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Outcomes of the Antiretroviral Treatment Intervention in Mankweng



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WITS School of Governance

Thesis presented in partial fulfilment for the degree of Master of Management (in the field of Public Sector Monitoring and Evaluation) to the Faculty of Commerce, Law, and Management, University of the Witwatersrand

March 2016

DECLARATION

I declare that this thesis/dissertation titled 'Outcomes of the antiretroviral treatment intervention in Mankweng' is my own, unaided work. I have acknowledged and referenced all sources that I have used and quoted. I hereby submit it in partial fulfilment of the requirements of the degree of Master of Management (Public Sector Monitoring and Evaluation) at the University of the Witwatersrand, Johannesburg. I have not submitted this report before for any other degree or examination to any other institution.

Ramatsobane Ledwaba

Johannesburg, March 2016

Supervisor: Dr Kambidima Wotela

ABSTRACT

The purpose of this research was to assess outcomes of the antiretroviral treatment intervention in Mankweng. The antiretroviral treatment intervention was conceived with the aim to reduce HIV transmission through viral load suppression. Literature has shown that viral load is used as a tool to measure the performance of the intervention and studies on viral load outcomes in rural settings of Limpopo are limited. For this reason, the research was focused on viral load suppression with the aim of (1) determining the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months, and (2) identifying factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months.

Binomial logistic regression model was used to identify factors associated with failure to suppress viral load. This study used the theory of change to interpret its findings as well as theories of behavioural planning and self-regulation models to understand the logic that underpins the theory of change. The findings revealed that the majority (78%) of adults achieved viral load suppression, and a quarter of the individuals failed to suppress the viral load. There was no significant difference in baseline characteristics between people who achieved viral load suppression and those who did not. In addition, males, with a low CD4 and opportunistic illnesses when in the primary disease stages were more likely to fail to suppress the viral load. Moreover, people who were initiated on a 3-pill containing treatment and do not have social support were also likely to fail to achieve viral load suppression. Although the study showed a trend of likelihood towards failure to achieve viral load suppression, the estimates were not statistically significant.

Theoretical arguments from this study suggest that failure to achieve viral load was attributed to poor adherence to treatment. This is supported by the logic that underpins the theory of change, in which the assumption of adherence was possibly violated. However, the results chain framework highlighted that the implementation of the intervention was effective as it led to good outcomes and an effective intervention. Drawing all this together, the study highlights the need for intensified adherence counseling during treatment in order to improve the performance of the intervention.

Author: Ramatsobane Johanna Ledwaba, **Thesis Title:** Outcomes of the antiretroviral treatment intervention in Mankweng, Johannesburg, March 2016

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1 INTRODUCTION TO THE RESEARCH

1.1 Background

Before getting to the research problem statement (Section 1.2.1) and consequently the purpose of this research (Section 1.2.2) as well as the research questions (Section 1.2.3), this chapter briefly introduces the terms that are used in conceptualising the research. Section 1.1.1 introduces the prevalence of HIV in South Africa while describing what HIV is. Section 1.1.2 introduces but briefly the HIV antiretroviral treatment intervention, as well as its conception, implementation and outcomes. Section 1.3 introduces the study setting, Mankweng.

1.1.1 The global HIV burden

The Human Immunodeficiency Virus type 1 (HIV-1) originates from Chimpanzees living in tropical forests of Southern Cameroon (Zhu, Korber, Nahmias, Hooper, Sharp & Ho, 1998). HIV-1 is a major cause of Acquired Immune Deficiency Syndrome (AIDS), a disease that was first discovered in patients in the USA in 1981 (Sharp & Hahn, 2010). In South Africa, the first case of AIDS was recognised in 1982 from a white homosexual man who contracted the virus while in the USA (Ras, Simson, Anderson, Prozesky, & Hamersma, 1983). HIV cannot live outside the body, it is transmitted from person-to-person through unprotected sexual intercourse, sharing of contaminated injection and transmission from mother-to-child during pregnancy, delivery and breastfeeding (Cohen, Hellmann, Levy, DeCock, & Lange, 2008). When the person is infected with HIV, the immune system becomes weak (drop in CD4) making the person susceptible to opportunistic infections and resulting in death (Westley, Greene, Tarr, & Hawes, 2012).

Since its inception three decades ago, HIV is widespread across the globe. The explosion is driven mainly by factors such as, older men having sexual relation with young females (Drimie, 2002; Gregson, Nyamukapa, Garnett, Mason, Zhuwau, Caraël, Chandiwana & Anderson, 2002; Shisana, Rehle, Simbayi, Zuma, Jooste, Zungu, Labadarios *et al.*, 2014), commercial sex, migration, and multiple sexual partners (Drimie, 2002; Hanson & Hanson, 2008). HIV continues to be a global public health concern. By 2013, an estimated 36.9 million people were living with HIV, globally (UNAIDS, 2014). According to UNAIDS (2014) Sub-Saharan Africa remains the

epicentre of the HIV epidemic with an estimated 25.8 million people infected with HIV. Seventy-one per cent of global HIV infections are localised in Sub-Saharan Africa, with Southern Africa accounting for almost two-thirds of all people living with HIV/AIDS worldwide.

Within the Southern Africa region, South Africa has the largest number of people infected with HIV (6.4 million, 12.2%) (Shisana *et al*., 2014). The overall HIV prevalence differs by province. In 2012, Kwazulu-Natal province had the highest HIV prevalence (16.9 per cent), while Western Cape, Northern Cape and Limpopo had the lowest HIV prevalence; 5.0 per cent, 7.4 per cent and 9.2 per cent, respectively (Shisana *et al*., 2014).

1.1.2 The national antiretroviral treatment intervention

Prior to 1994, the National AIDS Convention of South Africa (NACOSA) developed a comprehensive and progressive AIDS plan in 1993 to curb the spread of HIV. The plan was adopted in 1994 by the newly elected democratic government (Nattrass, 2008). However, the lack of political will, authoritarian leadership, and bureaucracy constrains and lack of collaboration between activists and government hampered the implementation of the AIDS policy (Johnson, 2004). Despite all the impediments, at the end, South Africa established a comprehensive AIDS policy that included rolling out antiretroviral treatment to all eligible people in 2004 (Johnson, 2004).

Just to put everything into perspective, the antiretroviral treatment is a combination of three or more antiretroviral (ARV) drugs administered to fight HIV by suppressing the virus (viral load suppression) (World Health Organisation (WHO), n.d). The principal goal of antiretroviral treatment is to improve patient health outcomes and prolong life expectancy (Goldschmidt & Dong, 2000). In addition, antiretroviral treatment reduces the risk of mother-to-child transmission of HIV through viral load suppression (Townsend, Cortina-Borja, Peckham, de Ruiter, Lyall & Tookey, 2008). This AIDS policy was implemented using the National Strategic Plan (NSP). The current National Strategic Plan for HIV, TB and STIs 2012-2016 is a build up from the previous two NSPs (2000-2006 and 2007-2011), and its goal is to start 80 per cent of people living with HIV on antiretroviral treatment plan and have 70 per cent in care for 5 years post-initiation. Currently, South Africa has the largest and the most comprehensive antiretroviral treatment intervention worldwide, in which over 2 million people were on antiretroviral treatment by end of 2014 (Johnson, 2012; UNAIDS, 2014).

1.1.3 Mankweng

Mankweng is a semi-rural area found in Limpopo Province. It is situated in the Capricorn District 30 kilometres east of Polokwane city (City of Polokwane, n.d). Mankweng is made up of a township and six surrounding villages with an estimated population size of 33 738 in 2011 (Limpopo DoH, 2011). The area has a large tertiary hospital and a university. Therefore, it attracts a lot of qualified experts and a large population of students from afar (Report of the Portfolio Committee on Health, 2011).

The majority of HIV infected individuals in Mankweng receive care and treatment at a government funded facility, Phela-O-Phedise (POP) ARV clinic. The facility is located in Mankweng hospital (Info4Africa, n.d). It is the largest ARV treatment site in the Capricorn district with over 2 000 individuals on antiretroviral treatment. (Info4Africa, n.d).

1.2 Assessing outcomes of the antiretroviral treatment intervention in Mankweng

1.2.1 The research problem statement

Improvements on outcomes of the antiretroviral treatment intervention require linkage of HIV diagnosed individuals to care, initiation on antiretroviral treatment, retention in care and viral load suppression (WHO, 2015). Failure to closely monitor these stages may lead to poor outcomes of the intervention. In the HIV continuum of care, retention in care and viral load suppression are the most critical outcomes as they are aligned with the intervention's goal of improving individual's health outcomes, and reducing HIV transmission (Cheever, 2007). In the context of monitoring and evaluation, the two outcomes also play a major role of measuring performance of the intervention (WHO, 2015). Data from the United States have showed low viral load suppression rates in people who are not retained in care (Doshi, Milberg, Isenberg, Matthews, Malitz, Matosky *et al.*, 2014). This is concerning because viral load suppression plays a key role in improving individual's health and reducing HIV infections in a community (Cohen, Hellmann, Levy, DeCock & Lange, 2008). In South Africa, less encouraging viral load outcomes were previously reported (Fielding, Charalambous, Stenson, Pemba, Martin, Wood, Churchyard & Grant, 2008) and adherence to treatment was a major determinant of viral load suppression (Jobanputra, Parker, Azih, Okello, Maphalala, Kershberger *et al.*, 2015). Other key factors described

elsewhere that influence viral load suppression include HIV disease progression and baseline viral load (Cescon, Cooper, Chan, Palmer, Klein, Machouf, Loutfy *et al.*, 2011), loss to follow up (Saka, Landoh, Patassi, d'Almeida, Singo, Gessner & Pitché, 2014) and early retention (Mugavero, Amico, Westfall, Crane, Zinski, Willig, Dombrowski *et al.*, 2012). However, determinants of the viral load suppression have not been extensively studied in rural parts of South Africa. Therefore, evaluation of viral load suppression is conducted in order to improve performance of the intervention by informing the intervention manager of the suppression rates in the community (McMahon, Elliott, Bertagnolio, Kubiak, & Jordan, 2013) and to influence informed decision making for public health planning.

1.2.2 The research purpose statement

The purpose of this study is to assess the outcomes of antiretroviral treatment intervention in Mankweng. This was achieved by determining proportions of adults with viral load suppression among people who have been taking antiretroviral treatment for 12 months, and identifying factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months. First, we reviewed literature to identify the knowledge gap and the theoretical framework used to interpret research findings. Second, we constructed and presented a robust results chain showing the link between inputs, activities, outputs, outcomes, and impact of the intervention. Third, we proposed a theory of change to assess whether the achieved change was influenced by the intervention. Fourth, we proposed a research strategy, a research design, research procedure and methods appropriate to assess the outcomes of the antiretroviral treatment intervention in Mankweng. Fifth, we collected and analysed data. Lastly, based on the findings, we used the theory of change and results chain to determine if at all the antiretroviral treatment intervention has achieved the desired outcome. We also used a theoretical framework that drives the logic that underpins the theory of change.

1.2.3 The research questions

1. What is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months?

Hypothesis: There are high proportions of adults with viral load suppression among people taking antiretroviral treatment for 12 month.

2. What are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months?

Hypothesis: Multiple factors are associated with failure to achieve viral load suppression.

1.3 Delimitations of the research

Antiretroviral treatment outcomes include the two stages that form part of the HIV continuum of care, which is retention in care and viral load suppression (WHO, 2015). In addition, other scholars have focused on mortality as another outcome of the intervention (Braitstein, Brinkhof, Dabis, Schechter, Boulle, Miotti *et al.*, 2006; Fox & Rosen, 2010). Literature has shown that viral load can be used; (1) to map the HIV burden at population level (also known as community viral load) (Castel, Befus, Willis, Griffin, West, Harder & Greenberg, 2012); (2) as a tool to measure performance and assess the efficacy of the antiretroviral treatment intervention (Montaner, Lima, Barrios, Yip, Wood, Kerr, Shannon, Harrigan, Hogg & Daly, 2010); (3) to inform public health surveillance (Das, Chu, Santos, Scheer, Vittinghoff, McFarland, Colfax, *et al.*, 2010); and (4) as well as to measure fidelity of health care services (Ortega, Eiros, Labayru, Hernandez, Bou & de Lejarazu, 2003). For these reasons, this research's main focus is on the outcome viral load suppression. This study is situated in the field of monitoring and evaluation; however it is only delimited to evaluation.

1.4 Justification of the research

It is over a decade since the introduction of antiretroviral treatment intervention in South Africa, therefore it is necessary to start measuring progress towards outcomes and impact of the intervention. International evidence suggests that, community viral load suppression reduces HIV transmission (Das *et al.*, 2010). In a country with the largest number of HIV infections in the world, this evidence encourages researchers to closely monitor and evaluate viral load outcomes, as this will detect potential individuals who are likely to transmit the virus if they are not retained in care thus reducing the risk of HIV transmission. The South African government has adopted the new UNAIDS treatment 90-90-90 targets, aimed at ending the HIV epidemic by 2030. The strategy aims to ensure that by 2020, 90 per cent of individuals living with HIV know their status, 90 per cent of those eligible are initiated on antiretroviral treatment and 90 per cent of people on antiretroviral treatment will have viral load suppression. The progress report on the National Strategic Plan 2012-2016 documented an overall 75 per cent viral

load suppression rate from various cohort studies (SANAC, 2014). Therefore, it is paramount to continue to monitor and evaluate viral load outcomes to highlight the performance of the intervention.

1.5 Preface to the research report

To this end, the report has six chapters. Following this introductory Chapter 1, Chapter 2 sets out to achieve three objectives. First, to introduce HIV and its prevalence, detailing the national antiretroviral treatment intervention. Second, to develop a theoretical framework for interpreting the research findings. Lastly, to propose a conceptual framework that provides a roadmap on how the research is undertaken. Chapter 3 is set out to discuss and commit to a research strategy, design, procedure and methods. Lastly, the Chapter shares some reliability and validity measures as well as limitations of the research design. Chapter 4 is set out to describe and analyse the research data by discussing all the issues raised under the two research questions and a conclusion to the Chapter. Chapter 5 discusses the findings in chapter 4 using a theoretical framework proposed in Chapter 2. Finally, Chapter 6 presents the knowledge gained from undertaking this research. The chapter summarises and concludes the research as well as highlighting study limitations and recommendations.

2 LITERATURE REVIEW

This chapter reviews the literature centred upon the research topic. It starts with a short description of the research setting (Section 2.1). Section 2.2 reflects upon the research problem that necessitated the conceptualisation of this study by highlighting the root causes and consequences, the extent of the problem globally, regionally and locally. The section further discusses the antiretroviral treatment intervention, its conception, implementation and outcomes. In Section 2.3, we review literature on the purpose, methods, findings and conclusions from past and current studies that have performed similar evaluations focusing on factors associated with the intervention outcomes. The research draws attention to limitations found in the past and current studies. Section 2.4, discusses the broad field of monitoring and evaluation giving prominence to the focal component under review that is outcomes evaluation. To be able to measure the outcomes of the intervention, Section 2.5, describes the key variables that may play a major role in assessing evaluation outcomes. In section 2.6, we discuss a theoretical framework that this study is founded upon. The last section 2.7, provides a roadmap on how the activities of this research will be performed to answer its two research questions: "what is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months and what are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months?"

2.1 Introduction to the Capricorn District in Limpopo Province

This section sought to describe thinly the population of Capricorn District and its socio-economic status (Section 2.1.1). In Section 2.1.2, the research focuses on the demography, and economic profile, and access to health care services in Polokwane sub-district paying more attention to the study setting Mankweng.

2.1.1 Demography and socio-economic profile

Capricorn District is located in the central part of Limpopo Province (Capricorn District Municipality, 2013). According to Capricorn District Municipality (2012), the district occupies a surface area of 21 705 kilometers^2 with an estimated population size of 1 261 463. The population is still young as the majority of the people are aged below 30 years. Capricorn district has the most educated population in the province with only 13 per cent of individuals aged 20 and above without formal education. Despite the

district having the third largest economy in the province, there is a high rate of unemployment (37.2 per cent) especially among the youth (47.4 per cent).

Figure 1 shows the district demarcations of Limpopo province after the apartheid regime. In 1996, the new South African constitution set a vision of local government to provide an equitable and effective public service delivery. It went on to draw district and sub-district boundaries. The Capricorn District is located at the centre of the province divided into five sub-districts, namely Aganang, Blouberg, Lepelle-Nkumpi, Molemole and Polokwane in the Capricorn District. The study setting, Mankweng is situated in Polokwane local municipality, 30 kilometers east of Polokwane city centre.



Figure 1: Five local municipalities within the Capricorn District

(Source: local government.co.za)

2.1.2 Polokwane sub-district

Demography and socio-economic status

Polokwane local municipality is located within the Capricorn district with an estimated population of 642 183 occupying three per cent of the total surface area of the province (Polokwane municipality, 2014). The Polokwane Municipality (2014) reported that this sub-district is predominantly comprised of Sepedi speaking black Africans followed by Afrikaans and English speaking whites, then coloureds and Indians (Polokwane local municipality annual report 2013-2014). The report highlighted that the sub-district serves as the economic hub of the province. It consists of 38 wards with a large population living in rural (71 per cent) or semi-urban areas, which for most part is under developed. The community service sector, comprised of local economic development, infrastructure and community upliftment projects, is the main contributor (32.1 per cent) towards the province's economy followed by the finance sector (21.5 per cent). By end of 2012, unemployment rates decreased from 19 per cent in 2009 to 16 per cent.

Access to health care

The DoH annual performance plan (2011), explicitly reported that health care service delivery in the Polokwane sub-district is provided via three regional hospitals, of which, two of them function as tertiary hospitals that form the Polokwane-Mankweng Hospital Complex. In addition, the complex is supported by one district hospital, Seshego Hospital, and one primary health care facility. In addition, there are over 40 primary health care clinics networked with all the three hospitals that send referrals to either of the hospitals.

2.1.2.1 Mankweng

Mankweng is a rural area situated 30 kilometres east of Polokwane (Limpopo DoH, 2011). In 2011, it had an estimated population size of 33 738. It is made up of a township surrounded by six villages, namely, Dikgale, Mamabolo, Mamabolo-Segopje, Molepo, Mothiba, and Mothapo (Limpopo DoH, 2011). The area has a large tertiary hospital and a university; it therefore attracts a lot of qualified experts (Limpopo DoH, 2011). The university and the hospital offer employment to its residents as well.

HIV infected individuals in the area receive care and treatment at a government funded facility, Phela-O-Phedise ARV clinic, which is located in the hospital. It is the largest HIV treatment site in the district with over 2 000 patients on antiretroviral treatment.

2.2 The history and description of Human Immunodeficiency Virus – 1 (HIV) epidemic and interventions

Here, the research undertakes a research problem analysis to understand the history and description of the HIV epidemic and interventions. Section 2.2.1 defines the origin of HIV and how it is spread. In this section, the study highlights the epidemiology of HIV; globally, in the Sub-Saharan region focusing on South Africa. The section also highlights the root causes and consequences of HIV. Section 2.2.2 discusses the antiretroviral treatment intervention initiated to curb the spread of HIV, focusing on the development of the AIDS policy, its implementation and outcomes. Section 2.3 reviews previous and current studies that have conducted similar research, focussed on the purpose, theoretical frameworks, methods, analysis, results and conclusions.

2.2.1 The global HIV epidemic

Human immunodeficiency virus (HIV) causes acquired immunodeficiency syndrome (AIDS), a disease of the human immune system (Sharp & Hahn, 2010). HIV is a contagious illness transmitted through coitus, mother-to-child during pregnancy, delivery and breastfeeding and through blood transfusions (Cohen *et al*., 2008). AIDS was first discovered in 1981 in the United States of America among men who have sex with men, and later HIV was identified (Sharp & Hahn, 2010). In South Africa, the first HIV case was identified in a homosexual man who travelled to the United States of America in 1982 and was diagnosed HIV positive upon his return (Ras, Simson, Anderson, Prozesky & Hamersma, 1983).

HIV is widespread to all parts of the world causing suffering to human beings. By end of 2014, there were an estimated 36.9 million people living with HIV, globally, of whom 2 million became newly infected with HIV down from 3.1 million in 2000 (UNAIDS, 2014). Over 1 million people died of AIDS-related illnesses in 2014, a decrease by 2 million from 2005 (UNAIDS, 2014). In view of the alarming HIV statistics, there is evidence of disparities in the number of HIV infections in the world, in particular Africa. Sub-Saharan Africa bears the brunt of the HIV disease with 79 per cent (25.8 million) of global infections concentrated in this region, while two-thirds of the infections are localised in Southern Africa. Among 79 per cent infections in Sub-Saharan Africa, 48 per cent are women and 5.4 per cent are children UNAIDS (2014). In the same year, 790 000 people died of AIDS-related causes in Sub-Saharan Africa, a fall by 48 per cent compared to 2004.

In South Africa, by end of 2013, there were 6.4 million people living with HIV — making South Africa a country with the largest number of people infected with HIV compared to the world (Shisana *et al.*, 2014). In 2012, an overall HIV prevalence of 29.5 per cent among pregnant women attending antenatal clinics was recorded (DoH, 2013) and 16.9 per cent of HIV prevalence was observed in the population. Figure 2 illustrates the 2012 HIV prevalence aggregated by province. The Kwazulu-Natal province had the highest HIV prevalence (16.9%) (Shisana *et al.*, 2014) while Western Cape, Northern Cape and Limpopo remain the lowest provinces affected by HIV. Limpopo has remained in the low end of HIV prevalence ranking since 2010. This trend demonstrates stabilisation of the HIV epidemic in the northern part of the country.

Figure 2 illustrates the HIV prevalence by province. The findings are from the national HIV incidence survey. Kwazulu-Natal is the most affected province, and Western Cape, Northern Cape and Limpopo have the lowest HIV prevalence.

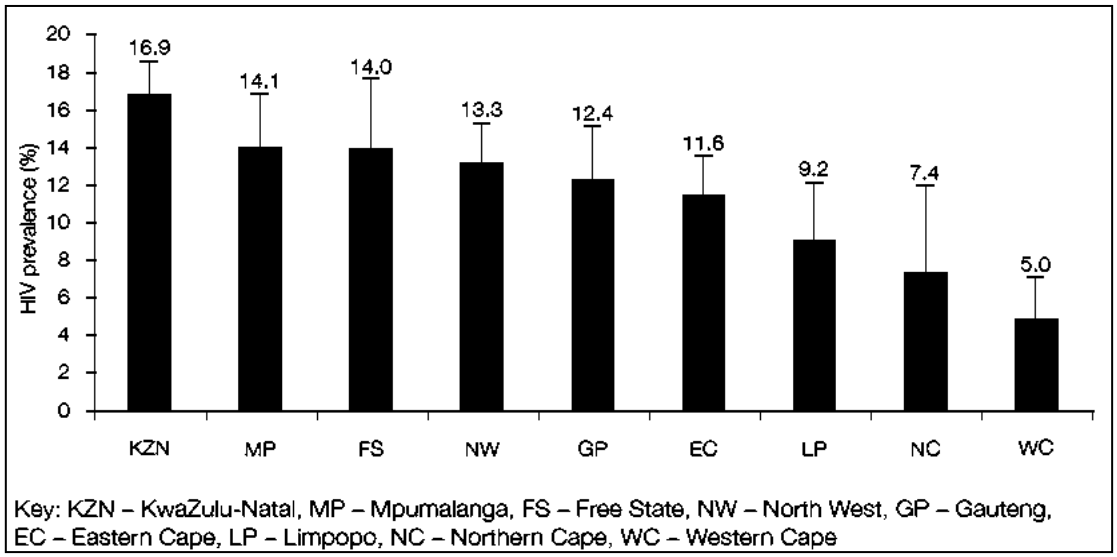


Figure 2: Overall HIV prevalence in South Africa in 2012

(Source: Shisana *et al*, 2014)

Across all the provinces, HIV prevalence is at its highest peak in young aged population of 15 to 34 years, in particular female adolescents aged 15 to 19 years (DoH, 2013). This is corroborated by the findings from the national HIV prevalence, incidence and behaviour survey (Shisana *et al.*, 2014). Literature also reported that young women are more likely to acquire HIV infection compared to young men, also female adolescents in relationship with older men have a greater chance of being infected with HIV (Pettifor, Rees, Kleinschmidt, Steffenson, MacPhail, Hlongwa-Madikizela *et al.*, 2005).

2.2.1.1 Root causes and consequences of HIV

A growing body of evidence purport that HIV is mainly a behavioural disease subject to environmental influence by factors that potentially drive the widespread of HIV in the region (Drimie, 2002). Through literature review, we found that the following symptoms authenticate challenges faced by HIV interventions. Such symptoms included female adolescence engaging in sex with older men who are more likely to be infected with HIV compared to young men in exchange of basic necessities (Drimie, 2002; Gregson et al., 2002; Shisana *et al*., 2014), commercial sex, migration, and multiple sexual partners that create sexual networks among communities further advancing the spread of HIV (Drimie, 2002; Hanson & Hanson, 2008). Another critical driver of HIV infections is gender imbalance, which leaves women vulnerable to HIV because they fail to negotiate safe sex as men refuse to use condoms (Langen, 2007).

Existing literature has shown challenges associated with HIV interventions. However, it is critical that HIV interventions move beyond exclusively targeting the so-called risky behaviours of the key populations to also address the root causes of the symptoms that make HIV interventions impossible (Drimie, 2002). Studies have shown that poverty and inequality are the main root causes of vulnerability to HIV infections (Mbirimtengerenji, 2007; Parkhurst, 2010). A number of authors have suggested that poverty can increase susceptibility to HIV infection through commercial sex, inferior health care, increased labour migration and the associated risk of having multiple partners (Drimie, 2002; Mbirimtengerenji, 2007; Parkhurst, 2010). Drimie (2002) further argued that poor people living with HIV are susceptible to illnesses and experience early mortality than wealthy people due to malnutrition, poor health and lack of access to health care and medication. Moreover, different scholars appear to agree that, perhaps as a consequence of poverty from their own households, young women engage in sexual activities with older men in exchange of basic necessities (Drimie, 2002; Mbirimtengerenji, 2007; Parkhurst, 2010).

On the other hand, Ghanotakis, Peacock, & Wilcher (2012) suggested that gender inequality influence vulnerability to HIV infection in women and girls. This was further explained by Ansari (2012) who observed that gender inequality manifests violence, stigma and discrimination against women, wherein women have no power over men to negotiate safe sex. The author further argued that stigma is another risk factor that potentially influences personal decision regarding HIV testing and disclosure. Similarly,

Magadi (2011) found that socioeconomically disadvantaged groups are most affected by HIV/AIDS. Similarly, a study conducted in the United States found that residential segregation, education and immigration are among the structural conditions that explain HIV/AIDS disparities among black communities (Denning & DiNenno, 2010). Therefore, poverty reduction and elimination of structural inequalities are key targets for improving efficacy of HIV interventions.

Despite all the sufferings caused by HIV globally, the other negative consequence of HIV/AIDS in Africa is the slowing down and to some extent reversal of social and economic development (Taraphdar, Chatterjee, Dasgupta, Saha & Mallik *et al*., 2011). An impact evaluation by Drimie (2002) indicated that HIV and AIDS-related mortality have disproportionately affected women and children due to gender inequality and mother-to-child transmissions, respectively. One important indicator of the impact of HIV/AIDS is the increased dependency ratio among children and the elders (>60 years). The increased child dependency ratio is a consequence of AIDS-related deaths among young adults, giving rise to the number of orphans that ultimately led to the rise in child-headed households. Furthermore, as a result of the epidemic, the public sector health systems are significantly overwhelmed due to increased demand of health services (Drimie, 2002; Kaul, Makadzange, & Rowland-Jones, 2000). According to Drimie (2002), the effects of HIV/AIDS towards the economic development include shortage of labour force and lower productivity due to absenteeism and illness. Economic consequences of HIV suggest that the economic growth will decline because funds will be shifted away from savings to cover the costs of illness (Drimie, 2002).

In summary, South Africa remains the epicentre of the HIV epidemic with young women being the most affected population. Risky sexual behaviours influence HIV transmission creating obstacles towards HIV interventions, and further hampering efforts to cope with the impact of the epidemic. Regrettably, HIV has left crippling economies and orphaned children in many African countries. Ultimately, Africa has to develop interventions that will recognise culture norms and traditions and to also address the predictors of poverty as to maximally fight the scourge of HIV.

2.2.2 The antiretroviral treatment (ART) intervention

In response to the HIV epidemic, HIV interventions focused on prevention, diagnosis and treatment were initiated (Drimie, 2002). These were labelled as priority

interventions by the World Health Organisation as they offer a comprehensive response to the HIV epidemic (WHO, 2010).

Although the South African apartheid government did very little to curb HIV, the new democratic government lacked the political will to promptly respond and develop an HIV/AIDS policy —this delay contributed towards the massive HIV explosion (Nunn, Dickman, Nattrass, Cornwall, & Gruskin, 2012). It was only with the help of AIDS activists that South Africa made significant progress towards HIV/AIDS policy (Nunn, Dickman, Nattrass, Cornwall & Gruskin, 2012). In the end, the National AIDS Convention of South Africa's (NACOSA) AIDS Plan from 1993 was the first credible response to the HIV epidemic and it was first adopted by the newly elected democratic government in 1994 (Westley, Greene, Tarr & Hawes, 2012).

After a long contestation of the AIDS policy between the government and AIDS activists the government finally introduced the HIV and AIDS Comprehensive Care, Management, and Treatment (CCMT) Plan in 2004 with a "goal to provide comprehensive care and treatment for people living with HIV and AIDS and to facilitate the strengthening of the national health system in South Africa" (DoH, 2003, p. 24). The adoption of HIV and AIDS Care, management and treatment plan led to the development of the National Strategic Plan 2007-2011 that promoted access to antiretroviral treatment and reduction of HIV infections by half (Nattrass, 2008). The National Strategic Plan was developed to fast track implementation of the AIDS policy. The established CCMT plan was accompanied by a vertical monitoring and evaluation system to monitor the programme (Kawonga, Blaauw, & Fonn, 2012; DoH, 2004).

UNAIDS (2014) estimated that 2.8 million of South Africans were accessing antiretroviral treatment by end of 2013, which makes South Africa's antiretroviral treatment intervention the largest in the world. Recently, the HIV continuum of care has become a key component of monitoring and evaluation of the antiretroviral treatment intervention, with emphasis on evaluation of linkage into care, retention of patients throughout the continuum and achievement of viral load suppression as outcomes of the intervention (Cheever, 2007). Viral load suppression can also be used as a measuring tool to improve performance of the intervention (McMahon, Elliott, Bertagnolio, Kubiak & Jordan, 2013).

2.3 Methods, data, findings, and conclusions of studies and evaluations on outcomes of the antiretroviral treatment intervention

This section reviews the methods, findings and conclusions from studies that were conducted in South Africa and elsewhere on outcomes of the antiretroviral treatment intervention. The section will also draw on limitations of the studies and highlighting the knowledge gap for this research. The section will first summarise studies that have focused on the viral load suppression, followed by mortality then retention and loss to follow up as outcomes of the antiretroviral treatment intervention.

Fielding *et al.* (2008) reported risk factors for sub-optimal viral load outcomes at 12 months among HIV-infected adults receiving antiretroviral treatment in a workplace-based HIV care programme in South Africa. Data was extracted from an electronic database. This study was a quantitative study using a cross-sectional design. The study was conducted from 1 July 2004 to 31 March 2006. Determination of risk factors associated to suboptimal viral load suppression was done using a logistic regression model. The analysis revealed that close to three-quarters of patients achieved viral load suppression (<400 copies/ml) at 12 months. A multivariate analysis demonstrated that ten times decrease in viral load at six weeks was the strongest predictor for sub-optimal viral load suppression at 12 months. In addition, site of treatment delivery had a significant influence on viral load outcomes. High baseline viral load and advanced HIV progression were risk factors for suboptimal viral load suppression at 12 months. In conclusion, the above findings suggest further probing on factors influencing outcomes at health facilities to guide development of effective antiretroviral treatment interventions.

Another study by Nachega, Hislop, Nguyen, Dowdy, Chaisson, Regensberg, Cotton & Maartens (2009) compared adherence and viral load outcomes in infected adolescents and adults enrolled in a large private sector HIV management program in Southern Africa. It was quantitative research strategy using cross-sectional design. The study evaluated records of HIV infected adults and infected adolescents who initiated antiretroviral treatment between January 1999 and August 2006. Viral load suppression at each time point was used as dependent variable in a log-liner model, with adolescent status as an independent variable. Both univariate and multivariate analysis were performed. Regarding missing data, the imputation by chained equations (ICE)

technique was employed in fewer than four per cent of adults and fewer than 10 per cent of adolescents. Cox proportional hazards model was utilised to evaluate the association between adolescent status and the time from viral load suppression to viral load rebound. A two-tailed p-value of <0.05 was considered statically significant. Fisher's exact test and the Wilcoxon rank-sum test were employed to compare binary and continuous variables, respectively.

Fewer adolescents achieved 100 per cent adherence at each time point compared to adults (adolescents: 20.7 per cent at 6 months, 14.3 per cent at 12 months, 6.6 per cent at 24 months; adults: 40.5 per cent, 27.9 per cent, and 20.6 per cent at each time point, respectively; p<0.01). Patients who achieved optimal adherence were more likely to suppress the virus at 12 months, regardless of age. In addition, adolescents who achieved viral load suppression had a shorter time to viral rebound (adjusted hazard ratio 2.03; 95 per cent CI 1.31–3.13; p<0.003) compared to adults. The authors concluded that HIV-infected adolescents and young adults on antiretroviral treatment in Southern Africa have poorer adherence rates, low rates of viral load suppression, and high rate of viral load rebound after initial suppression than their adult counterparts. Limitations noted for the study were small sample size among the adolescents and failure to explore reasons for non-adherence.

Cescon, Cooper, Chan, Palmer, Klein, Machouf, Loutfy, Raboud, Rachlis &Cescon, Cooper, Chan, Palmer, Klein, Machouf, Loutfy, Raboud, Rachlis & Ding *et al* [OBJ]sought to probe time to viral load suppression and also identify factors associated with viral load suppression among individuals receiving antiretroviral treatment in Canada. This was a quantitative study conducted using cross-sectional design. Data was extracted from medical files of patients who initiated treatment on or after 1 January 2000 and had their last viral load test prior 31 December 2008; however data was only collected from March 2008. The primary outcome measure was attainment of viral load suppression defined as viral load below 50 copies/ml. Categorical variables were compared between groups using Pearson X^2 test or Fisher exact test while continuous variables were compared using Wilcoxon rank-sum test. Time to viral load suppression was analysed using Kaplan-Meier methods, and stratified life table were used to compare to suppression by drug class of initial therapy. The effects of covariant of time on viral load suppression were assessed using piecewise survival exponential models. Multivariate analysis was done to assess factors associated with viral load suppression.

Statistical significance was recognised by a two-sided p-value below 0.05. Cescon *et al* found the median time to suppression to be 4.55 months. Male patients of older age receiving treatment in Ontario, who had no history of injectable drug use, who were diagnosed with AIDS at initiation were most likely to suppress. Similarly, patients who had low baseline viral load were also likely to suppress. The study had three limitations. First, it is failure to generalise findings to entire Canadian HIV positive population. Second, there was a high chance of patient selection and clinic based selection bias. Lastly, there was missing data at some of the sites.

Another study by Jobanputra, Parker, Azih, Okello, Maphalala, Kershberger, Khogali, Lujan, Antierens, Teck *et al*., (2015) investigated factors associated with detectable viral load, and viral re-suppression after enhanced adherence counselling in adults and children on ART in Swaziland. In addition, the authors sought to establish whether adherence counselling is associated with viral load suppression amongst patients who previously had detectable viral load. This was a quantitative study that used a cross-sectional design. Data was extracted from laboratory records of patients who underwent viral load testing from 1st October 2012 to 31st March 2013. The study measured viral load suppression as outcome. Pearson's Chi Square test was employed to compare categorical variables while Kruskal-Wallis test was used to compare medians for continuous variables. A multivariate and bivariate logistic regression model was performed to assess factors associated with viral load suppression. Bivariate analysis revealed that being a child, longer time on antiretroviral treatment, WHO clinical stage 3 and 4, and recent CD4 count fewer than 350 cells/mm^3 were significant predictors for viral load detectability. Patients who had a detectable viral load at six months were more likely to re-suppress than those who underwent annual viral load monitoring. The multivariate model demonstrated that being a child, having an initial viral load between 1000 and 50, 000 copies/ml and recent CD4+ count below 350 cells/mm^3 were factors associated with virologic failure. Patients with high viral load who received adherence counselling were more likely to re-suppress than those who did not receive counselling. Issues such as data quality and missing data limited the study.

Elul, Basinga, Nuwagaba-Biribonwoha, Saito, Horowitz, Nash, Mugabo, Mugisha, Rugigana & Nkunda (2013) conducted a study to determine predictors of optimal adherence and viral load suppression among patients receiving antiretroviral treatment in Rwanda. The researchers employed a quantitative research strategy. Data was

collected using chart abstraction, patient face-to-face interviews and site assessment from September 2008 to April 2009. Stratified multi-stage sampling was employed, with treatment sites as clusters and further stratified into six strata according to type of facility (public or faith based) and duration of antiretroviral treatment (6, 12 and 18 months). Initial sampling included random selection of 14 public and 6 faith-based sites from 113 sites. During the second stage of sampling, patient registers and charts at selected sites were utilised to develop a sampling frame of all eligible patients in each strata. Potential participants were chosen from site-specific sampling frame using simple random sampling. Individual records were reviewed for each potential participant selected using random sampling to confirm that they met the study eligibility criteria.

Descriptive statistics was employed to describe study sites and patient characteristics by time since the start of antiretroviral treatment. Logistic regression analysis was utilised to identify patient and site level characteristics associated with two of the outcomes: sub-optimal 30-day adherence and detectable viral load. Of 837 patients who received viral load test 83% achieved viral load suppression. Regression models revealed that being on antiretroviral treatment for 18 months (versus 6 months), younger age, severe side effects in the prior 30 days (versus no or few), missing CD4+ cell count at antiretroviral treatment initiation (versus having a CD4 cell count of 200 cells/ml), alcohol use, attending sites that initiated antiretroviral treatment services in 2003-2004 and 2005, and sites with peer educators were more likely to have sub-optimal 30-day adherence. While participation in association for HIV-infected people, and receiving care at sites that conduct home visits were associated with lower odds of having non-adherence, and being female and using a reminder tool were associated with lower odds of high viral load. The authors observed high levels of optimal adherence and viral suppression in the Rwandan antiretroviral treatment intervention. The study prohibits the researchers from ruling out reverse causality due to the cross-sectional design used.

Doshi *et al.* (2014) conducted a quantitative study assessing proportion of clients at critical stages of the HIV continuum of care and further examining factors associated with achieving retention in care and viral load suppression. The study employed a longitudinal design. Primary outcome variables were defined as retention in care and viral load suppression. Odds ratios and frequencies were calculated for outcome of each predictor variable. In 2011, over 500 000 clients sought health care services at an insurance-funded facility in the United States. Of these, 62 per cent attended at least one

medical visit. Of these, 82 per cent were retained in care, and 72 per cent achieved viral load suppression. Viral load suppression was higher among retained clients versus clients who were not retained. Low levels of retention and viral suppressions were among youth and young adults (13-34 years). A critical shortcoming for the study was missing data for viral load values.

Another study by Fox *et al.* (2012) assessed antiretroviral treatment outcomes over seven years at an urban clinic in South Africa. This was a quantitative study that utilised a cross-sectional design, in which data was collected from April 2004 to March 2010. Data was retrieved from an electronic patient management system. About 90 per cent of patients on antiretroviral treatment achieved viral load suppression at 6 month and beyond. Much of the poor outcomes happened in the first year of treatment. The proportion of those who died within the first year on treatment was under 11 per cent at all calendar years, while the proportion lost by one year increased from 3.4 per cent in 2004 to 12.1 per cent in 2009. The authors estimated that 25 per cent of patients were lost to follow up and 16 per cent died after seven years on antiretroviral treatment. The overall mortality rate was 3.51 per 100 person-year. Summarily, most patients suppressed the virus, and 76 per cent were retained in care after a year on treatment. One-year mortality was below 11 per cent. After the first 12 months on treatment, monthly rates of death and loss decreased significantly and remained unchanged. The study experienced three shortcomings, first was missing data, second was misclassification of death and lastly, one clinic was not generalizable to all settings.

Budgell, Maskew, Long, Sanne, & Fox (2015) conducted a study comparing death in patients who are retained in care and lost after the start of treatment and further assessed the sensitivity of estimates different definitions of loss to follow up. This was a quantitative study conducted using a cross-sectional design; in which data was prospectively collected among HIV-infected patients enrolled for antiretroviral treatment between April 2004 and May 2012. The primary outcome variable was mortality, defined as death either in care or lost after the start of treatment. The authors aggregated baseline clinical information and mortality by in care status. Further, mortality rate in care and lost was assessed with matching death rate differences attributable risk (AR %) with 95 per cent confidence interval. The cox proportional hazard models were employed to determine the relationship between in care status and all-cause mortality. Model analysis revealed that 14.6 per cent of patients who have died

and being lost accounted for fewer proportions of deaths across multiple stages of loss to follow up. Even though, mortality rates in patients lost to follow up were superior to patients in care, most antiretroviral treatment -associated deaths occurred while on treatment. The drawbacks to this study were the misclassification of lost to follow up and non-differential misclassification of death.

Wandeler, Keiser, Pfeiffer, Pestilli, Fritz, Labhardt, Mbofana, *et al.* (2012) evaluated outcomes of antiretroviral treatment intervention in rural settings of Southern Africa. The study was conducted to examine the significance of no loss to follow up, mortality and loss to follow up over three years on antiretroviral treatment in Zimbabwe, Mozambique and Lesotho. Data was retrieved from an electronic database between January 2005 and June 2010. The three outcome variables assessed were no loss to follow up after antiretroviral treatment initiation, loss to follow up (attrition) and death. Logistic regression model was used to determine factors associated with no loss to follow up after antiretroviral treatment initiation, no returning to facility after the start of antiretroviral treatment and further competing models were used to analyse loss to follow up and death. The analysis revealed high rates of mortality in loss to follow up. Young age and male gender were associated with the likelihood of no loss to follow up. Limitations identified in this study were biasness towards mortality rates and missing data.

A quantitative study by Fatti, Grimwood, & Bock (2010) was conducted using a cross-sectional design to relate baseline information and treatment outcomes between individuals who seek care and treatment at different levels in the health system. Data was collected between December 2001 and December 2007 at 59 health facilities in both urban and rural areas of South Africa. The outcome variables assessed were death, lost to follow up and viral load suppression. The Kaplan-Meier estimates, competing risks cox and logistic regression models were employed to compare death, loss to follow up and viral load suppression between primary health centre, district and regional hospitals. The authors found that patients receiving care at the primary health centre were very ill at the start of antiretroviral treatment. Retention in care was high at primary health centres, followed by district then regional hospitals. Loss to follow up was independently high at regional hospital, and mortality was also independently high at district hospital compared to primary health centre after 12 months on antiretroviral treatment. To sum up, antiretroviral treatment outcomes were superior at primary health

clinic facilities despite primary health clinic having more advanced clinical stage diseases when starting antiretroviral treatment.

Nguyen, Do, Shiraishi, Le, Tran, Nguyen Medland *et al.* (2013) and colleagues conducted an evaluation study in Vietnam aimed to examine programmatic outcomes of HIV infected adults who are on antiretroviral treatment and factors associated with the outcomes. The evaluation used a cross-sectional design as data was abstracted from medical records of patients who initiated antiretroviral treatment between 2005 and 2009. Retention proportions were calculated using stratified Kaplan Meier. Key factors associated with attrition were assessed using cox proportional hazards model. There was good retention of patients in the programme, further; other factors such as advanced disease stage, being male, low CD4 count were associated with attrition. The limitations for the study were missing data and failure to explore reasons for loss to follow up or cause of death.

Another retrospective cross-sectional study by Saka *et al.* (2014) sought to determine factors associated with attrition was conducted in Togo. Data was abstracted from medical records of HIV-infected individuals on antiretroviral treatment who were lost to follow up between January 2008 and October 2011. The primary outcome variable was loss to follow up at six months or less compared to loss to follow up greater than six months. Medians and interquartile ranges were reported for continuous variables while proportions and respective 95 per cent confidence interval were reported for categorical variables. Multivariate logistic regression analysis was performed to determine risk factors for outcome loss to follow up or not lost to follow up. The multivariate analysis revealed age below 35 years, female sex, advanced HIV disease, presence of opportunistic infection as factors associated with early loss to follow up and confirmed high mortality in these patients. Predictors of early loss to follow up were age below 35 years, presence of opportunistic infections at the start of antiretroviral treatment, living in rural area and receiving HIV treatment at public health system. Summarily, loss to follow up precedes advanced disease stage then death, explicitly among women and young adults.

A quantitative study by Huang, Tan, Ma, Zheng, Lu, Wang *et al.* (2015) aimed to evaluate antiretroviral treatment outcomes in China. This study was conducted between 2003 and 2014. Huang and colleagues used Chi-Squared test-to-test categorical variables while Mann-Whitney was used for interval data. Survival rates were tested using Log

rank test, while the Cox model was used to assess possible risk factors. Eighteen per cent of the patients had a detectable viral load. In addition, baseline viral load, clinical stage IV were significantly associated with failure to suppress viral load. The strongest risk factor low CD4 count and clinical stage IV. Patients who were on treatment for long (10 years) maintained viral load suppression and low mortality.

Another study by Syed, Sulaiman, Hassali, Syed, Shan & Lee (2015) sought to determine factors associated with poor viral load and immunological outcomes in Malaysia. Syed and colleagues employed a quantitative strategy and a cross-sectional design to answer their research questions. The study was conducted between July and October 2012. Data was sourced using face-to-face interviews and extraction of information from patient medical records to a questionnaire. Chi-squared test was employed to determine the relationship between categorical variables. Comparison between two groups with normally distributed data was performed using student t-test and one-way ANOVA. Pearson correlation test was conducted to assess correlation between mean scores. Drug toxicity and co-morbidity was associated with poor immunological and viral load outcomes.

Another study conducted by Mutevedzi, Lessells, Heller, Bärnighausen, Cooke & Newell (2010) in rural Kwazulu-Natal sought to evaluate trends in baseline characteristics and antiretroviral treatment intervention. The study was conducted on adults who initiated treatment between October 2004 and September 2008. The study assessed retention in care, loss to follow up, mortality and viral load outcomes. Data was collected from a database using a questionnaire. Regression analysis was used to compare groups. Survival analysis was performed to assess trends in time death and viral load suppression. Cox model was also used to determine factors associated with death and viral load suppression. Overall, mortality occurred in the first three months of antiretroviral treatment and 23 per cent had a detectable viral load. Retention was high at 84 per cent, 10 per cent died, 3.7 per cent were loss to follow up. Outcomes were not influenced by the expanding decentralised antiretroviral treatment intervention.

Nglazi, Lawn, Kaplan, Kranzer, Orrell, Wood & Bekker (2011) performed a quantitative study in Cape Town between September 2002 and September 2009 aimed at evaluating trends in mortality and attrition. Data was collected using a questionnaire to transfer information from the database. Survival analysis was done to determine time to event. Log rank test was done to compare time to event after the start of antiretroviral

treatment. Cox proportional model was employed to determine the hazard of the event. After six years of antiretroviral treatment enrolment the probability to death and loss to follow up was estimated at 37 per cent, failure to achieve viral load suppression was 23 per cent. There were fewer death risks and good immunological and virological outcomes in the first 12 months of the start of antiretroviral treatment. However, loss to follow up and failure to achieve viral load suppression increased between successive calendar years. The findings show successful antiretroviral treatment outcomes in the early years of the antiretroviral treatment rollout.

All of the above reviewed studies used a quantitative strategy to evaluate outcomes of the antiretroviral treatment intervention around the world. A cross-sectional design was popular in such evaluations together with the use of multivariate logistic regression model to determine factors associated with the outcomes. The reviewed studies highlighted key factors associated with likelihood of achieving viral load suppression. Such factors included being an adult, female gender, low baseline viral load, using a reminder tool, participating in a group of people living with HIV, and attending clinics that do home visits. It was proven that children and adolescents are more prone to having high viral loads making it unlikely to achieve viral load suppression. Rather, there is general consensus that failure to achieve viral load suppression is largely attributed to non-adherence to long term HIV treatment. Low rates of viral load suppression were observed in patients who were not in care while retention rates were higher after a year of treatment and decreased afterwards. The low rates of retention pose a threat to sustainability of antiretroviral treatment in Sub-Saharan Africa, especially in rural areas. Similarly, high mortality rates were more common in patients who were lost to follow up. Missing data was a common limitation identified in all the studies. There are limited studies that evaluated outcomes of the antiretroviral treatment interventions in rural areas of Limpopo Province, and none of them have used a theoretical framework to interpret the findings.

2.4 An introduction to monitoring and evaluation studies

Section 2.4.1 describes the concept overview of monitoring and evaluation by further describing components of evaluation (Section 2.4.2) while highlighting the main purpose of evaluation (Section 2.4.3). In Section 2.4.4 the research emphasises the key steps followed when undertaking an evaluation and it also shares the key debates around evaluation (Section 2.4.5).

2.4.1 Describing monitoring and evaluation

There is increasing evidence showing that monitoring and evaluation (M & E) play a significant role in development, worldwide. It is a tool adopted by governments and organisations to improve accountability, effectiveness and efficiency (Kusek & Rist, 2004). In development, monitoring and evaluation is essentially utilised to monitor activities of interventions while promoting learning consequently providing improved performance and achievement of results of the intervention (Görgens-Albino & Kusek, 2009; Holvoet & Inberg, 2014). Guerra-López & Hicks (2015) purport that monitoring and evaluation can influence policy and planning of interventions.

Figure 3 demonstrates two distinct beasts, monitoring and evaluation and how they complement each other. Monitoring and evaluation is anchored on four components that enable the whole system to function— thus monitoring, formative evaluation, process evaluation and summative evaluation. The monitoring component is essentially concerned about collection of data or information through indicators that are designed to supply information by means of tracking activities and monitoring for results (Bhana & Govender, 2010). Further, Kusek & Rist (2004) sub-divided monitoring into two levels, implementation monitoring and results monitoring. The two levels are both responsible for tracking of results. The authors further describe implementation monitoring as tracking inputs, activities and outputs utilised to attain an intended outcome while results monitoring focus on alignment of outputs with the intended results of the intervention. The remaining three components are housed under the main component of evaluation. Bhana & Govender (2010) purport that evaluation can be performed at the final stage of an evaluation in a systematic approach seeking to improve interventions (formative) or making a judgment about the worth of and effectiveness of an intervention.

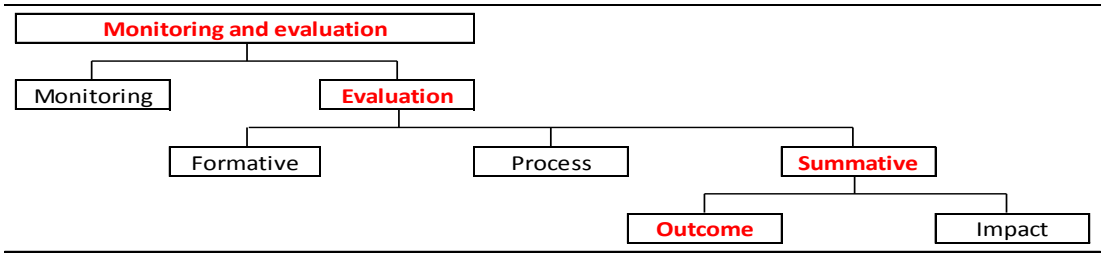


Figure 3: Schematic representation of monitoring and evaluation field highlighting its components and sub-components.

Ongoing debates in monitoring and evaluation are focused on methodological approaches employed to conduct an evaluation (Lucas & Longhurst, 2010), how to accurately measure and correlate successes of the intervention (Tsui, Hearn, & Young, 2014). The debates are also focussed on data use, as it may improve service delivery, thereby maximising intervention outcomes and informing evidence-based decision making (Patton, 2008). Some scholars base their arguments on attribution and contribution (White, 2010) and utilisation of monitoring and evaluation to understand causality (Guerra-López, 2012). The tension between accountability and learning is often highlighted in literature (Shutt, 2011).

2.4.2 Describing evaluation

According to Patton (2008, p. 5) to evaluate something is "determining its merit, worth, value or significance". There are three main goals for evaluation reported, that is, to measure, understand and learn (Berriet-Solliec, Labarthe, & Laurent, 2014). Others view evaluation as a tool used to improve design and operations of interventions in order to promote continuation or cessation of an intervention or even support the intervention (Stoltzfus & Pillai, 2002). In essence, evaluations are used to measure the effectiveness, appropriateness, acceptability and efficiency of interventions (Stoller & Rutherford, 1989).

2.4.3 The purpose of evaluation

The main purpose of evaluation is to assess the effectiveness of an intervention. However, Berriet-Solliec *et al.*, (2014) assume that the three main goals for evaluation is to measure, understand and learn. According to Berriet-Solliec *et al.* (2014), 'measuring' —here the focus of an evaluation is to determine whether an intervention has produced the anticipated results given the resources at disposal. The goal of 'understanding' —an evaluation is conducted to assess the underlying theory of the intervention to be able to produce the anticipated results. Lastly, evaluation is done for learning processes as it is meant to improve on current and future interventions. It can further assist decision makers to adapt the need for evaluation (the why) into an appropriate design (the how) (Habicht, Victora, & Vaughan, 1999), hence at times it is also conducted to select a proper design. After all, the overarching goal is to utilise the data generated to inform decision-making that leads to improved performance (Guerra-López, 2012).

2.4.4 **Major components of evaluation**

To ensure that interventions deliver effective and efficient information, evaluation of all the stages of the intervention is important. Stoller & Rutherford (1989) suggested that a thorough evaluation must entail assessment of events at various stages of developing and implementing an intervention. These different measures include the three forms of evaluation that succeed one another —formative, process and summative evaluation (Stoller & Rutherford, 1989; Wimbush, Montague, & Mulherin, 2012).

Formative evaluation is focused on interventions that are under development. Different scholars agree that formative evaluation is conducted during the planning phase to identify research gaps by means of needs assessment, it also involve elements such as the programme logic model (Bhana & Govender, 2010; Stetler, Legro, Wallace, Bowman, Guihan, Hagedorn & Kimmel *et al.*, 2006; Stoller & Rutherford, 1989). Further, Stetler *et al.*, (2006) argue that formative evaluation is important because it offers researchers an opportunity to study factors that may affect implementation of the programme as it provides important data about the implementation. These factors include (a) the extent of unaccomplished standard of practice (b) factors associated with the existing practice (c) potential barriers towards practice changes and implementation of the adopted strategy (d) and strategy feasibility (Stetler *et al.*, 2006). It is performed specifically to improve plans and implementation as to achieve intervention results (Bhana & Govender, 2010; Stoller & Rutherford, 1989).

Process evaluation assesses fidelity to ensure that implementation of interventions is done according to the plan (Bhana & Govender, 2010; Linnan & Steckler, 2002). It emphasises implementation of an intervention by monitoring progress on activities while it provides information for planning and feedback on progress (Bhana & Govender, 2010; Stetler *et al.*, 2006). There is general consensus that process evaluations assist in finding reasons why some of the intended outcomes were not realised, as it draws on the implementation conclusions of an intervention. If the conclusions are not detrimental, the intervention can be further developed and fine-tuned (Stoller & Rutherford, 1989).

A summative evaluation focuses on interventions that are in progress or have been completed —by probing intervention's results (intended and unintended) (Bhana & Govender, 2010). It is also emphasised on measurements of performance and the effects of an initiative (Bhana & Govender, 2010; Stoller & Rutherford, 1989). The

purpose of a summative evaluation is to determine if results occurred and if they contribute to learning (Stetler *et al.*, 2006; Wimbush *et al.*, 2012). Findings from this type of evaluation are utilised to inform decisions about the evaluated intervention, as utilisation of data in evaluation is highly needed (Habicht, Victora & Vaughan, 1999). During summative evaluation outcomes that are being evaluated can be short-term — also referred to as outcomes evaluation or long-term, referred to as an impact evaluation (Bhana & Govender, 2010). Bhana & Govender (2010) described that the purpose of outcomes evaluation is that of assistance with strategic intervention planning and influencing policy decisions. McNamara (1997) argues that outcomes evaluation seeks to assess progress by identifying gaps and improving implementation of the intervention. This imply that summative evaluation moves away from assessing intervention results against intervention objectives, towards assessing how these results have contributed to changes in HIV interventions.

2.4.5 Major processes of evaluation

Evaluation is comprised of three key steps; planning, implementation and utilisation of data. In accordance to Kellogg Foundation (2004), the planning phase focuses on setting of objectives and stakeholder analysis. Stakeholder analysis is identifying key people who are affected by the intervention, users of the intervention as well as people who are responsible for operations of the intervention. Implementation phase reflects on collection, analysis and interpretation of data. During this phase the evaluator must ensure continuous engagement with the involved community or stakeholders, that the evaluation meets its projected timelines, and check compliance to operating standards. Lastly, data generated during evaluation is used to improve the programme and generate knowledge.

There are two key tools that are used to design an evaluation, namely, logic model and logical approach framework. The conception of a logic model is a fundamental initial step in every programme evaluation (Renger & Titcomb, 2002). It is developed during the planning phase where all stakeholders are involved in identifying intervention objectives responsible for driving the programme (Kellogg Foundation, 2004). The programme logic model provides a roadmap on how the intervention works. It unpacks the underlying theory of how the programme will function under predefined assumptions (McLaughlin & Jordan, 1999, 2004; Kellogg Foundation, 2004). Logic model provides hypothesis (a series of if-then statement) in order to check how the

intervention is supposed to function to be able to achieve the anticipated results, by reading "if assumptions about contextual factors remain correct and the programme uses these resources with these activities, then it will produce these short-term outcomes for identified customers who will use them leading to longer term outcomes"(McLaughlin & Jordan, 1999, p. 70).

There are 3 types of logic models, namely, outcome model, activities model and the theory model (Kellogg Foundation, 2004). The outcome model is the commonly used model in evaluations and it is represented below.

Figure 4 shows a schematic illustration of a logic model that can function under certain assumptions and risks to be able to solve a problem (Renger & Titcomb, 2002).

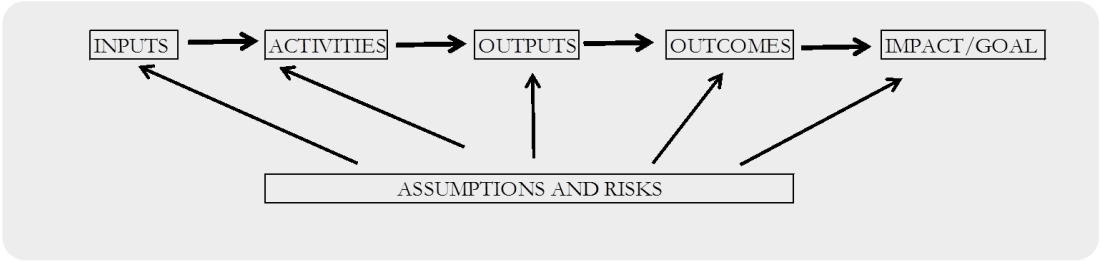


Figure 4: Logic model

Source: McLaughlin & Jordan, (1999, 2004)

According to McLaughlin & Jordan, (1999, 2004) the elements of a logic model are: (a) resources— inputs needed to support the programme such as human and budget, (b) activities reflect action steps necessary to produce programme outputs, (c) outputs focus on goods and services provided to the intervention participants, (d) outcomes focus on changes resulting from activities and outputs provided by the programme and lastly (e) impact or longer term outcomes are benefits accumulated from outcomes. In sum, logic model links outcomes to programme activities (McLaughlin & Jordan, 2004).

The Logical Framework Approach (LFA) is another tool used during evaluation planning phase when the objectives and goals are being set. According to NORAD (1999) the logical framework approach was first employed in project management for planning and appraisals prior to its adoption into monitoring and evaluation field by donor agencies and their bi- or multilateral governments. Since its inception, the LFA development has evolved over the years, however the fundamentals and principles of

the log frame have remained the same. Crawford & Bryce (2003) purport that a log frame must include goals and objectives of an intervention; means of verification for each indicator level (Impact/outcomes/outputs/inputs); and the assumptions stating conditions by which the attainment of outcomes will be achieved (if-then causality). The log frames are no longer deemed relevant for measuring effectiveness, rather different scholars are taking the initiative of extending the currently used frameworks to assess the successes and fidelities of interventions (Diehl & Major, 2015).

2.4.6 Established facts in evaluation

There are key facts to be taken into consideration before conducting an evaluation. Evaluations are a knowledge base (Peersman & Rugg, 2004), they are conducted to answer questions of efficiency and effectiveness (Peersman, Rugg, Erkkola, Kiwango, & Yang, 2009). Through process evaluation, evaluation improves implementation of the intervention by increasing efficiency thereby highlighting its weaknesses in order to improve the intervention (Bhana & Govender, 2010; Stoller & Rutherford, 1989). Evaluations are used to verify whether the intervention is following the implementation plan thereby granting a full examination (adaptability, feasibility, plausibility and adequacy) —describing an effective intervention for duplication elsewhere (Habicht *et al.*, 1999). The ability to generate data that will be meaningful and utilised for informed decision-making an evaluation must be designed during the planning phase of an intervention (Steckler, Linnan, & Israel, 2002; Stetler *et al.*, 2006b). An evaluation is a critical means to discriminate successful interventions from those that are unsuccessful. Evaluations are conducted to verify impact or effects of the intervention on the beneficiaries (Habicht *et al.*, 1999; Stoller & Rutherford, 1989).

2.4.7 Key issues in the study of evaluation

Recent debates are fixated on the credibility of evaluation results. The debate is largely focused on how to measure impact, whether or not experimental design in the form of randomized controlled trials are the most optimal way to provide credible evidence on the past performance of an evaluation rather than improving future performance evaluations using diverse methodologies (Gargani & Donaldson, 2011). The proponents of randomized controlled trials suggest the use of experimental design as a benchmark or gold-standard for evaluations (Bhana & Govender, 2010). However, evaluation practitioners do not always have time, resources or control over intervention design. De Lay & Manda (2004) argue that another key issue facing evaluation is political

interference, which is done by misusing data and lack of response towards evaluation results. However, De Lay & Manda (2004) suggest that this can be corrected by promoting adequate and appropriate use of data.

Another difference is failure to articulate the theory of change that underpins each intervention (Edgington, 2010). Theory-based evaluation is highly recognised amongst theorists and evaluation practitioners. However, there is still challenges on how to apply this approach in practice and how to make valid deductions about contributions of certain interventions to observed changes (Nakrošis, 2014). According to White (2006), a theory-based approach focuses on efficiency (how an intervention is working), not just how it operates, and this requires both quantitative and qualitative data.

2.5 Key attributes of an evaluation exercise

This section discusses key variables that are involved in an evaluation of the antiretroviral treatment intervention. In monitoring and evaluation, variables function as indicators that are utilised to collect data by tracking change over time, identifying problem areas as well as to determine the effectiveness of the programme or monitor programme goals (WHO, 2015). Selection of indicators for an intervention is a cautious process, as the indicators have to be good and a good indicator must be SMART, Specific – Measurable – Achievable – Relevant – Time bound (Rajalahti, Woelcke, & Pehu, 2005). Monitoring indicators are used to measure inputs, processes and outputs in order to monitor the efficiency of the intervention (process evaluation) while evaluation indicators are aligned to outcomes and impact and are used to assess the effectiveness of the intervention (summative evaluation).

2.5.1 The inputs

Inputs are among the important elements of the planning phase of an evaluation and they are usually overlooked during evaluation processes (Nikkhah, Sharif, & Talebi, 2011). Inputs are comprised of elements that are entered into the system in order to drive evaluation processes (Parsons, Gokey & Thornton, 2013). The inputs for the antiretroviral treatment intervention are budget, HIV policies and standardised treatment guidelines, antiretroviral treatment clinic stationery, human resource, antiretroviral drugs, equipment and infrastructure. One big challenge is to ensure that people who are initiated on antiretroviral treatment are maintained on treatment so they live longer and further participate in the economy. Sustainability of the intervention is

achieved by a large amount of money from the fiscus and budget; and expenditure is monitored using the medium term expenditure framework (DoH, 2004). South African government offers antiretroviral treatment for free in a public health approach; therefore it developed and implemented standardised treatment guidelines to use for patient management.

2.5.2 The activities

Activities focus on actions or processes, that is, what needs to be done to achieve results (Parsons, *et al.*, 2013). According to Parsons *et al.* (2013) these are tasks that are needed to implement and manage interventions, and the tasks to be executed require inputs to yield anticipated results. Generally, this variable is essential in detecting challenges during implementation as well as measuring programme coverage (Parsons *et al.*, 2013). According to The Presidency (2007), efficiency indicators are used to measure how quickly inputs are translated into results, as they address the implementation stage of the intervention. In the context of this research, activities variables for the antiretroviral treatment intervention are adherence counselling, laboratory services and prescription of antiretroviral drugs. Government recommends that each individual undergo adherence counselling prior antiretroviral treatment. According to literature the most common measure for medication adherence is pill count (Lee, Kusek, Greene, Bernhard, Norris, Smith & Wilkening *et al.*, 1996) among others. Patient's health outcomes are monitored frequently by testing for CD4 and viral load. CD4 is a measure of the strength of the immune system, while viral load is level of the HIV virus in the body. The two tests are measured using a laboratory value. The national treatment guideline recommends one pill fixed dose per day. Depending on the reaction towards treatment this might change to a combination of three different drugs. Data collected for this variable is sourced from medical records at the facility.

2.5.3 The outputs

This variable measures what needs to be produced by the intervention in order to be able to achieve the programme's outcomes (UNDP, 2011). Parsons *et al.* (2013) assumes that outputs are generally time-bound, similar to inputs and activities outputs are measured quantitatively. This variable can also be used to measure the efficiency of a program by describing the relationship of resources invested in a programme and the products. In practice when a programme fails to achieve its output there is high chance

of it being unsuccessful, however having achieved the outputs does not guarantee a successful program (DPME, 2011). The main output for the antiretroviral treatment intervention is the number of people initiated on antiretroviral treatment, number of viral load and CD4 tests performed, number of people who attended adherence counselling sessions, number of health workers trained on the national treatment guidelines and the antiretroviral treatment clinic stationery. Data source for the output variables is sourced from medical records at the facility and district health information system.

2.5.4 The outcomes

The outcome variable measures short or medium term results. It focuses on immediate changes brought by the intervention (UNDP, 2011). Parsons *et al.* (2013) purport that an outcome is a consequence of a specific output. This variable is always aligned to the programme's objectives; it essentially measures what the programme achieves. According to literature, the primary outcomes of the antiretroviral treatment interventions are (a) retention in care (Doshi *et al.*, 2014) (b) viral load suppression (Cescon *et al.*, 2011; Fielding *et al.*, 2008; Jobanputra *et al.*, 2015; Nachega *et al.*, 2009) and (c) mortality (Budgell *et al.*, 2015; Wandeler *et al.*, 2012). The dependent outcome variable for this research is viral load suppression, defined as viral load value below 50 copies as per national guidelines. Data for the outcome variables is collected from medical records at the facility and district health information system and vital registers.

Other explanatory variables are clinical characteristics comprised of baseline CD4, opportunistic infections, WHO clinical staging and treatment history; while demographic characters include age, sex, type of residency (township or village/farm).

2.5.5 The impact

The impact focuses on the vision or overall goal of the intervention (UNDP, 2011). It measures the ultimate benefits for the target population (UNDP, 2011). The Presidency (2007) states that impact is a result of achieving a specific outcome of the programme with the aim of changing a situation. Such change is likely to happen after a period of three to five years or even more depending on the type of an intervention. The impact variable measures the effectiveness of a programme, under the assumption that the achievement of inputs and outputs will translate into outcomes. It can be measured using both quantitative and qualitative methods. In the context of the antiretroviral

treatment intervention, the impact variables are life expectancy and HIV incidence. Life expectancy is defined as number of years alive while HIV incidence is new HIV infections. Data for the impact variable can be collected from surveys.

Figure 5 illustrates variables used in monitoring and evaluation of the intervention of the antiretroviral treatment intervention. Each result level is aligned to a variable or indicator that will be used to collect information for that level.

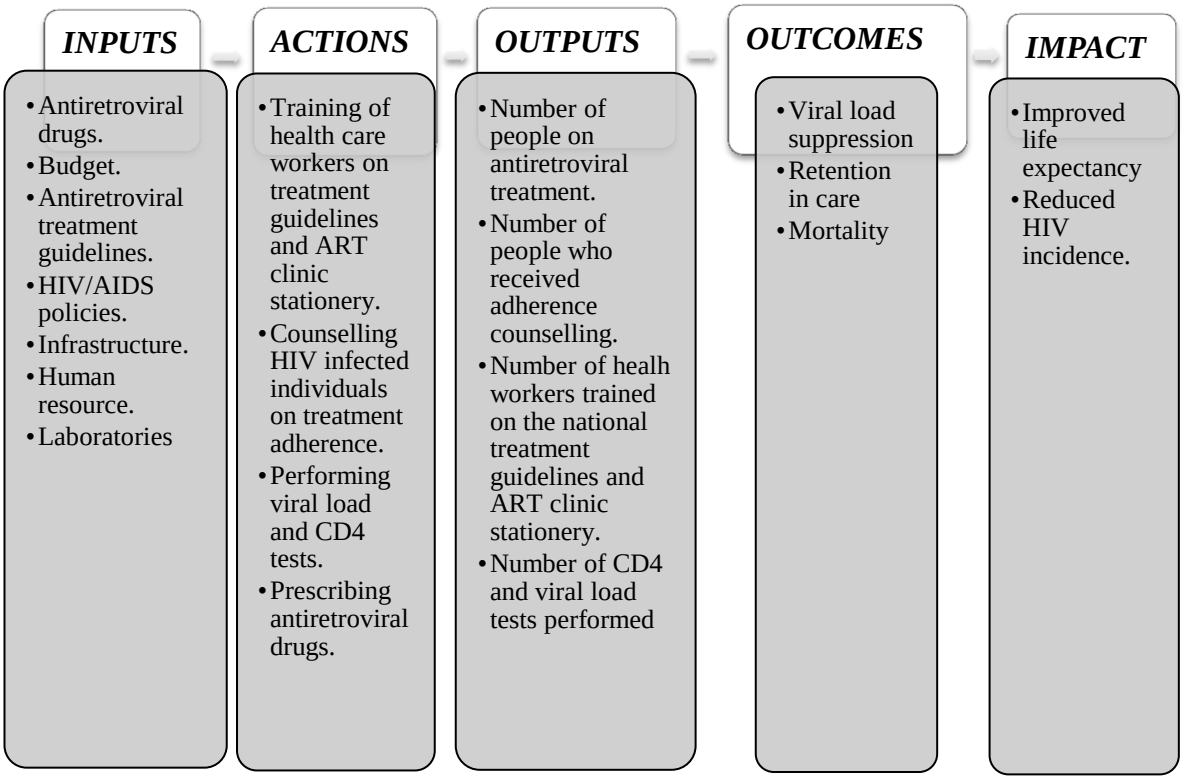


Figure 5: Variables or indicators used in monitoring and evaluation of the antiretroviral treatment intervention.

2.6 Theoretical framework

Interventions that are geared towards development are grounded on theory and evidence, and this is no different to HIV interventions. Many scholars have developed frameworks and theories that can be used to understand behavioural change in HIV interventions at individual, community or ecological level. These include Health belief model (Rosenstock, Strecher, & Becker, 1988), Theory of planned behaviour also called Theory of reasoned action (Fisbein & Ajzen, 1975), Stages of change model (Prochaska & Velicer, 1997), AIDS risk reduction model (Catania, Kegeles, & Coates, 1990), Social cognitive theory (Redding, Rossi, Rossi, Velicer, & Prochaska, 2000) and Empowerment

theory (Zimmerman, 2000). For evaluation of interventions the theory of change is used to explain the causal link from resources to results and can be explicitly tested (Funnell & Rogers, 2011).

In HIV infected individuals, the antiretroviral treatment suppresses the virus; however this outcome is achieved only when the person living with HIV is at least 80 per cent adherent to treatment (McNabb, Ross, Abriola, Turley, Nightingale & Nicolau., 2001). Therefore, adherence plays a key role for people living with HIV to enable them to achieve viral load suppression and improve the quality of life. As such, social and behavioural factors have an influence on adherence behaviour, consequently having an influence on health care utilisation and health outcomes of people living with HIV (Kagee, 2008). The WHO (2003) has determined three factors that are an impediment to optimal antiretroviral treatment adherence, namely, treatment characteristics, patient characteristics, and the relationship between the health professional and patient. To further understand the influence exerted by some of these variables towards the outcomes of the antiretroviral treatment intervention two social cognitive theories are reviewed to conceptualise the phenomenon of antiretroviral treatment adherence. In combination with the theory of change, results chain and framework the health belief model and theory of planned behaviour will be carried forward to explain findings of this study. In addition, the theory of gender and health will be used to explain differences in health practises and illness experiences amongst males and females.

2.6.1 **Health belief model**

Health Belief Model was first developed in the 1950s by Rosenstock *et al.* (1988) to address problem behaviours that evoke health concerns by exploring why people do not take preventative health measures. The model was based on them wanting to understand why free tuberculosis health screening programme was unsuccessful (Conner & Norman, 2005). This model was conceptualised on the basis of six determinants or independent predictors of health behaviour. According to the model, an individual's (1) perceived susceptibility to a health condition and (2) gravity/severity (leaving disease untreated) of the disease influences individual's perceived risk of disease, (3) perceived benefits of avoiding risk and (4) perceived barriers associated with the condition influences perception of the worth of the health behaviour, (5) cues to action to activate a readiness to change and (5) confidence in the ability to take action (self-efficacy) influence perceived threat (Rosenstock *et al.*, 1988). The model is more

advantageous in that it has successfully increased voluntary screening rates of various illnesses. It formed basis of various health behaviours and it does not have strict rules on variable combinations thus providing flexibility and adaptability to various health interventions (Orji, Vassileva, & Mandryk, 2012).

As with other theories, the model is subjected to criticism. The model does not provide clear definitions of individual variables leading to the lack of rules for combination formulation of the perception variables and their relationships (Armitage & Conner, 2000). Secondly, the model has a low predictive capability of determinants. Further weaknesses are its failure to include positive effects of health impairing behaviour patterns (e.g smoker may disregard health risks because they enjoy smoking) and social influence variables (Stroebe & de Wit, 1996).

2.6.2 Theory of planned behaviour

Theory of planned behaviour is a cognitive theory developed by Azjen (1988), which is an extension of theory of reasoned action developed by Fisbein & Ajzen (1975) by including measures of perceived behavioural control as determinants of intention and behaviour. It is concerned about factors that influence a person's decision to undertake a particular behaviour as long as that behaviour is intentional and this is explained by a causal chain that links attitudes, subjective norms, and perceived behavioural control to belief in a behaviour through behavioural intention (Brewer & Rimer, 2008). The causal chain is described using the following logic: behaviours are most likely to be influenced when individuals adopt positive attitudes about the behaviour; the behaviour is perceived positively by key people who influence the individual (subjective norm); and the individual has a sense that he or she can control the behaviour (perceived behavioural control) (Sutton, 1997). It posits intention as the most important determinant of behaviour (Fisbein & Ajzen, 1975). Intention is defined as a motivation required in performing certain behaviour (Armitage & Conner, 2000). Consequently, the more one intends to engage in this behaviour the more likely is its performance (Armitage & Conner, 2000).

Armitage & Conner (2000) highlighted advantages and limitations of using this theory in public health interventions. Theory of planned behaviour can be used to explain why other people engage in particular health behaviour. It also takes into consideration other external factors and does not only focus on individual's beliefs. Its major weakness is

that it functions under the assumption that all behaviour is planned and controlled by the individual. Another weakness of theory of planned behaviour is that it does not take into consideration times when people may not be responsible for their behaviour.

Figure 6 shows an integrative model of health belief model and theory of planned behaviour to show the relationship of health beliefs and behaviour variables that can influence optimal adherence. In this figure it can be seen that the adherence behaviour can be adopted if there is the intention to perform the behaviour, if the individual is equipped with the skills to perform the behaviour, and if there are no impediments to prevent behavioural performance there is chance that the adherence behaviour will be performed. Also, intention to perform the behaviour is underlined by having people that positively influence the individual, the right attitude and the confidence that he or she can perform the behaviour. All these variables are underpinned by the beliefs or perceptions on susceptibility, severity, risks, benefits, barriers and signs to act on an illness.

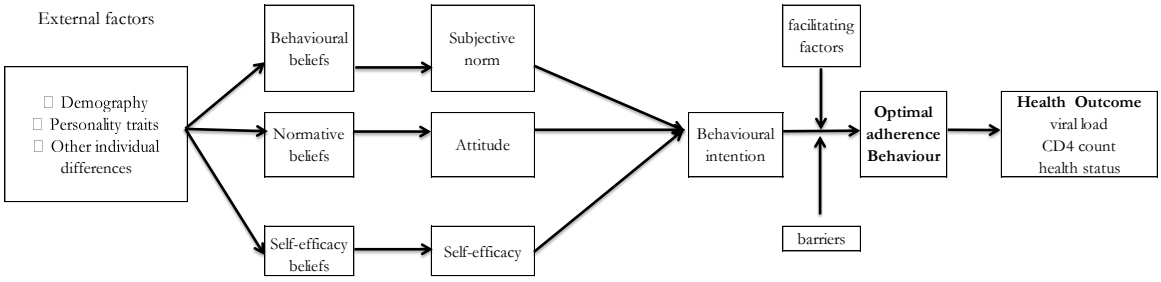


Figure 6: Integrative model that depicts factors that influence optimal adherence behaviour.

Adapted from Fishbein 2000, DeBruin *et al.*, 2005, Munro *et al.*, 2007

2.6.3 **Theory of gender and health**

This theory sought to explain disparities in health practices and illness experiences accounted for by gender (Courtenay, 2000). Connell purport that many cultures nurture masculinity in order to maintain the male power. Masculinity is accompanied by qualities of a 'real man' —tough, fearless and physical strength. The theory posits that health related beliefs and behaviour are a means of demonstrating femininity and masculinity (Courtenay, 2000). It proposes that "the social practices that undermine men's health are often signifiers of masculinity and instruments that men use in the negotiation of social power and status" (Courtenay, 2000, p.1385). In accordance to Connell & Connell

(2005), men often dismiss their health needs and engage in behavioural risks because they view themselves as a stronger sex. This allows men's perpetual use of unhealthy beliefs and behaviours that help them to sustain and reproduce social inequalities that, in turn highlight men's poor health habits. It is the pursuit to maintain this dominant status that puts men's health at risk. Literature suggests that health behaviours have been found to be key explanatory variables that highlight the differences in health status between men and women (Verde, Li, & George, 2003).

2.6.4 The theory of change

The theory of change is one form of theory-based evaluation where the causal link from resources to results can be explicitly tested (Pawson, 2003). Theory of change requires an explicit clear articulation of the road map of how the intended outcomes will be achieved (Weiss, 1995). A theory-driven evaluation narrates how, for whom, and under what assumptions do interventions produce or fail to produce results (Nakrošis, 2014). The theory of change emanates from the work done at Aspen Institute Roundtable (Fulbright-Anderson, Kubisch, & Connell, 1998) where it was aimed at planning community-based interventions. A theory of change approach states that "…activities A1, A2, and A3, if properly implemented (and with the ongoing presence of contextual factors X1, X2, and X3), should lead to outcomes O1, O2 and O3; and, if these activities, contextual supports (assumptions), and outcomes all occur more or less as expected, the outcomes will be attributable to the intervention" (J. P. Connell & Kubisch, 1998, p. 2).

The key proponents of the theory of change Connell & Kubisch (1998) and Mason & Barnes (2007) posit that the theory of change can enhance intervention planning, promote decisions focused on prioritisation of evaluation methods and questions, can prove that the evidence of change can be attributed to the intervention without using experimental studies in evaluation. Development of the theory of change requires stakeholder participation, whereby all relevant stakeholders must have their theories of what are the outcomes they anticipate to attain, how they wish to achieve them and why they should be delivered, not forgetting the context in which the programme operates (Connell and Kubisch, 1998). Despite the challenges experienced with the use of theory of change, it is still valued by many evaluators (Prinsen & Nijhof, 2015). One of the valued aspects is that it reflects more on the impact of an intervention on the outset. Consequently, interventions put more emphasis on the change rather than the

deliverables and outcomes. The second aspect is that it is concerned about a detailed pathway to change (Anderson, 2006). Another key principle of theory of change is the ability to implicitly state external factors, such as assumptions and risks that underpin programme processes (Weiss, 1997) in order to provide the credibility that observed changes are attributed to the intervention. The fourth and last valued principle is that the theory of change endeavors to assist understand and pin down the complexities of change processes in interventions (Prinsen & Nijhof, 2015).

Some of the challenges identified regarding theory of change are starting to re-surface as more evaluators adopt this theory-derived evaluation approach. Firstly, Stufflebeam & Shinkfield (2007) noted that theory of change requires a lot of data and that it could hinder the development of a successful intervention. Secondly, Coryn, Noakes, Westine, & Schröter (2011) noted that there's arising confusion during evaluation, as to whether evaluation is conducted on the intervention itself or the theory underpinning the evaluation. When an intervention fails to achieve its intended outcomes is the problem centered on a weak theory of change or mismanagement of the intervention. The third activist argues that theories will not necessarily solve societal problems and elaborate why the intervention fail (Scriven, 1998). However, proponents such as Weiss (1997) advocate that black box evaluation, which is the measurement of outcomes without focusing on process of change from intervention inception to outcomes can still be done systematically. Despite, the theory of change being highly utilised in evaluations it has a shortfall in that it does not detail the methods to use in evaluation and how and who articulates it, hence there is wide variation in implementation of the theory of change (Mason & Barnes, 2007).

In the context of the antiretroviral treatment intervention the theory of change for the intervention is to 'provide universal access to antiretroviral treatment to improve survival rate and further reduction of HIV transmissions through viral load suppression'. Drawing from the programme theory the following assumptions are described to sequentially link inputs, activities, outputs, outcomes and impact(s);

- Linking HIV diagnosed individuals to care until such time of antiretroviral treatment initiation to achieve increased antiretroviral treatment coverage.
- Individuals on antiretroviral treatment remain in care.
- Optimal treatment adherence to achieve sustained viral load suppression and survival.

- Continued awareness of responsible sexual behaviour to reduce HIV transmissions.

Figure 7 depicts the proposed theory of change for the intervention illustrating a sequence of events under predefined assumptions. The successes of this intervention are dependent on strengthened health systems that are easy to access, strong political will and stability to support HIV policies, clear policy and clinical guidelines, financial sustainability to support HIV care services, and lastly, HIV infected persons taking the responsibility to seek health together with awareness and understanding of the disease (self-efficacy). The relationship between Department of Health, facility staff, laboratory staff is critical to the change process; hence there is a need for close collaboration and good coordination to improve patient's health status.

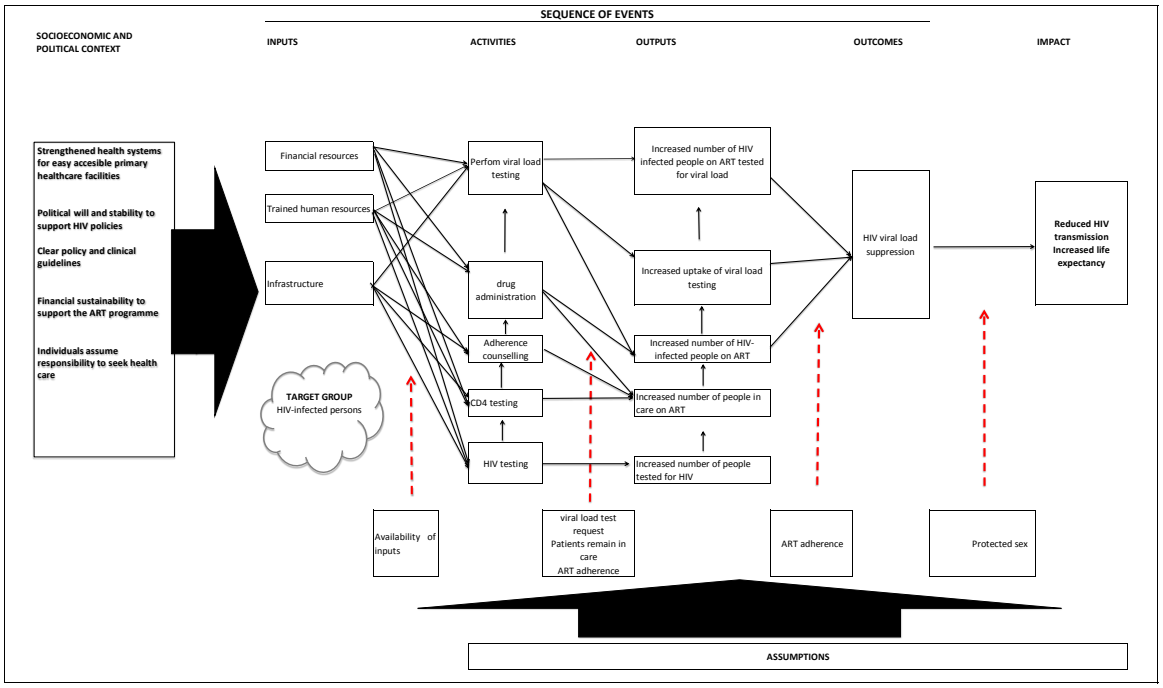


Figure 7: The proposed theory of change for the South African antiretroviral treatment intervention.

2.6.5 The results chain and framework

The results chain is a tool used to measure performance; it provides answers to two questions, whether the invested resources resulted in intended outputs and whether there is tangible progress on outcomes and impact (WHO, n.d). According to Margoluis, Stem, Swaminathan, Brown, Johnson, Placci, Salafsky & Tilders (2013) a results chain represents an assumed causal relationship between impact and outcomes through invested resources. The results chain is developed in such a way that it

apprehends the essential elements of the logic model and the cause-effect relationship between inputs, activities, outputs, outcomes and impact. As indicated in the Section 2.5.3, 2.5.4 and 2.5.5, outputs are services or immediate results provided by the programme, outcomes are the benefits of that service to the target population while impact is the change in behaviour as a consequence of the outcome to the target population.

Figure 8 is a schematic representation of the results chain for the intervention. The figure highlights a causal link from the intervention's inputs to the impact. This study will put more emphasis on the outcomes.

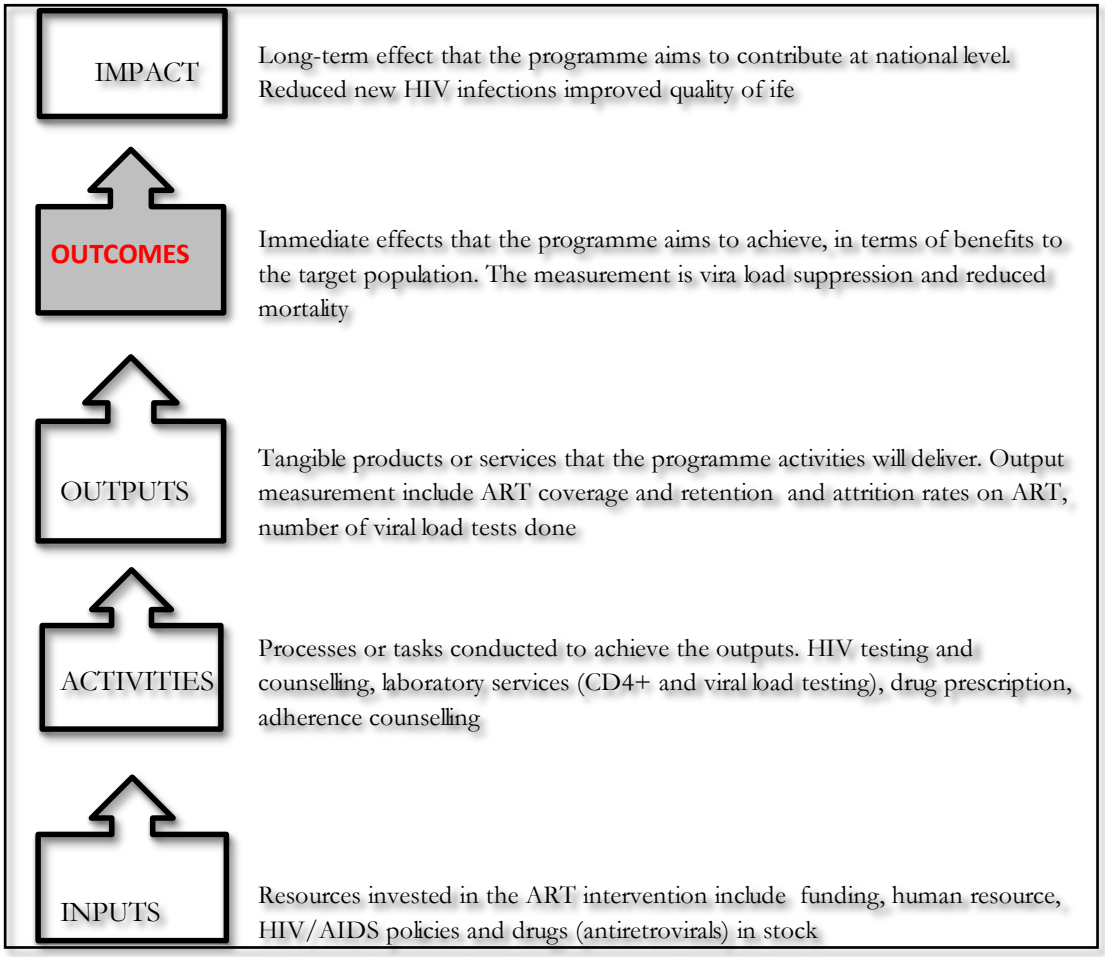


Figure 8: Results chain of the antiretroviral treatment intervention, depicting a link of inputs to outcomes.

2.7 Assessing outcomes of antiretroviral treatment intervention in Mankweng, a conceptual framework

After introducing the research problem statement and the methodology, thereof, this paper began by reviewing literature that allows us to understand challenges of monitoring and evaluation systems. This section provides a road map on how research will be conducted post literature review. A conceptual framework is a summary of all the sections Chapter 1 and 2 discussed in the literature review.

Figure 9 shows a summary of how the research question links in with the literature that trails its origin and the literature that is explicitly detailing the procedures of resolving the question. Our preliminary analysis (Section 2.2) and past evaluation studies (Section 2.3) suggest that retention in care; viral load suppression and mortality are the outcome measures of the antiretroviral treatment intervention. However, so far, none of the studies have assessed antiretroviral treatment outcomes in rural parts of Limpopo Province. Further, previous studies have failed to explicitly explain their findings using a theoretical and/or explanatory framework. The theory of change and results chain will be used to interpret the findings.

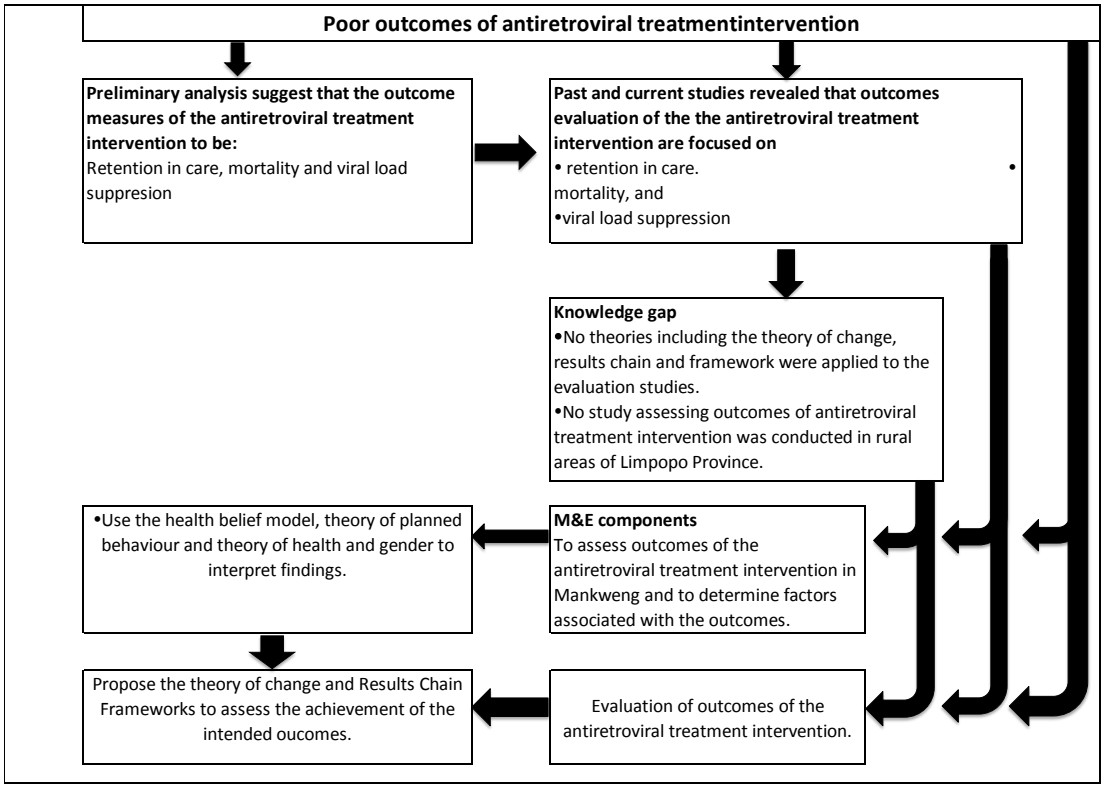


Figure 9: Diagram depicting the research problem, possible explanations and proposed methodology of pursuing the problem

At this point, the research has two research questions, (1) "What is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months?" We downplay the other two outcomes of the antiretroviral treatment interventions for two reasons. The literature has always reported evaluation on outputs of the intervention. However, it is over a decade since the introduction of antiretroviral treatment, by far it is evident that the intervention is efficient therefore it is now necessary to focus on the effectiveness of the intervention. Second, with the new UNAIDS targets that are aimed at ending the epidemic in 2030, it is imperative to start evaluating outcomes that will fast track the intervention to 2020 targets. Lastly, current focus must shift towards evaluations that measure tangible progress towards the impact. Another research question is "What are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months? The research opt to understand factors that may influence or lead to failure to achieve the intended outcome.

Second, the research sought to provide insight on outcomes evaluation of the antiretroviral treatment intervention in rural parts of Limpopo, by conducting the study at the largest HIV treatment site that offers HIV care and treatment to dominantly rural residents of Mankweng. To understand factors that may influence failure to achieve the anticipated results will be probed using binomial regression model. The method has been previously used in studies that employed a cross-sectional design. The research uses the last value carried forward rule to avoid some limitations associated with missing data.

The research is situated within the monitoring and evaluation field, which is a system used for managing and improving results. It provides sponsors and governments with information on progress towards achieving results thus providing evidence on what is working and what seem to not be working. The research will in particular focus on evaluation as it measures the effectiveness of the intervention. The main components of evaluation are formative, process, outcome and impact evaluation. This research will focus on outcomes evaluation as we are assessing the performance of the intervention. The outcome variable, viral load suppression is defined as virus level below 50, which will be sourced from laboratory results obtained for each individual.

This research sought to propose the theory of change for the intervention to interpret evaluation findings. The theory assume viral load suppression will be achieved under the

assumption that people are adherent to treatment. Further, the thesis will evaluate the results using the results chain to explain the causal link from inputs to the intended outcome. The research will also apply the theories of behavioural planning and models of self-regulation to determine other factors that drives change.

It is this systematic summary of and decision-making based on chapter 2 of a literature review that provides us with a conceptual framework for our research or evaluation.

3 RESEARCH TECHNIQUES, PROCEDURE AND METHODS

This chapter sets out to discuss and commit to a research strategy, design, procedure and methods. First, Section 3.1 discusses different research strategies underpinned by the key paradigms that guide research. Drawing from the literature, this section commits to a research strategy that will inform the study further detailing the selected strategy with support from literature. Third, Section 3.2 provides a brief introduction to different research designs and the author selects a single research design that conforms to the research guided by current and past studies that have conducted similar research. Fourth, Section 3.3 shares key techniques and procedures that were applied to assess outcomes of the antiretroviral treatment programme, the data collection instrument, target population, sampling and ethical considerations. Sub-section 3.3.1 and 3.3.2 details the preferred instrument used to collect data and further describes the target population and sampling procedures. Section 3.3.3 demonstrates whether the participants in this research were safeguarded. This section also highlights data handling and analysis. Lastly, the chapter shares some reliability and validity measures as well as limitations of the research methods.

3.1 Research strategy

In research, a theory is always guided by a paradigm that further guides the researcher to the methods applied (Bryman, 2012). As defined by Bryman (2012, p. 35) a research strategy is "a general orientation to the conduct of social research". Literature has strongly affirmed that the three research strategies are quantitative, qualitative and mixed methods (Bryman, 2012; Wagner, Kawulich, & Garner, 2012). This study used a quantitative research approach reason being that the author has formulated a theory guided by the literature. The data collected in a quantitative study will either support or disprove the theory (Creswell, 2013). To make it clear, Bryman (2012) explains that quantitative method is a measurement in the form of numbers during collection and analysis of data, it further determines a relationship between variables. Meanwhile, emphasis on large sample size is critical so the research can be able to make inferences to a large population size free of bias and sampling error (Wagner et al., 2012). The approach is highlighted in the studies that have investigated similar research questions as illustrated below.

A study by Fox, Shearer, Maskew, Fox, Shearer, Maskew, *et al.* (2012) antiretroviral treatment assessed antiretroviral treatment outcomes over a period of seven years at an urban clinic in South Africa. Primary outcomes were death and loss to follow up. Log binomial regression containing Poisson regression and robust error estimation were used to investigate predictors of death and loss to follow up. Summarily, 90 per cent of patients suppressed the virus, and 76 per cent were retained in care after a year on treatment. One-year mortality was below 11 per cent in all calendar years. After the first 12 months on treatment monthly rates of death and loss to follow up decreased significantly and remained unchanged. The authors estimated that 25 per cent of patients were lost to follow up and 16 per cent died after seven years on ART. Overall, more interventions are required to specifically address the issue of attrition.

In rural areas of the Southern Africa a logistic regression model was used to determine factors associated with no loss to follow up after ART initiation, no returning to facility after the start of ART and further competing models were used to analyse loss to follow up and death. The analysis revealed high rates of mortality and loss to follow up. Young age and male gender were associated with the likelihood of no loss to follow up (Wandeler, Keiser, Pfeiffer, Pestilli, Fritz, Labhardt, Mbofana, Wandeler, Keiser, Pfeiffer, Pestilli, Fritz, Labhardt, Mbofana, *et al.*, 2012).

Another study by Doshi Doshi et al. (2014)sought to assess sought to assess proportion of clients at key stages of the HIV continuum of care and further examining factors associated with achieving retention in care and viral load suppression. Odds ratios and frequencies were calculated for outcome of each predictor variable. In year 2011, over 500 000 clients sought health services at the insurance-funded facility in the USA. Of these, 62 per cent attended at least one medical visit. Of these, 82 per cent were retained in care, and 72 per cent achieved viral load suppression. Viral load suppression was higher among retained clients versus clients who were not retained. Low levels of retention and viral suppressions were among youth and young adults (13 - 34 years).

Lastly, in Canada a study was conducted to examine time to viral load suppression also the authors hypothesised that there was no association between socio-demographic factors, clinical factors and viral load suppression. The authors found that the median time to suppression was 4.55 months (Inter quartile range (IQR) 3.99 - 7.89 months). Multivariate analyses found that age, male sex, province ethnicity, history of injectable drug use, and baseline viral load were associated with viral load suppression (Cescon Cescon et al., 2011) .

From the above discussion, it was noticeable that relationship between variables and testing of theories is the core of the quantitative strategy. This conforms to Bryman

(2012)'s argument that quantitative strategy is able to reveal relationship between variables. This study will benefit from reporting proportions of patients who achieved viral load suppression.

3.2 Research Design

Literature defines a research design as a blueprint of any research project as it provides credibility, feasibility as well as the relevance of a research project (Babbie, 2015). There are five prominent research designs described in literature, namely, experimental, cross-sectional, longitudinal, case study and comparative (Wagner *et al*., 2012).

This research applied a cross-sectional design because data was collected simultaneously at a single time point (Wagner *et al*., 2012). A cross-sectional design provides a snapshot of an occurrence as it happens, describing or comparing a variable to a particular standard therefore summarising the relationship between two or more variables (Bickman & Rog, 2008). However, the design has to be applied with caution as it cannot postulate cause-effect relationships (Bickman & Rog, 2008). Below is a review of studies that have applied a cross-sectional design to the studies that conducted research similar to this.

Fatti, Grimwood, & Bock (2010) conducted a study to compare baseline characteristics and treatment outcomes between patients managed at different levels in the health system. Data was collected from medical records of patients who started treatment between December 2001 and December 2007 at 59 health facilities in both urban and rural areas of South Africa. Kaplan-Meier estimates, competing risks cox and logistic regression models revealed that attrition, retention and death were superior at primary health clinics (PHC) despite PHC patients having more advanced clinical stage diseases when starting ART. Fielding and colleagues (2008) sought to determine risk factors associated to suboptimal viral load suppression by extracting data from an electronic database of HIV-infected patients receiving ART from 1 July 2004 to 31 March 2005 in a workplace-based HIV care programme in South Africa. A multivariate analysis revealed that a ten times decrease in viral load was a strongest predictor for viral load suppression at 12 months, while high baseline viral load and advanced HIV progression were risk factors for suboptimal viral load suppression. Another study by Budgell *et al.* (2015) that compared mortality in patients who were in care and those lost after treatment initiation. Data was prospectively collected among HIV-infected patients

enrolled for antiretroviral treatment between April 2004 and May 2012. The primary outcome variable was death either in care or lost to follow up. The cox proportional hazard models revealed that 14.6 per cent of patients who have died and being lost accounted for a minority of deaths across multiple stages of loss to follow up. Although, mortality rates in patients lost to follow up were superior to patients in care, most ART-associated deaths occurred while on treatment.

The articles clearly demonstrated different outcomes that occurred during a specified period of time among patients receiving antiretroviral treatment, thus providing a snapshot of outcomes during that time interval. It is clear that time interval can range from 12 months and above, however there is no standard time interval to use during research. Notably, the articles determined relationship between variables. The study aims to follow a similar approach but focusing on outcomes achieved after a year of antiretroviral treatment initiation the study will also benefit from being able to determine factors associated with failure to determine viral load suppression. Therefore, this study falls within the research design norms.

3.3 Research procedure and methods

This section sought to provide detailed specifications on how the research was conducted, detailing the type of instrument used to collect data, the target population that was studied and the sampling techniques used further demonstrating the ethical considerations applied when conducting this research. The section further zooms onto aspects of data collection, storage and analysis.

3.3.1 Data collection instrument

Alongside with choosing the type of design, the researcher explores potential tools for data collection (Bickman & Rog, 2008). There is common understanding among scholars that a data collection instrument is utilised to gather information from a studied population in order to answer a specific research question and draw conclusions (Bickman & Rog, 2008). In research, the sources of data usually informs the type of instrument to use for data collection, virtually instruments are designed and implemented to collect what needs to be known (Wagner *et al.*, 2012). The two fundamental instruments for data collection are structured and unstructured interview schedules (Wagner *et al.*, 2012; Gill, Stewart, Treasure, & Chadwick, 2008). A structured interview is often referred to as a questionnaire (Gill et al., 2008).

For this research a questionnaire was used to gather data originating from patient medical records without interacting with the participants. In accordance to Gill *et al.* (2008), a questionnaire is comprised of a pre-determined list of questions in a closed-ended format —where there is no opportunity for follow up to responses that requires further elaboration. It is often a preferred tool to use in survey research, field research, experiments and other forms of observation (Babbie, 2015). The variables listed on the questionnaire in order to collect data were in alignment with the clinical stationery used at South Africa's antiretroviral treatment facilities. The questionnaire measured five components: (1) Patient profile or demographics, (2) clinical characteristics, (3) treatment history, (4) viral load monitoring, and (5) adherence characteristics. In total there were 23 variables on the questionnaire.

We reviewed previous studies that have used similar data collection instrument in their research. Cescon *et al.* (2011) used a fully structured questionnaire often referred to as data abstraction form to extract data at data centres of the participating cohort sites to probe time to viral load suppression and factors associated with viral load suppression among a national cohort of persons on antiretroviral treatment in Canada. The study found that the median time to suppression was 4.55 months (IQR 3.99 - 7.89 months) while older age, male sex, treatment in Ontario rather than British Columbia, non-injectable drug users history, and having an AIDS diagnosis at baseline were likely to achieve viral load suppression. Another retrospective cross-sectional study by Saka *et al.* (2014) sought to determine factors associated with loss to follow up was conducted in Togo. Data was abstracted from medical records of HIV-infected individuals on antiretroviral treatment who were lost to follow up between January 2008 and October 2011. The multivariate analysis revealed factors associated with early loss to follow up and confirmed high mortality in these patients. Predictors of early loss to follow up were ages below 35 years, presence of opportunistic infections at the start of antiretroviral treatment, living in rural area and receiving HIV treatment at public health system.

The articles above show that a questionnaire is an appropriate instrument used to abstract data from databases or patient medical records in order to assess outcomes of the antiretroviral treatment intervention in both developed and developing countries. Although, one article extracted data on different outcomes there were still commonalities within the questionnaires including patient demographics and clinical characteristics. This study will accrue benefits of being able to extract data on

demographics, clinical information including adherence characteristics. This study conforms to norms of developing a questionnaire that is used for transferring information from medical records.

3.3.2 Target population and sampling

A target population for a study is "that group (usually of people) that participate in research who we want to draw conclusions" (Babbie, 2015, p. 116). The study population for this research is HIV-infected adults whom are on antiretroviral treatment for 12 months attending primary healthcare clinic, Phela-O-Phedise, at Mankweng from 01 January 2013 to 31 December 2014. The participants include adults of 18 years and above. To evaluate the viral load outcomes at 12 months, patients that were lost to follow-up, died, or transferred out to other facilities were excluded from the study. A threshold of 12 months on treatment was selected because previous studies have proven that it takes close to six months for HIV viral load to diminish to below undetectable levels (Mellors, Margolick, Phair, Rinaldo, Detels, Jacobson & Muñoz, 2007).

Table 1: Sample size estimation for the assessment of outcomes of the antiretroviral intervention programme in Mankweng.

Viral load suppression level	Confidence interval	Estimated Sample Size	Number needed to screen (adjusted for 10% loss rate)
60%	90%	369	406
75%	90%	288	317
90%	90%	138	152

3.3.3 Ethical considerations when collecting data

Ethical research is conducted with the aim to protect the research participants. In accordance to Wagner *et al.* (2012), when conducting research the following ethical considerations must be applied. Firstly, gatekeepers grant permission to conduct a study. Secondly, it is the responsibility of the researcher to ensure that participants are not subjected to any type of harm when participating in the research. Reciprocity means giving back something to those who have provided data, such as sharing research results. Deception happens when the participants are intentionally led to have false

beliefs. Informed consent is "an individual's personal right to agree to participate in a research study after fully understanding the total research process and consequences" (Wagner *et al.*, 2012, p. 68). An informed statement should explicitly clarify the research to be conducted (Bickman & Rog, 2008). Lastly, anonymity and confidentiality refer to safeguarding of the identity of the participants (Wagner *et al.*, 2012). Anonymity means the researcher does not have evidence on the identity of the participant while confidentiality means that the researcher knows the identity of the participant but keeps it a secret (Wagner *et al.*, 2012). The paragraph below is the researcher's biosketch declaring interest in the research.

I, Ramatsobane Johanna Ledwaba a Master of Management (specialising in Monitoring and Evaluation) student from University of the Witwatersrand, School of Governance am conducting this research as a partial fulfilment for my degree. The key gatekeepers have granted permission to conduct this study. Ethical clearance was obtained from University of the Witwatersrand Human Ethics Research Committee. Permission to conduct the study was granted by the Limpopo Provincial Department of Health and Mankweng hospital Chief Executive Officer (CEO). The study was not sponsored by any organisation. The research did not bring harm to any human being as information was transferred to the questionnaire without talking to patients. A unique patient identifier was allocated to each patient's information; therefore patient names remained anonymous and confidential. Research report will be submitted to the Department of Health to serve as a resource.

3.3.4 Data collection and storage

The study was conducted by reviewing medical records of adults receiving antiretroviral treatment at Mankweng Hospital using a customised questionnaire (data abstraction form). After obtaining ethical clearance from University of the Witwatersrand and permission from Limpopo provincial Department of Health the researcher sought permission to conduct the study from the hospital CEO. After the permission was granted, the researcher made an appointment with the facility manager to discuss the processes to be undertaken during the period of data collection. The facility manager with the help of the administrator clerk and data capturer provided a sampling frame containing a list of all patients who initiated treatment between 01 January 2013 and 31 December 2014. Eligible participants, those who were 18 years and older and remained in care after 12 months on treatment were computer randomised in Microsoft Excel

using unique patient identifiers. The researcher employed a questionnaire to abstract information for each patient. Collected data was entered into Microsoft excel spreadsheet, duplicated and stored on two password protected cloud drives (Google drive and Dropbox) and a computer. Completed questionnaires were stored in a locked cabinet.

3.3.5 Data processing and analysis

Data from the questionnaire was entered into excel, but prior to data entry text responses were number coded. When coding the responses, the researcher started with a small number (e.g 0) and missing data was represented with a period. The unique patient identifier for each patient medical record was entered vertically while the measured variables were entered horizontally. All the entered data was duplicated to create a backup copy of the file.

After data entry, data was cleaned to ensure accuracy. Each questionnaire was crosschecked for data entered into the database. Frequencies for variables were ran to identify errors that were committed during data capturing. Univariate analysis and binomial logistic regression were used to investigate association between variables. Bryman (2012, p. 713,717) defines univariate analysis as an "analysis of single variable at a time, [while] multivariate analysis is an examination of relationships between three or more variables". In this study, binomial logistic regression analysis was done to identify factors associated with failure to achieve viral load suppression (detectable viral load).

Frequencies and proportions were calculated to describe study participants in relation to key variables. Chi-Squared test and Fisher Exact test (if an expected cell value was less than 5) were employed to compare categorical variables between participants who obtained viral load suppression to those who did not. Continuous variables were compared using Mann-Whitney test. A confidence level of 0.05 was considered significant in all tests. During data analysis, any missing data was controlled carrying forward values (Sterne *et al.*, 2009). All the analysis was conducted in IBM SPSS Statistics software, version 19 (SPSS Inc., an IBM company, Chicago, Illinois, United States). Here we reviewed previous studies that have used this type of data analysis to answer similar research questions.

A study by Fielding and colleagues (2008) that sought to assess risk factors for sub-optimal viral load suppression at 12 months among HIV-infected adults receiving ART

in a workplace-based HIV care programme in South Africa using logistic regression model. The analysis revealed that close to three-quarters of patients achieved viral load suppression (<400 copies/ml) at 12 months. A multivariate analysis demonstrated that ten times decrease in viral load at six weeks was the strongest predictor for sub-optimal viral load suppression at 12 months. In addition, site of treatment delivery had a significant influence on viral load outcomes. High baseline viral load and advanced HIV progression were risk factors for suboptimal viral load suppression at 12 months. In conclusion, the above findings suggest further probing on factors influencing outcomes at health facilities to guide development of effective ART programmes.

Also, Wandeler *et al.* (2012) employed logistic regression model to determine factors associated with no loss to follow up after ART initiation, no returning to facility after the start of ART. The analysis revealed high rates of mortality in patients who were lost to follow up after ART enrolment. Young age and male gender were associated with the likelihood of no loss to follow up. Similarly, a study conducted by Saka *et al.* (2014) sought to determine factors associated with loss to follow up implemented multivariate logistic regression analysis to determine risk factors for outcome loss to follow up or not lost to follow up. The multivariate analysis revealed key factors associated with early loss to follow up and high mortality in these patients. Predictors of early loss to follow up were age below 35 years, presence of opportunistic infections at the start of antiretroviral treatment, living in rural area and receiving HIV treatment at public health system.

The articles utilised logistic regression analysis to determine factors and predictors of outcomes of the antiretroviral treatment programme. Quantitative studies use bivariate and binomial logistic regression analysis in cross-sectional studies to assess the relationship between viral load suppression and other co-variables (demographics, clinical characteristics or adherence). Above studies have used binomial regression with Poisson when the risk outcome is above 20% this conforms to the norms of regression analysis. Taking these into consideration, this study will accrue benefits by being able to apply the binomial regression model with Poisson regression to address the following research question: what are the factors associated with failure to achieve viral load suppression?

3.3.6 Description of the respondents

Data was abstracted from patient medical records to the questionnaire; this was done without talking to patients. Respondents were HIV-infected adults who are on antiretroviral treatment for twelve months. There were a total of 415 respondents, of which 284 were females and 131 were males. The respondents were between 18 and 70 years of age, the majority (84%) were amongst the age group 34 – 41 years. Hundred and seventy-eight were residing in a rural informal settlement (village or farm) and 161 were living in a rural formal settlement (township).

3.4 Research reliability and validity measures

Validity and reliability are key characteristics of an instrument as they are very critical in judging accuracy and meaning of the results (Bryman, 2012). Therefore it is necessary to evaluate the reliability and validity of the instruments during study design. The concept of validity refers to a judgement on how well it measures what it intended to measure (Bryman, 2012). To ensure face validity for the questionnaire used in this research was piloted to experts in the field to check it measures what it should measure. In research, external validity refers to the extent to which study findings can be inferred or generalised to a larger population (Bryman, 2012). Bryman (2012) points out that in cross-sectional designs external validity is strong if population sampling is randomly selected. On that note, this research employed random sampling method to sample respondents from a larger population.

The reliability of an instrument reflects its stability and the degree of consistency among questions (Kimberlin & Winterstein, 2008). Research reliability measures refers to the ability to repeat study findings (Bryman, 2012). Literature states the three types of reliability: stability, internal consistency and equivalence (Kimberlin & Winterstein, 2008). Stability tests the reliability of a questionnaire if it used consecutively twice or more. It uses test-retest (intra-rater test) method to test reliability. Internal consistency measures interrelatedness among items by using Cronbach alpha coefficient. Equivalence is when two or more observers study a single phenomenon at the same time. Inter-rater reliability is measured on information collected by different observers. The inter-rater reliability is commonly used to estimate reliability when data is abstracted from medical files (Allison, Wall, Spettell, Calhoun, Fargason, Kobylinski & Farmer *et al.*, 2000). Rather, the research performed test-retest method on 10 randomly selected medical records twice and utilising Cohen Kappa for nominal and interval (age, CD4,

viral load) variables (McHugh, 2012). According Landis & Koch (1977) the minimum acceptable coefficient is 0.6. Cohen Kappa co-efficient(s) for the variables assessed were age, κ=0.65; CD4, κ=1; clinical stage, κ=1; baseline ART, κ=1; viral load κ=0.66; adherence counselling (undetermined, all values were constant) and type of adherence support, κ=0.60. Overall, all the tested variables obtained an excellent agreement.

3.5 Research limitations

This study has the following methodological limitations. First, the ART facility was purposively selected; therefore, it may not represent other treatment sites in Limpopo province. Second, due to time constrains evaluation was only conducted at one facility. Therefore, the study findings may not be generalised to all settings but only limited to the population at the facility. Third, the study collected data by transferring information from medical records to a questionnaire; this procedure has inherent limitations of data incompleteness as observed by missing data for some variables. The missing data have affected the statistical power of the study resulting in a larger p-value. However, 95 per cent confidence intervals were also reported. Fourth, the cross-sectional design was selected for collecting data for this study. However, this design prohibits definitive statements regarding the direction of associations among study variables. Lastly, the study lacks ecological validity because it uses a questionnaire that does not capture the daily life conditions of the studied participants.

4 PRESENTATION OF RESEARCH FINDINGS

The primary objective of this study is to determine proportion of HIV infected adults who achieved viral load suppression in the first year of antiretroviral treatment. The second objective is to determine factors associated with failure to achieve viral load suppression. The research found that so far no literature is available that report viral load outcomes in Limpopo Province. Therefore, this chapter is set out to present and discuss findings to the first research question (Section 4.1) — what is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months? This discussion is accompanied by its hypothesis; there are high proportions of adults with viral load suppression among people taking antiretroviral treatment for 12 month. Section 4.2 sought to share and discuss findings to the second research question — what are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months? This section further discusses the hypothesis that states that multiple factors are associated with failure to achieve viral load suppression. Lastly, Section 4.3 provides conclusions to the answers for research questions one and two.

4.1 Proportions of adults with viral load suppression among people who have been taking antiretroviral treatment for 12 months

Table 2 describes baseline characteristics of people who achieved viral load suppression and those who did not achieve viral load suppression most importantly highlighting the differences and associations between the two groups.

The goal of the antiretroviral treatment is to achieve viral load suppression, which is defined as a threshold where virus levels remain undetectable (Gagnon & Guta, 2014). This outcome was realised in 78 per cent of the people who were taking antiretroviral treatment for 12 months, while 22 per cent failed to achieve viral load suppression. The 78 per cent suppression rate was comparable to another study conducted in rural settings of KwaZulu-Natal (Mutevedzi *et al.*, 2010). A study that was conducted in Canada using a similar viral load threshold reported better outcomes (86%) (Cescon *et al.*, 2011). Another study conducted in South Africa reported 71.5 per cent suppression using a higher viral load cut-off below 400 copies per ml at 12 months. A strict cut-off (< 50 copies per ml) was used for this research to be able to identify flaws within the

programme. However, this also makes it challenging to make comparison to other programmes that selected a different threshold.

Among the people who visited the primary health clinic, Phela-o-Phedise, between January 2013 and December 2014 majority were females (67%) and 69 per cent of the people were in the primary stage of the disease (WHO clinical stage 1&II) while 31 per cent had advanced disease progression (WHO clinical stage III&IV). This trend is consistent to a study conducted in Togo on people who started treatment between 2008 and 2011 (Saka *et al.*, 2014). However, this was different to studies conducted before 2010 in Southern Africa and Vietnam, in which the majority of people who visited the health facility for the first time were at the advanced stage of HIV (Fatti *et al.*, 2010; Fielding *et al.*, 2008; Nglazi *et al.*, 2011; Nguyen *et al.*, 2013; Wandeler *et al.*, 2012). This finding suggests that in the last decade people sought HIV care and treatment when they were in their advanced stages of the disease. However, recent studies show a change in trend in this group of people.

Table 2: Proportions of baseline characteristics in total and stratified by viral load suppression status

Variables	Total n (%)	Suppressed viral load, n (%)		p-value
		YES 247 (78%)	NO 68 (22%)	
Sex				
Female	277 (67)	162(77)	48 (23)	0.439
Male	138 (33)	85 (81)	20 (19)	
Median age, years	37	38	39	0.225
Locality type				
Rural informal	178 (52)	107 (80)	26 (20)	0.660
Rural formal	161 (48)	97 (78)	27 (22)	
WHO clinical stage				
I&II	242 (69)	143 (76)	45 (24)	0.397
III&IV	111 (31)	67 (81)	16 (19)	
Baseline CD4 count (x 10^6/l)				
<350	359 (91)	211(79)	58 (21)	0.313
>350	34 (9)	23 (67)	3 (33)	
TB co-infection				
no	344 (83)	203 (77)	60 (23)	0.284
yes	69 (17)	42 (84)	8 (16)	
TB treatment outcome				
on treatment	60 (87)	36 (82%)	8 (18%)	0.572
completed/defaulted	9 (13)	4 (100%)	0 (0%)	
Other opportunistic infections				
no	362 (88)	223 (79)	58 (21)	0.443
yes	49 (12)	22 (73)	8 (27)	
Baseline ART prescription				
1-pill a day	402 (97)	191 (78)	53 (22)	0.467
3-pills a day	13 (3)	56 (91)	15 (9)	
Adherence counseling				
no	2 (1)	0 (0)	2 (100)	0.006
yes	358 (99)	221 (79)	58 (21)	
Type of adherence support				
Buddy or home support	192 (54)	114 (81)	26 (19)	0.355
none	165 (46)	105 (77)	31 (23)	

People who sought care and treatment during that period majority (91%) were sick as they started treatment with a CD4 count (a measure of immune system) below 350. These findings were also seen in similar studies conducted in the Sub-Saharan Africa (Fox et al., 2012; Saka et al., 2014). People living with HIV often get infected with Tuberculosis (TB) because they have a weakened immune system (Nglazi et al., 2011). In this study few individuals (15%) were co-infected with TB, of these 87% were on treatment and 13 per cent completed treatment, this is in line with South African treatment guidelines that recommend early initiation of TB treatment in people co-infected with TB. In 2013, patients with CD4 below 350 were initiated on either 1-pill a day treatment or 3-pills a day treatment (SA treatment guidelines, 2013). Here, a large proportion (97%) of the people were prescribed 1-pill a day treatment. The 1-pill per day prescription was effected to reduce pill burden in patients taking long-term treatment leading to improved adherence to long-term treatment, as reported in other studies (Chesney, 2000; Sax, Meyers, Mugavero, & Davis, 2012). In accordance to South African treatment guidelines, almost everyone (99%) received pre-ART adherence counselling. Although it was shown that adherence support structures improve treatment efficacy (Wilkinson, 2013), close to half (46%) of the people did not have any form of support structure either at home or in the community while the remaining individuals (54%) had a treatment buddy.

Twenty-two per cent of the people who were prescribed one pill a day failed to achieve viral load suppression compared to those who were on 3-pills a day treatment (9%). A quarter of people (24%) who were at the primary stage of the disease failed to achieve viral load suppression at 12 months. This was similar to a study conducted in South Africa (Fielding et al., 2008) and Swaziland (Jobanputra et al., 2015). In addition, 21 per cent of them had a CD4 count below 350. This is comparable to findings by Jobanputra et al. (2015). Among the people who were co-infected with TB, 16 per cent failed to achieve viral suppression compared to 84 per cent that achieved viral load suppression. Although there were noticeable differences in baseline characteristics of people who achieved viral load suppression and those who did not, the difference was not significant. Overall, there was no significant difference according to gender, age, locality type ($p=0.660$), baseline CD4 count ($p=0.081$), WHO clinical stage ($p=0.397$), TB infection status ($p=0.284$), opportunistic infections ($p=0.443$), baseline antiretroviral treatment ($p=0.915$), and type of adherence support ($p=0.355$), except for prior antiretroviral treatment adherence counselling ($p=0.001$) among people who achieved

viral load suppression and those that did not achieve viral load suppression. The findings show that there was evidence of high proportions of people who achieved viral load suppression among the people who were taking antiretroviral treatment for 12 months.

Although this is beyond the scope of the study, of 1 061 people who initiated antiretroviral treatment 64 per cent remained in care 12 months after ART initiation, compared to the proportion of patients who were lost to follow up (25%), transferred out (9%) and died (1%).

4.2 Factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months

This programmatic evaluation of outcomes of the antiretroviral treatment intervention has identified factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months. Table 3 shows risk factors associated with failure to achieve viral load. Risk factors were made up of demographics, clinical and treatment characteristics as well as adherence characteristics. Although the majority of the people were females, the male sex was more likely to fail to achieve viral load suppression (RR: 1.21; 95% CI: 0.68 – 2.14), this is in contrast with an evaluation study conducted in Canada and Asia that have shown that females were at risk of failing to achieve viral load suppression (Cescon *et al.*, 2011; Huang *et al.*, 2015; Syed *et al.*, 2015). Though, the dissimilarity may be due to differences in population characteristics the research still highlights the need of interventions that will engage males from our study into HIV care and treatment early.

Table 3: Risk factors associated with failure to achieve viral load suppression

Variable	Relative Risk	95% Confidence Interval	p-value
Male Sex	1.21	0.68 – 2.14	0.509
Age	0.80	0.61 – 1.06	0.125
Locality type	1.06	0.62 - 1.81	0.824
Baseline CD4 count (< 350 x10^6/l)	2.09	0.71 – 6.14	0.178
WHO clinical stage I &II	1.48	0.75 – 2.91	0.248
WHO clinical stage III	1.06	0.51 - 2.18	0.865
WHO clinical stage IV	0.65	0.15 - 2.85	0.575
TB co-infection status	0.83	0.37 – 1.85	0.748
Other opportunistic infections	1.48	0.74 - 2.96	0.257
Baseline ART (3-pill per day)	1.43	0.77 – 2.64	0.253
Lack of treatment support	1.58	0.91 – 2.73	0.097

People who were living in a village, farm or a township were not associated with failure to attain viral suppression (RR: 1.06; 95% CI: 0.62 – 1.81). Several previous studies have found no significant difference in viral load suppression between people living in rural and urban areas of South Carolina in USA (Weissman et al., 2015) and KwaZulu-Natal (Mutevedzi et al., 2010). People who were in the primary stage of the disease showed a trend towards failure to achieve viral load suppression (RR: 1.48, 95% CI: 0.75 – 2.91). On contrary, people who have reached the advanced stage of the disease were less likely fail to achieve viral load suppression (RR: 0.69; 95% CI: 0.15 – 2.85). This differs to other studies that have shown that people in the advanced stage of the disease were more likely fail to achieve viral load suppression (Fielding et al., 2008; Jobanputra et al., 2015; Nglazi et al., 2011). People who have failed to achieve viral load suppression tended to have advanced immune suppression (CD4 below 350) (RR: 2.09; 95% CI: 0.71 – 6.14, p=0.178), although this was not statistically significant. This is consistent with other studies conducted in South Africa and Swaziland (Jobanputra et al., 2015; Nglazi et al., 2011). Also, a large randomised controlled trial have proven that people who initiate treatment when they are ill (CD4 count below 350) have a higher risk of developing serious illnesses even death (Lundgren et al., 2015).

TB co-infection decreased the risk of failing to achieve viral load suppression (RR: 0.83: 95% CI: 0.37 – 1.85), while people with opportunistic illnesses showed a trend towards failing to achieve viral load suppression (RR: 1.48; 95% CI: 0.74 – 2.96). This was different to what was observed in Swaziland, where the opposite what was reported (Jobanputra et al., 2015). In this study, people who were prescribed three-pill per day

treatment were more likely to fail to achieve viral load suppression (RR: 1.43; 95% CI: 0.77 – 2.64). This is consistent to a study by Cescon et al. (2011) that showed that combination ART (3-pill treatment) showed a trend towards failure to achieve viral load suppression. Selection of baseline antiretroviral treatment is important to treatment adherence. Hence, government is switching three-pill regimen with a 1-pill fixed dose single tablet. Also, people who did not have social support had a risk of failing to achieve to viral load suppression this is consistent with a previous study from Kwazulu-Natal that showed that adherence support structures improved viral load suppression (Wilkinson, 2013). Although these factors showed a trend towards failure to achieve viral load suppression, the estimates were not statistically significant.

4.3 Conclusion

Among the people on antiretroviral treatment at Phela-O-Phedise facility in Mankweng, 78 per cent suppressed viral load at 12 month following the start of antiretroviral treatment, while 22 per cent failed to achieve viral load suppression. The majority of people who visited the facility during that time were females and 69 per cent were in the primary stage of the disease, while 31% were in the advanced stage of the HIV disease (AIDS). The males had an increased probability of failing to achieve viral load suppression. Most notably, the majority of the people were sick (CD4 count below 350) and were most likely fail to suppress viral load. On the contrary, people who were on the advanced stage of HIV had less probability of failing to suppress viral load. There was no association between type of residence and viral load suppression. However, people who were co-infected with TB have a less likelihood of failing to suppress viral load, mainly because most of them received TB treatment. On the contrary, patients who had opportunistic infections, prescribed 3-pill containing treatment and did not have any form of treatment support were more likely to fail to achieve viral load suppression.

5 DISCUSSION OF RESULTS

This chapter exhibits interpretation of the research findings on the basis of a theoretical framework that has been outlined in Section 2.6. The interpretation is divided into two sections; the first one aims to interpret findings from the first research question—proportions of adults with viral load suppression among people who have been taking antiretroviral treatment for 12 months and the second part is focused on the second research question, factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months. The interpretation of findings is performed by first the outlining the theory that will be used to interpret the findings followed by the findings then the implications.

5.1 Proportions of adults with viral load suppression among people who have been taking antiretroviral treatment for 12 months

As it was indicated in Section 4.1, there was evidence of viral load suppression in people who were on antiretroviral treatment for 12 months at Mankweng, although almost a quarter of them did not achieve the intended outcome. The outcome is driven by the theory of change that underpins the intervention. According to the theory of change "…activities A1, A2, and A3, if properly implemented (and with the ongoing presence of contextual factors X1, X2, and X3), should lead to outcomes O1, O2 and O3; and, if these activities, contextual supports, and outcomes all occur more or less as expected, the outcomes will be attributable to the intervention" (Connell & Kubisch, 1998, p. 2). In addition, the results chain is a tool used to measure performance as it provides answers to two questions; whether the invested resources resulted in intended outputs and whether there is tangible progress on outcomes and impact (WHO, n.d).

Under the assumption that treatment adherence was mentioned the intervention was able to produce the intended outcome (viral load suppression) at 78 per cent. However, the intervention's effectiveness was not 100 per cent, suggesting that the assumption was violated in some individuals. How the people achieved viral load suppression is explained the results chain. The activities that led to the outcome for this intervention—adherence counselling, laboratory services (CD4 count and viral load tests), and prescription of antiretroviral drugs were performed as indicated on Table 2. This finding implies that implementation of the intervention was efficient and it led to good outcomes. The turnout of events on the results chain shows that the chain was not

broken. As a result, all the assumed inputs, performed activities, and outputs have resulted in the intended outcome of viral load suppression; however this was not true for everyone who was sampled. This suggests the assumption did not hold for everyone. Regrettably, adherence levels were not measured hence we cannot say to what extent the assumption was violated. Because outcomes are markers of the success of the intervention, and 78 per cent was achieved the intervention was sub-optimally successful in this setting.

5.2 Factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months

This section exhibits interpretation of the research findings that relate to the factors that have an influence on viral load suppression. The factors discussed in this section include patient characteristics, clinical characteristics and adherence characteristics.

The theory of gender and health hypothesise that the quest for men to sustain authoritative status puts their health at risk (Connell & Connell, 2005). This is consistent with literature that reports that the cultural nurturing of male masculinity tends to deter men from attending health facilities (Verde *et al.*, 2003) and this phenomena makes them vulnerable to HIV. The findings from this research revealed that majority of females visited the facility compared to males. Most importantly males were more likely to have detectable viral load compared to females. Therefore, it is possible that this pursuit for men to maintain and show 'real man' characteristics deter them from visiting the facility but they only visit a health facility when they are too sick and that leave them at risk of failure to suppress viral load. As alluded by the health belief model that a person's belief in a personal risk of an illness together with a person's belief in the performance of the health behaviour predict the likelihood that the person will adopt the behaviour (Rosenstock *et al.*, 1988). The vulnerability to HIV in men could be driven by the lack of belief in personal threat to HIV and lack of perception of the severity of the illness. The implication of this finding is that efforts need to be made to encourage and engage males into HIV care and treatment.

The study also shows that a low baseline CD4 count (below 350) is a risk factor for failure to achieve viral load suppression after 12 months of antiretroviral treatment initiation. Generally, people with a low CD4 count are very sick and that means that this group of people sought HIV care and treatment late. The health belief model suggest

that a person's belief in a personal risk of an illness together with a person's belief in the performance of the health behaviour predict the likelihood that the person will adopt the behaviour (Rosenstock *et al.*, 1988). According to the model, this group of individuals lacked the perception on the risk of HIV, which influenced their perception gravity of the disease when they left the disease untreated on hence they did not adopt the behaviour of seeking care early. This finding implies that there is a need for scale up of early HIV diagnosis that will lead to early treatment, thus making sure that the antiretroviral treatment intervention reaches all the people that need it.

As shown in Section 4.2, people who visited the facility in the early stages of illness (clinical stage I&II) were more likely to fail to suppress viral load. The theory of planned behaviour suggest that behaviours are most likely to be influenced when individuals have positive attitudes about the behaviour; the behaviour is viewed positively by key people who influence the individual (subjective norm); and the individual has a sense that individuals can control the behaviour (perceived behavioural control) (Sutton, 1997). This group of patients still feels well because at this stage of the disease they do not show any symptoms of the disease, therefore it is hypothesised that after 12 months of treatment they would fair better than those who are at the advanced stages of the disease. However, this was not the case in this study. Based on the model this group seems to lack the right attitude that adherence result in better health leading to failure to adopt adherence behaviour. This finding implies that this group of people requires intensified adherence counselling during antiretroviral treatment. Table 2 indicated that people who received three pill containing treatment and those who lacked social support were more likely to fail to suppress viral load. According to the theory of planned behaviour the lack of subjective norm or motivation is highlighted in people who did not have people (treatment buddies or family) whom they know that they belief they always take treatment accurately, hence they lost the intention to adhere to treatment. This implies that the individuals need motivation to comply to treatment correctly this can be done through intensified adherence counselling.

Based on the theory of planned behaviour, prescription of three-pill containing treatment and occurrence of opportunistic infections were barriers to adoption of the adherence behaviour. This group experienced difficulty in taking treatment because of the 3-pill burden and being too ill from other illnesses hence they did not adopt treatment adherence behaviour. The national treatment guidelines recommend a one pill

fixed dose and preventative treatment for other illnesses. Therefore, this finding implies that there is a need for continued training of health care professionals to improve adherence to the guidelines.

6 SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

This chapter encapsulates the research taking into consideration the findings and the conclusion that reaffirms the purpose of the study. It further shares the recommendations with respect to the overall study.

6.1 Summary

The study is set to assess outcomes of the antiretroviral treatment intervention in Mankweng. HIV viral load suppression is a key outcome indicator for intervention performance and in the context of public health concerns, it provides an insight into viral load suppression rates in a community in order to prevent or reduce continuous HIV transmissions. Mankweng is located in the Capricorn District of Limpopo Province. It is a rural area, which is made up of a township and six surrounding villages. The general academic literature on this subject, specifically in the context of rural Limpopo is limited. The study sought to answer two research questions:

1. What is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months?
2. What are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months?

The study randomly sampled medical records of patients who were on treatment for 12 months and transferred information into a questionnaire. The study further used a logistic regression model to determine risk factors that alluded to failure to suppress viral load. Theoretical frameworks for HIV treatment adherence are revisited in order to further understand the interaction of ART adherence and failure to achieve viral load suppression. Treatment adherence is drawn from theories of psychological behaviour and self-regulation models. The health belief model, theory of planned behaviour and theory of gender and health were used to interpret findings of the study. In addition, the theory of change and the results chain were employed to assess the performance of the intervention.

The main empirical findings are in Chapter 4 and were summarised within the respective of the research questions. This section synthesises the empirical findings to answer the study's two research questions.

1) *What is the proportion of adults with viral load suppression among people taking antiretroviral treatment for 12 months?*

Hypothesis: There are high proportions of adults with viral load suppression among people taking antiretroviral treatment for 12 month.

Viral load suppression was evident in 78 per cent of the people who were on antiretroviral treatment at Phela-O-Phedise primary health clinic. However, 22 per cent failed to achieve viral load suppression. Overall, the study refute the hypothesis that they were differences in demographics (age, sex and place of residence), clinical characteristics (baseline antiretroviral treatment, baseline CD4 count, clinical stage, TB co-infection and infection of other illnesses) and adherence characteristics (social support) between those who have achieved viral suppression and those who did not achieve viral load suppression. But there was significant difference in people who received adherence counselling and those who did not receive adherence counselling.

2) *What are the factors associated with failure to achieve viral load suppression among people on antiretroviral treatment for 12 months?*

Hypothesis: Multiple factors are associated with failure to achieve viral load suppression.

The male sex has a probability of failing to achieve viral load suppression because men want to maintain the 'real man' character. Most notably, people who are too sick (CD4 count below 350) and those in the early stages of the disease (clinical stage I&II) are also likely to fail to suppress viral load. People who had other illnesses were more likely to fail to suppress viral load. Moreover, individuals that were prescribed 3-pill containing regimen and did not have any form of social support were more likely to fail to achieve viral load suppression. On the contrary, people who were on the advanced stage of HIV had less probability of failing to suppress viral load as well as people who were co-infected with TB had less probability of failing to suppress viral load. There was no association between type of residence and viral load suppression. However, the estimates of the above mentioned risk factors were not statistically significant.

6.2 Conclusions

The findings show that the antiretroviral treatment intervention in Mankweng is successful as it achieved its intended outcome. The study shows that implementation of antiretroviral treatment intervention at primary health clinics in rural parts of Limpopo

is feasible, as it produced viral load outcomes that were comparable to other evaluation studies conducted in other parts of South Africa and elsewhere. The study supports the scale up and implementation of the intervention to other rural settings. However, the relatively high rates of unsuppressed viral loads is concerning in a country that is moving towards universal access of antiretroviral treatment. Efforts are needed to alleviate failure to suppress viral load for individuals who are on antiretroviral treatment.

The findings suggest that the male sex needs focussed interventions to promote their early engagement into the HIV continuum of care. Further, this study highlights the need for early diagnosis for HIV through scaling up of the HIV testing so that the antiretroviral treatment can reach all those that need it. Moreover, the study identified risk factors that showed a trend of likelihood towards failure to suppress viral load. On the basis of the discussed theoretical framework the findings affirm the theory that failure to suppress viral load is highly associated to suboptimal adherence to treatment.

6.3 Recommendations

Based on the findings viral load suppression is achievable provided individuals remain adherent to treatment. Currently adherence counselling is offered prior to treatment initiation in order to psychologically prepare patients for life long treatment also in selective cases where the health worker suspects a case of poor adherence. However, theoretical arguments highlight the need for regular intensified (step up) adherence counselling sessions for people who are on treatment. Therefore, adherence counselling should be implemented more often during treatment.

The national antiretroviral treatment guidelines recommend initiation at a CD4 below 500 and most of the individuals had a CD4 below 350. This finding highlights possible variation in the use of the guidelines. Another variation in the implementation of the guidelines was observed in individuals who were taking three pill containing treatment versus one pill fixed dose treatment. Therefore, there is a need for continuous capacity building of health professionals on the national treatment guidelines especially when there are amendments.

To generate achievable policy strategies and development targets with regards to HIV treatment, there is a need for more studies to allow further assessment of other dimensions of the intervention. Exploring the following as future research strategies can facilitate the attainment of the goal of universal coverage of the antiretroviral treatment

in order to prevent HIV transmissions as well as achievement of the UNAIDS 90-90-90 initiative targets (an initiative to help end HIV epidemic by 2030):

1. More research on all stages (diagnosis, linkage to care and retention) of the HIV continuum of care is required.
2. The national viral load suppression targets needs to be measured inclusive of all the provinces.
3. A national monitoring and evaluation system is supported by good quality data in order to improve the intervention and to also inform decision makers. Therefore, continuous mentoring and technical support of facility staff on good data qualities need to be provided at all the levels that generate data.

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Appendix 1.1: Data Collection Instrument

Patient viral load monitoring

1. DEMOGRAPHIC CHARACTERISTICS

1.1 Patient Identifier

1.2 Sex

☐ Male

☐ Female

1.3 Age

1.4 Marital Status

☐ Single

☐ Married

☐ Divorced

☐ Widowed

☐ Other:

1.5 Highest education level

☐ Tertiary

☐ Secondary

☐ Primary

☐ None

1.6 Employment Status

☐ Employed

☐ Unemployed

1.7 Residential area

☐ Rural

☐ Semi-Urban

☐ Urban

2. CLINICAL CHARACTERISTICS

2.1 Baseline CD4 cell count [cells/ul]

2.2 Baseline WHO clinical staging

☐ Stage 1

☐ Stage 2

☐ Stage 3

☐ Stage 4

☐ Unknown

2.3 TB infection

☐ Yes

☐ No

2.4 Patient currently on

☐ TB treatment

☐ Completed treatment

☐ Defaulted

2.5 Any other opportunistic infections

3. TREATMENT HISTORY

3.1 ART initiation date [DD/MM/YYYY]

3.2 Initial ART Regimen

3.3 Current ART Regimen

3.4 Any drug switch

3.5 Reason for switch

4. VIRAL LOAD MONITORING

4.1 Baseline viral load [copies/ml]

4.2 Viral load follow-up (12 months)

Visit date [DD/MM/YYYY]; VL [copies/ml]

Visit date [DD/MM/YYYY]; VL [copies/ml]

5. ADHERENCE INTERVENTION

5.1 ART adherence support enrolment date [DD/MM/YYYY]

5.2 Type of adherence support

☐ Adherence counselling

☐ Treatment buddies

☐ Adherence support group

☐ Community worker adherence group

☐ None

5.3 Patient ever missed follow-up visit in the past 12 months

☐ Once

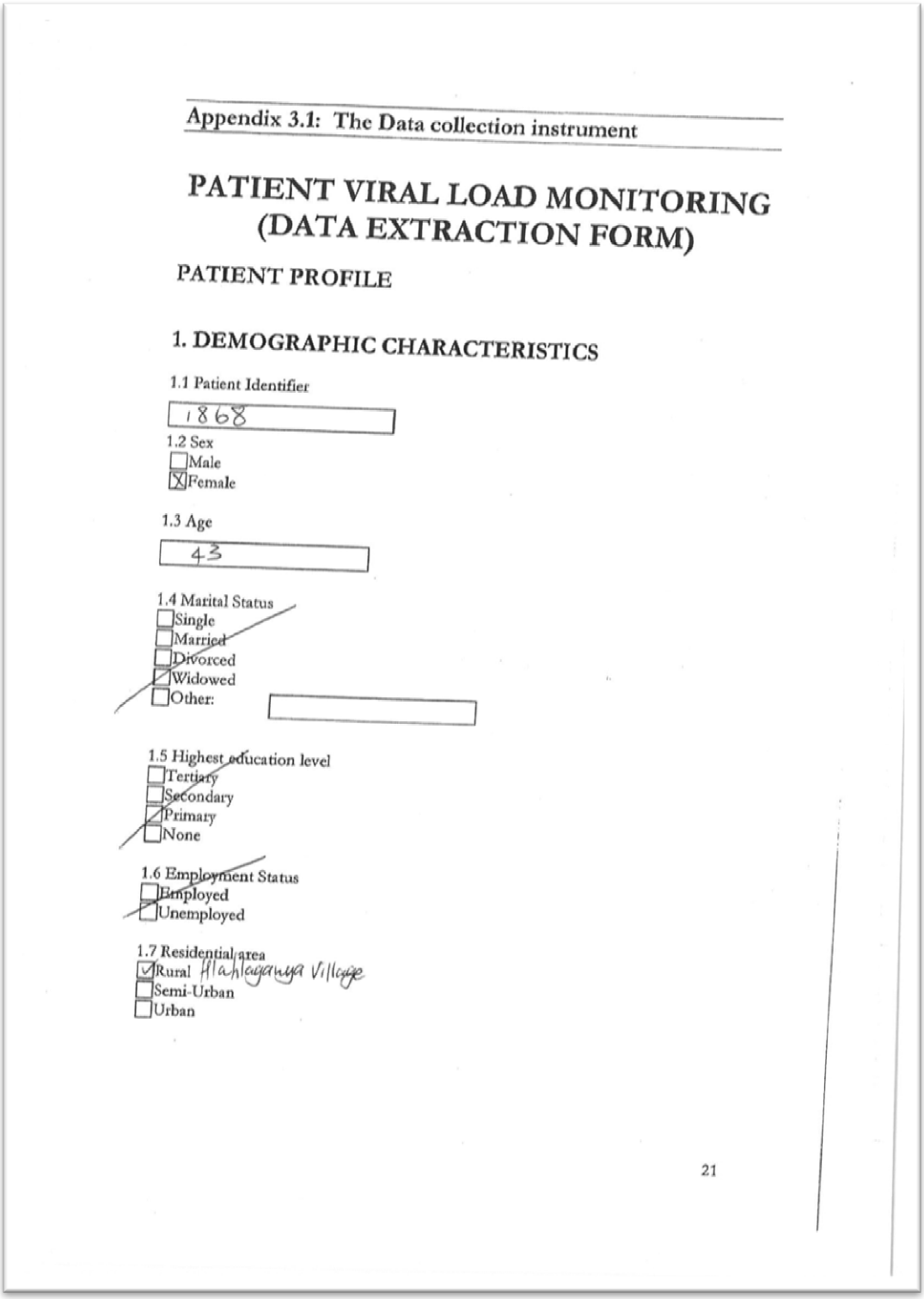
☐ Twice

☐ More than 3 times

☐ Never

5.4 Facility reported reasons for patient's poor ART adherence (if any)

Appendix 1.2: Completed questionnaire



Appendix 3.1: The Data collection instrument

PATIENT VIRAL LOAD MONITORING
(DATA EXTRACTION FORM)

PATIENT PROFILE

1. DEMOGRAPHIC CHARACTERISTICS

1.1 Patient Identifier

1868

1.2 Sex

☐ Male
☒ Female

1.3 Age

43

1.4 Marital Status

☐ Single
☐ Married
☐ Divorced
☑ Widowed
☐ Other:

1.5 Highest education level

☐ Tertiary
☐ Secondary
☑ Primary
☐ None

1.6 Employment Status

☐ Employed
☐ Unemployed

1.7 Residential area

☑ Rural Hlahlaganya Village
☐ Semi-Urban
☐ Urban

21

4. VIRAL LOAD MONITORING

4.1 Baseline viral load [copies/ml]

4.2 Viral load follow-up (12 months)

Visit date [DD/MM/YYYY]; VL [copies/ml]

18/11/2013	15 807

Visit date [DD/MM/YYYY]; VL [copies/ml]

20/06/2014	30 516

5. ADHERENCE INTERVENTION

5.1 ART adherence support enrolment date [DD/MM/YYYY]

24/04/2013

5.2 Type of adherence support

- ☐ Adherence counselling
- ☑ Treatment buddies
- ☐ Adherence support group
- ☐ Community worker adherence group
- ☐ None

5.3 Patient ever missed follow-up visit in the past 12 months

- ☐ Once
- ☐ Twice
- ☐ More than 3 times
- ☑ Never

5.4 Facility reported reasons for patient's poor ART adherence (if any)

patient admit no taking medication
no reason.

Appendix 1.3: Biosketch

I, Johanna Ledwaba a Master of Management (specialising in monitoring and evaluation) student from University of Witwatersrand, School of governance am conducting this research as a partial fulfilment for my degree.

I am conducting this research to assess outcomes of the antiretroviral treatment programme in Mankweng hospital, Limpopo province. A sponsor or any other organisation does not fund this study; this is solely my research under the supervision of University of the Witwatersrand. The research will bring no harm to any human being, as data will be abstracted from patient medical records. A unique patient identifier allocated to each patient file will be used to collect data. Therefore, patient names will remain anonymous, as it is not requested on the questionnaire. The researcher have obtained ethical clearance and granted permission to conduct the study by Limpopo Department of Health and the Mankweng hospital Chief Executive Officer. Collected data will remain confidential and the questionnaire will be filed in a locked cabinet. Research report will be submitted to the Department of Health to serve as a resource.

Appendix 1.4: Human Ethics Clearance certificate and relevant study approvals

R14/49 Ms Ramatsobane Johanna Ledwaba

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M151016

NAME: (Principal Investigator)	Ms Ramatsobane Johanna Ledwaba
DEPARTMENT:	School of Governance Phela-o-Phedise Clinic at Mankweng Hospital
PROJECT TITLE:	Outcomes of the Antiretroviral Treatment Programme in Mankweng Hospital
DATE CONSIDERED:	30/10/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Kambidima Wotela
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	30/10/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Enquiries: Latif Shamila Ref:4/2/2

Ledwaba RJ
Human Research Ethics Committee

Greetings,

RE: Outcomes of the Antiretroviral Treatment Programme in Mankweng Hospital

The above matter refers.

1. Permission to conduct the above mentioned study is hereby granted.
2. Kindly be informed that:-
    - Research must be loaded on the NHRD site (http://nhrd.hst.org.za) by the researcher.
    - Further arrangement should be made with the targeted institutions.
    - In the course of your study there should be no action that disrupts the services.
    - After completion of the study, a copy should be submitted to the Department to serve as a resource.
    - The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
    - The above approval is valid for a 3 year period.
    - If the proposal has been amended, a new approval should be sought from the Department of Health.

Your cooperation will be highly appreciated.

Head of Department

18/12/15
Date

18 College Street, Polokwane, 0700, Private Bag x9302, POLOKWANE, 0700
Tel: (015) 293 6000, Fax: (015) 293 6211/20 Website: http/www.limpopo.gov.za

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

MANKWENG HOSPITAL

Ref: S5/3/1/2

Enq: Makola M.M

From: HR Utilization and Capacity Development

Date: 13 January 2016

To: Ledwaba R.J
University of Witwatersrand
Johannesburg

PERMISSION TO CONDUCT RESEARCH AT MANKWENG HOSPITAL: LEDWABA R.J

1. The above matter has reference.
2. This is to confirm that Ledwaba R.J has been granted permission to conduct research on "Outcomes of the Antiretroviral Treatment Programme in Mankweng Hospital".
3. She will be conducting research as from Monday, 18 January 2016 to Thursday, 31 March 2016.
4. Attached please find his application letter, Human Research Ethics Committee (Medical) Clearance certificate(University of Witwatersrand), approval letter from Provincial Office and Research proposal, Informed consent for adult patients attending at Mankweng Hospital for HIV treatment and care and Data collection tool.

Thanking you in advance

Chief Executive Officer

2016/01/14
Date

Department Of Health
Mankweng Hospital
Recieved: Nkhue
2016 -01- 13
Office No. 106
Tel: 015 286 1016
LIMPOPO PROVINCE