies that explore and investigate the factors that influence retention in care from the patients’ perspectives.

There are interventions that could be undertaken in the short term to increase the retention in care rates. For example, intensive counsellor-driven interventions should address adherence and other issues relating to retention in care and viral load suppression. The system for tracking patients who miss appointments should be
implemented earlier rather than later; the current programme for tracking patients only commenced at least two weeks or longer after the missed next follow-up visit.

There is a need to review the kind of information that is captured in the patient’s records. The completeness of patient demographic information is crucial in the profiling of patients that are likely to leave care prematurely or are at higher risk. Since an increasing number of patients are initiated through UTT, record review will continue being an important method for analysing retention in care and other factors. Therefore, it is important that health care facilities ensure the quality of patients’ records. This will assist the ART programme to be more proactive than reactive to challenges. The implementation of clinical guidelines on management of detectable viral load needs to be closely monitored especially for those patients that fail to suppress at six months.

5.12 LIMITATIONS OF THE STUDY

One of the key challenges of the study was the use of patients’ records to extract data. However, since one of the objectives was to measure lost to follow-up, this was the most appropriate study design. Nevertheless, during data extraction, the researcher learned that some of the records/files lacked accuracy and completeness. This may have led to the underestimation or overestimation of some outcome of interest because the demographic information was scantily presented in the files. For example, level of education could not be used to measure retention in care.

Death was ascertained by patient records but there is likelihood that deaths which could have occurred at home were missed because there was no mechanism for the deceased’s family members to report the death to the health facility. This may have led to the underestimation of the rate of mortality in the current cohort. The silent transfer out could have overestimated LTFU. A further limitation is the possible misclassification of outcomes where patients classified as LTFU may be silent TFO or dead or vice versa.
REFERENCES


District Health Information System (DHIS) report (October to December 2016), Ekurhuleni North sub-district.


https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/822/cd4-count

https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/1650/viral-suppression

CDC (2018) AIDS and Opportunistic Infections


Miller, C.M., Ketlhapile, M., Rybasack-Smith, H. & Rosen, S., 2010. Why are antiretroviral treatment patients lost to follow-up? A qualitative study from South Africa. Tropical Medicine & International Health, 15, pp.48-54.


ANNEXURE A: DATA EXTRACTION TOOL

Data extraction tool

Section 1 Demographic Information
Code: _______________________

1. Gender
   Female
   Male

2. Age in years
   _______________________

3. Is current partner Wife/husband
   Yes
   No

4. Marital status
   Single
   Married
   Divorced
   Widow

5. Race (standard)
   Black
   Coloured
   Indian
   Other

6. Source of income
   Employed
   Grant
   Pension
   Family or friend

7. Adherence sessions
   1 session
   2 sessions
   3 sessions

8. Disclosed
   Yes
   No
Section 2 CLINICAL INFORMATION

10. Year of diagnosis

11. ART start date - month and year.

12. Is there a lag between year of diagnosis and the ART start date

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<tbody>
<tr>
<td>Yes</td>
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<tr>
<td>No</td>
<td></td>
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</table>

13. How long is the lag period.

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<tbody>
<tr>
<td>Less than a month</td>
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<tr>
<td>Within 2 months</td>
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<tr>
<td>More than a month</td>
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</table>

14. The reason for the lag

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<tbody>
<tr>
<td>Was on Pre-ART programme</td>
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<tr>
<td>Was taking TB treatment</td>
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<tr>
<td>No documented reason</td>
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16. BMI

17. CD4 Count done at initiation

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<td>No</td>
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</table>

18. CD4 count results

19. CD4 count classification

<p>| | |</p>
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<tr>
<td>CD4 Below 500</td>
<td></td>
</tr>
<tr>
<td>CD4 above 500</td>
<td></td>
</tr>
</tbody>
</table>
20. WHO staging done at initiation
   Yes
   No

21. WHO staging
   Stage I
   Stage II
   Stage III
   Stage IV

22. What is the opportunistic disease?
   __________________________________________

23. Regimen on initiation
   __________________________________________

24. Any switching to other regimen
   Yes
   No

25. If yes at what month on ART.
   __________________________________________

26. The regimen
   __________________________________________

27. Was the viral load done?
   Yes
   No

28. The viral load results documentation
<table>
<thead>
<tr>
<th>Date test done</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

Section 3 ATTRITION FACTORS

29. Did the client visit the clinic in line with the follow-up dates as prescribed by the clinician?
   Yes
   No

30. How many times did the client visit the clinic in the period of 12 months?
    ___________________

31. Did the patient miss any appointment/s during the 12 months?
32. How many appointments were missed during the 12 months?

<table>
<thead>
<tr>
<th>Not applicable</th>
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<tbody>
<tr>
<td>Once</td>
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<tr>
<td>Twice</td>
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<tr>
<td>Thrice</td>
<td></td>
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<tr>
<td>More than thrice</td>
<td></td>
</tr>
</tbody>
</table>

33. What is the last visit date for treatment collection?

_____________________________

34. If the last visit date is older than a month on the day of data collection is there documentation of tracing.

<table>
<thead>
<tr>
<th>Yes</th>
<th></th>
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<tbody>
<tr>
<td>No</td>
<td></td>
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</table>

35. If yes, what is the reason for non-retention?

<table>
<thead>
<tr>
<th>Lost to Follow (LTF)</th>
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</thead>
<tbody>
<tr>
<td>Rest in Peace (RIP)</td>
<td></td>
</tr>
<tr>
<td>Transfer Out (TFO)</td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
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</table>
ANNEXURE B: PERMISSION LETTER

3 Nico Street
Birchleigh North
Kempton Park
1618
9 August 2017

Ekurhuleni Health District
Bertha Gxowa Hospital
Villa Heidi building
Germiston

Dear Sir/Madam

Re: Permission to conduct a study in Ekurhuleni North sub district health facilities

My name is Patricia Chauke I am currently enrolled for a Master of Public Health (MPH) Degree at the School of Public Health, Sefako Makgatho Health Science University. I would like to request permission to undertake a research in the Ekurhuleni North sub district as a requirement to submit a research report in partial fulfilment of my degree. The purpose of the study is to determine the retention in care rate and the viral load suppression rate of the patients initiated through Universal Test and Treat (UTT) programme in Ekurhuleni North facilities.

My study received ethical clearance as shown in the attached certificate from the Sefako Makgatho University Research Ethics Committee (SMUREC). I will observe all ethical considerations pertaining to obtaining permission from the facility managers, confidentiality and disclosure of potential risks and benefits during data collection. Your permission to conduct this study will be greatly appreciated.

Sincerely

Patricia Chauke
Student No: 201709926
Contact details: 0828523280
ANNEXURE C: SMUREC APPROVAL LETTER

Sefako Makgatho Health Sciences University
Research & Postgraduate Studies Directorate
Sefako Makgatho University Research Ethics Committee
(SMUREC)

Molotlegi Street, Ga-Rankuwa 0208
Tel: (012) 521 5617/3698 | fax: (012) 521 3749
Email: lorato.phiri@smu.ac.za
P.O. Box 163 Medunsna 0204

APPROVAL NOTICE - NEW APPLICATION

02 November 2017

Ms PP Chauke
Department of Public Health
P.O Box 215
Medunsna, 0004

MEETING: 09/2017

SMUREC Ethics Reference Number: SMURECH/296/2017: PG

The New Application received on 18 October 2017, was reviewed by members of Sefako Makgatho University Research Ethics Committee 02 November 2017 and was approved on 02 November 2017.

Title: Viral load suppression and retention in care amongst adult HIV positive patients at 12 months on antiretroviral treatment, initiated through the Universal Test and Treat Programme in the Ekurhuleni-North sub-district, Gauteng Province

Researcher: Ms PP Chauke
Supervisor: Mrs M Humma
Co-supervisor: Prof S Madiba
Department: Public Health
School: Health Care Sciences
Degree: MPH

Please note the following information about your approved research protocol:

Approval Period: 02 November 2017 – 02 November 2018

Please remember to use your protocol number (SMURECH/296/2017: PG) on any documents or correspondence with the REC concerning your research protocol.

Please note that the REC has the prerogative and authority to ask further questions, seek additional information, require further modification, or monitor the conduct of your research and the consent process.

After Ethical Review: Please note a template of the progress report is obtainable in the Research Office and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit. Translation of the consent document in the language applicable to the study participants should be submitted.

International Organisation (IORG00008691), Institutional Review Board (IRB000010388) Expiry date: 09 December 2018, Federal Wide Assurance (FWA000023043) Expiry date: 03 March 2021 and NHREC No: REC 210408-003

Sincerely

[Signature]

DRGP OSUNBANJO
CHAIRPERSON SMUREC
ANNEXURE D: EKURHULENI RESEARCH CLEARANCE CERTIFICATE

EKURHULENI RESEARCH CLEARANCE CERTIFICATE

Research Project Title: Viral load suppression and retention in care rate amongst adult HIV positive patients at 12 months on antiretroviral treatment, initiated through the Universal Test and Treat Programme in Ekurhuleni North sub-district, Gauteng Province.

NHRD No: GP_201802_011

Research Project Number: 08/03/2018-07

Name of Researcher(s): Ms Patricia Chauke

Division/Institution/Company: Sefako Makgatho Health Science University

DECISION TAKEN BY THE EKURHULENI HEALTH DISTRICT RESEARCH COMMITTEE (EHDRDC)

- THIS DOCUMENT CERTIFIES THAT THE ABOVE RESEARCH PROJECT HAS BEEN FULLY APPROVED BY THE EHDRDC. THE RESEARCHER(S) MAY THEREFORE COMMENCE WITH THE INTENDED RESEARCH PROJECT.

- NOTE THAT THE RESEARCHER WILL BE EXPECTED TO PRESENT THE RESEARCH FINDINGS OF THE PROPOSED RESEARCH PROJECT AT THE ANNUAL EKURHULENI RESEARCH CONFERENCE.

- THE RESEARCH COMMITTEE WISHES THE RESEARCHER(S) THE BEST OF SUCCESS.

DEPUTY CHAIRPERSON: EKURHULENI METROPOLITAN MUNICIPALITY
Dated: 08/03/2015

CHAIRPERSON: GAUTENG DEPARTMENT OF HEALTH (EKURHULENI REGION)
Dated: 08/03/2018