VIEWS OF PROFESSIONAL NURSES REGARDING THE NEW ANTIRETROVIRAL THERAPY DRUG TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR IN SELECTED CLINICS OF LIMPOPO PROVINCE

by

RAMUSILEI FHULULEDZANI INNOCENTIA

STUDENT NUMBER: 11605855

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Department of Public Health

University of Venda

SUPERISOR: DR MABUNDA J.T

CO-SUPERVISOR: DR TSHIVHASE S.E

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DECLARATION

I Ramusilei Fhululedzani Innocentia, hereby declare that the mini dissertation titled **'*Views of professional nurses regarding the new antiretroviral therapy drug tenofovir, lamivudine and dolutegravir in selected clinics of Limpopo Province*'** submitted by me, during this or other university has not been submitted previously for a degree, that's my very own work in design and execution, and that all reference materials included has been duly acknowledged.

Signature:  Date: 20 August 2023

DEDICATION

This study is dedicated to my beloved sons Lupfumo and Dziphathutshedzo Muligwe for keeping me motivated. My Parents Ramusilei TP and Ramusilei ME, my siblings, and my lovely mother-in-law Vho-Sarah Muligwe who takes care of my sons when I am at work and pursuing my studies for the love and support. My dear husband Fulufhelo Muligwe for the love, support, and encouragement.

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ACRONYMS AND ABBREVIATIONS

3TC:	Lamivudine
AE:	Adverse Event
AIDS:	Acquired Immune Deficiency Syndrome
ART:	Antiretroviral Therapy
DTG:	Dolutegravir
ECDC:	European Center for Disease prevention and Control
EFV:	Efavirenz
FDC:	Fixed-Dose Combination
FTC:	Emtricitabine
HAART:	Highly Active Antiretroviral Therapy
HIV:	Human Immunodeficiency Virus
MOHW:	Ministry of Health and Wellness
NIAID:	National Institute of Allergy and Infectious Diseases
NIMART:	Nurse-Initiated Management for Antiretroviral Therapy
NNRTI:	Non-nucleoside Reverse Transcriptase Inhibitor
PEPFAR:	President's Emergency Plan for AIDS Relief
PI:	Protease Inhibitor
TB:	Tuberculosis
TDF:	Tenofovir Disoproxil Fumarate
TEE:	Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz

TLD:	Tenofovir Disoproxil Fumarate, Lamivudine and Dolutegravir
UNAIDS:	United Nations on Program for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
USAIDS:	United States for Acquired Immuno-Deficiency Syndrome
VL:	Viral Load
WHO:	World Health Organization

ABSTRACT

Introduction: Tenofovir, Lamivudine and Dolutegravir, also known as TLD drug, is a new fixed dose combination Antiretroviral therapy drug that is taken once daily by individuals living with the Human Immunodeficiency Virus. TLD drug has demonstrated dominance over efavirenz and antiviral drug dependent regimens with greater tolerability, rapid viral load suppression, and a high genetic barrier-resistance. **Purpose:** The purpose of the study was to explore the views of professional nurses regarding the new Antiretroviral therapy drug TLD in selected clinics in Sekhukhune district, Limpopo Province. **Methodology**: The study used the qualitative exploratory descriptive design. Permission was obtained from the participants before the study commenced. Fourteen professional nurses participated in the study, and non-probability convenience sampling was used. Riba, Motlolo and Selala clinic were chosen as they are near the mining industry and many of the patients are from the mines. An unstructured interview guide was used as an instrument to provide directions when collecting data and the central question was asked, followed by probing questions. A pre-test using four participants was conducted to evaluate the feasibility of the study. An unstructured interview was conducted to gather information using a voice recorder and field notes until saturation occurred. Tesch's Open Coding Steps were used to analyze the data. Measures to ensure trustworthiness were followed to ensure the quality of data. Ethics were considered to protect the participants from any harm. **Results:** According to the findings, professional nurses had favorable opinions of TLD since they had seen it work on variety of patients. TLD drug have more benefits: It is time convenient, can be used in conjunction with other medications, reduced pill burden, quick viral load suppression, suitability of drug to all patients and low resistance build up. **Recommendations:** The study recommended that the department should provide guidelines and policies to facilities before implementing changes for health providers to be well informed and to conduct workshops for professional nurses to impart knowledge on current changes in treatments. **Conclusion:** The professional nurses have a positive views regarding TLD drug and support it hundred percent.

Keywords: Antiretroviral drugs, Professional nurse, Tenofovir, Lamivudine and Dolutegravir (TLD), Views.

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OVERVIEW OF THE STUDY

1.1. INTRODUCTION

Tenofovir, Lamivudine and Dolutegravir, also known as TLD drug, is the new fixed dose combination antiretroviral therapy drug that is taken once daily by individuals living with the Human Immunodeficiency Virus (HIV). TLD drug demonstrated dominance over efavirenz and antiviral agent (PI) dependent regimens, with greater tolerability, rapid viral load (VL) suppression and a high genetic-resistance barrier. This clinical evidence, combined with the availability of a convenient and cost-saving TLD drug that can be used in adolescents and adult populations, makes it an optimal regimen for patients on first-line antiretroviral therapy (World Health Organization, 2016). According to the Ministry of Health and Wellness(MOHW), the decision to shift patients to TLD drug was driven by the desire to reduce pill burden and provide rapid viral load suppression, with fewer side effects and greater potency, as TLD drug reduces the possibility of drug resistance (USAID Global Health Supply Chain Progress, 2019). The Ministry of Health and Wellness(MOHW) has developed two phases: phase one focuses on new treatment initiations and shifting patients that have been using the two-pill combination, Tenofovir/Emtricitabine(TDF/FTC) to TLD drug and phase two shifts patients who are using legacy drugs Nevirapine, Lopinavir/ritonavir and Efavirenz combination to TLD drug (USAID Global Health Supply Chain Progress, 2019).

1.2. BACKGROUND

Globally, approximately 37.9 million people live with HIV/AIDS, of which 36.2 million are adults and 1.7 million are children (United States President's Emergency Plan for Acquired Immune Deficiency Syndrome Relief (PEPFAR, 2018). In 2018, 23,3 million of HIV-infected people were receiving antiretroviral (ARV) drugs at a rate of 62%. In Europe, 2.3 million people are living with HIV (Beyrer, 2012; Zang, Peng, Wu et al, 2019). According to Cousins (2018), the Asia and Pacific region is home to an estimated 5.8 million people living with HIV. In 2017, 160 000 people were newly diagnosed with HIV in Europe and over half of those were diagnosed at the advanced stage of infection (WHO, 2018). However, the pace of increase is slow, compared to the previous years (WHO, 2018). According to the Population Reference Bureau (2013); Maatouk and Assi (2022), the Middle East and North Africa region has the lowest HIV prevalence in the world, with 240 000 people living with HIV in 2019. According to the United Nations program for HIV/AIDS (UNAIDS,

2019), East and Southern Africa is the region with the high prevalence of HIV, it is the epicenter of HIV with 20.6 million people living with HIV. South Africa is the leading country in the region with 240 000 of the region's new infections in 2018 (WHO, 2018). Seven other Southern Africa countries accounted 50% of new infections, with Mozambique at 150 000 people and lowest being Malawi and Zimbabwe at 38 000 people (UNAIDS, 2019).

In 2019, there was an estimated 20 000 new infections across the Middle East and North Africa region (Population Reference Bureau, 2013; Shakiba et al, 2021). According to Cousins (2018), 300 000 people became infected with HIV in Asia and the Pacific Region. According to UNAIDS (2019), in East and Southern Africa there were 800 000 new HIV infections, just under half of the global total in 2018. In addition, one fifth of people living with HIV in Europe are unaware of their infection (Beyrer,2012; Cousins, 2018). According to the European Center for Disease Prevention and Control (ECDC, 2019), many people living with HIV initiate ART too late and present with symptoms of widespread immune system damage at time of initiation. In Asia and pacific region, 75% of people living with HIV were aware of their status in 2019 (Cousins, 2018). Algeria was one of the few countries in the region close to achieving the first 90 target in 2017 with 84% of people living with HIV knowing their status. Botswana, Namibia and Eswatini have reached a coverage of the 90% goal.

By end of 2017, an estimated 66% of people diagnosed with HIV were receiving treatment and 84% had suppressed viral loads in Europe. Among those who were aware, 80% were on ART of which 91% virally suppressed (ECDC, 2019). According to the Population Reference Bureau (2013), in the Middle East and North Africa region, around 8 000 people have died of HIV-related illnesses, despite its low prevalence. The high death rates are due to poor access to ARVs. The epidemic is driven by sexual transmission and affects the population as a whole (Vearey, 2018). In 2019, mostly infected were mainly men who have sex with other men, people who inject drugs and clients of sex workers in Asia and the Pacific Region (Cousins, 2018). According to Mumtaz, Hilmi, Majed and Abu-Raddad (2020), Middle east and North Africa region mostly affected groups are female sex workers, people who inject drugs, migrants, mobile populations, and men who have sex with men. According to the United Nations Children's Fund (2015), population affected are mostly young women aged 15-24 years, with 1.6 million living with HIV, and children aged 0-14 years, at 1.1 million. According to UNAIDS (2018), there is still limited access to HIV and Counselling in the Middle East and North Africa, although the service is an integral component of HIV prevention programs. According to UNAIDS (2019), In 2018, 13.8 million people living with

HIV were on ART in the East and Southern African region. Botswana, Namibia and Eswatini have reached a coverage of 90% goal.

According to the National Institute of Allergy and Infectious Diseases (NIAID, 2018), Zidovudine was the first drug to gain approval for treating AIDS in 1987 March by the United States Food and Drug Administration. Patients on Zidovudine alone developed drug resistance in a matter of days. In 1990, a combination therapy was introduced, that showed more effectiveness than Zidovudine alone (NIAID, 2018). Research conducted by Terry Beirin Community Programs for Clinical Research on AIDS has found that the two-drug therapy had no significant benefit in slowing disease progression or death. A triple-drug therapy was introduced in 1996, also known as highly active antiretroviral therapy (HAART), which included protease inhibitors. The triple-drug therapy reduced viral loads to low levels for up to a year. Dolutegravir was approved in 2013 by the United States Food and Drug Administration (NIAID, 2018). However, this drug has a high barrier to development of HIV drug resistance. Globally, HIV was managed by two drugs from one group of Nucleoside Reverse Transcriptase Inhibitors; namely, Tenofovir and Emtricitabine, as well as a Non-Nucleoside Reverse Transcriptase Inhibitor named Efavirenz as a First-line Regimen (Wang, De Clercq and Li, 2019). Many people complained of nightmares due to efavirenz. Furthermore, were defaulting and had poor compliance, which led to an increased viral load and a high defaulter rate. In response, a new drug (TLD) was launched as the first combination Antiretroviral therapy for people living with HIV (WHO, 2016). The combination contains the drug Dolutegravir, which is an Integrase Inhibitor believed to have lesser side effects and greater efficacy for viral suppression. In August 2017, the United States Food and Drug Administration approved the use of the generic antiretroviral and asked the suppliers from India for TLD drug (USAID,2019). The transition to TLD drug started in 2018 in countries such as Botswana, and the response was overwhelming because TLD drug is not restricted by weight and age. TLD drug is also available at a value affordable to countries with small and median incomes (WHO, 2016).

The United States PEPFAR states that populations that are recommended for transition to TLD drug include all new adolescents aged above 10 years and above 30 kg, as well as adult first-line populations, all existing adolescents and adult first-line populations, patients currently failing first-line based regimen on the non-nucleoside reverse transcriptase (NNRTI), or who have failed an NNRTI-containing regimen in the past and are currently on a PI-based second-line regimen in programs that can confirm virology suppression 3-6 months after transition to TLD drug (PEPFAR, 2018). The improved tolerability, potency, convenience, and high genetic barrier to resistance associated with TLD drug may also be advantageous for adolescents, as this population remains

one of the most difficult in achieving viral suppression (USAID Global Health Supply Chain Progress, 2019).

According to WHO (2018), Brazil has recommended TLD drug as a first-line regimen for ART-naïve patients since January 2017. More than 50 000 persons living with HIV are using TLD drug currently in the first-line regimen, while 30 000 are using DTG-containing regimen in the third line. Furthermore, approximately 8 000 new patients are initiated on TLD drug monthly. The proportion of people living with HIV, treated with TLD drug, and with undetectable viral load, was more than 81% from the first three months of treatment and 88% at 10-11 months of treatment; at 12 months of ART initiation patients on TLD drug were at 88% compared to those on TEE at 83%. Finally, viral load suppression is faster amongst those on TLD drug with 81% and 61% in those on TEE within 3 months of ART initiation (WHO, 2018).

In May 2018, Botswana introduced the DTG-based first-line ART for all adults, including pregnant women (WHO, 2018). In September 2018, Botswana transitioned to TLD drug, as it is the preferred first-line regimen for managing HIV. Approximately 60 000 people with HIV are currently on TLD drug where 10 000 patients switched to it. Furthermore, patients with tuberculosis, using the Rifampicin treatment, pregnant women and breastfeeding women are using TLD drug in Botswana. More than 90% of individuals living with HIV on TLD drug achieved full viral load suppression in 6 months, with less than 6% reporting adverse events of gastrointestinal disturbances. People living with HIV have completed the tuberculosis treatment while taking the double dose of DTG-based regimen and no difference in adverse events has been observed with an increased dose of DTG. In addition, only 3 patients were found to have integrase mutations (WHO, 2018). According to the Ministry of Health and Wellness, the decision to switch patients to TLD drug was driven by the desire to reduce pill burden, rapid viral load suppression; achieve fewer side effects and for greater potency, as TLD drug reduces the possibility for drug resistance (USAID Global Health Supply Chain Progress, 2019). The MOHW has developed two phases: phase one focuses on new treatment initiations and shifting patients to TLD drug, who had been using the two-pill combination (TDF/FTC) and phase two switches patients who were using legacy drugs Nevirapine, lopinavir/ritonavir and efavirenz combination to TLD drug. In Kenya, approximately 13 000 people are using TLD drug since 2017 (WHO, 2018). About 88,7% of the people living with HIV on TLD drug were virally suppressed and 90% in 2018 were suppressed due to TLD drug. Salim is the one of first people in Kenya to access TLD drug and is happy with the new treatment (WHO, 2018).

According to Pembere (2020), Zimbabwe transitioned to TLD drug in May 2018; Zimbabwe has 1,3 million people living with HIV and 1,1 million on ART. South Africa has the high HIV epidemic levels in the entire world with 7,7 million people, where 5,2 million people are on ART in the public sector with 64% of virally suppressed and the government is planning to switch them to TLD drug UNAIDS (2019). TLD drug was rolled out on World Aids Day on 1 December 2019 in South Africa. The goal was to add 3 million people with HIV on ART by December 2020. TLD drug has been shown to greatly reduce new infections and AIDS deaths. The Minister of Health Dr Zweli Mkhize (2018) has described TLD drug as the fastest drug to reduce the viral load while showing fewer side effects and being easier to take.

According Matiru (2019), TLD drug is a significant change and major milestone for South Africa. According to Dr Michelle Moorhouse (2018), transitioning to TLD drug could halve the number of new infections in South Africa between now and 2030. Furthermore, according to UNAIDS (2017), South Africa accounts for 15% of all new infections and more than 10% of all HIV-related deaths globally. Furthermore, South Africans are currently on treatment and less than 50% of the youth who come forward for HIV care successfully initiate ART. Finally, South Africa's new HIV infections in adults has decreased by 39% since 2010 (Matiru, 2019).

KwaZulu-Natal Province was the first to launch TLD drug by the Minister of Health Dr Zweli Mkhize at Turton Community Health Centre in Ugu District (Matiru, 2019). Ugu District has 27% of the people living with HIV and is considered the epicenter of the disease (Matiru, 2019). This is because it has the highest prevalence of HIV among pregnant women, where about half (43.4%) are HIV positive, as stated by Dr Zweli Mkhize (2018). HIV is a global concern that needs to be addressed urgently in order to reach the 2030 global goal

1.3. PROBLEM STATEMENT

TLD antiretroviral drug in South Africa rolled out in December 2019(UNAIDS, 2019).TLD drug became available in February 2020 at Riba clinic. However, nurses have shown no interest in the drug, as they have not been switching patients to TLD drug, as required, as TLD drug is considered a game changer in the lives of HIV-infected people, due to its efficacy and fewer side effects. The clinic Stock Visibility System reporting portal has shown that only fifteen out of thirty-seven clinics were reporting few patients being switched to TLD drug. These put adult patients <40kg on disadvantage as well as adolescents >10kg as they still have pill burden (taking single doses), that can be avoided if being switched because TLD drug accommodates most people as it does not require specific weight and age like other triple therapy (PEPFAR, 2018). The

researcher observed the negative attitudes portrayed by professional nurses regarding switching patients on TLD drug and identified this to be a gap and an opportunity to conduct a study on TLD drug, that will help achieve the 2030 Global Goal. This study seeks to explore the views of professional nurses regarding TLD drug in selected clinics in Limpopo Province.

1.4. RATIONALE OF THE STUDY

The study was conducted to gain more knowledge and understanding in relation to TLD drug and how professional nurses perceive its use in order to improve and assist in the management of people living with HIV. There is no known study about or relating to the views on TLD drug in South Africa and other countries.

1.5. SIGNIFICANCE OF THE STUDY

The study results may assist in improving nurses' attitudes towards change in order to assist in HIV management at clinical level. Furthermore, patients and nurses could benefit from this study by understanding better about the drug. In addition, the views of professional nurses in this study might be used to the guideline for the provision of TLD drug and in so doing, the Global Goal and Department of Health Goal to achieve 90/90/90 by 2020 and 95/95/95 by 2030 might be reached and may help policy makers to gain latest information.

1.6. STUDY PURPOSE AND RESEARCH QUESTION

1.6.1 PURPOSE

The purpose of this study was to explore and describe the views of professional nurses regarding TLD drug at selected clinics in Sekhukhune District, Limpopo Province.

1.6.2. RESEARCH QUESTION

What are the views of professional nurses regarding TLD drug in selected clinics in Sekhukhune district, Limpopo province?

1.7. DEFINITION OF TERMS

Antiretroviral therapy

A therapy that has minimum of three antiretroviral drugs to maximally suppress the HIV and hinder HIV disease progression (WHO, 2016). For the purpose of this research, antiretroviral therapy refers to medication used by HIV infected patients in selected clinics in Sekhukhune District.

Professional Nurse

Section 31 of Nursing Act (Act 33 of 2005) states that a professional nurse is a person who is skilled and competent to practice comprehensive nursing independently in manner and with respect to the degree specified, and who may take responsibility for such practice and be responsible for it. For the purpose of this research, a professional nurse refers to someone who is professionally trained to take care of patients at selected clinics in Sekhukhune District.

Tenofovir, Lamivudine and Dolutegravir (TLD)

According to The South African National AIDS Council (2020), TLD Is a new HIV treatment taken once a day. For the purpose of this research, TLD is HIV drug containing three drugs in one taken by people living with HIV.

Views

Views refer to the ability to see something in a particular way (Gordon, 2016). For the purpose of this research, views refer to how a nurse outlook thing in selected clinics in Sekhukhune District.

1.8. OUTLINE OF THE CHAPTERS

Chapter 1: Overview of the study.

Chapter 2: Literature review.

Chapter 3: Research methodology.

Chapter 4: Results.

Chapter 5: Discussion, Limitation of the study, Recommendations and Conclusion.

1.9. CONCLUSION

This chapter presented an overview of the study including introduction, background, problem statement, rationale of the study, significance of the study, study purpose and research question and definition of terms and outline of chapters. The next chapter deals with literature review.

CHAPTER TWO

LITERATURE REVIEW

2.1. INTRODUCTION

The previous Chapter provided the introduction to this study, discussed the aim of this study, the brief methodological procedures to be followed and ensuring the quality of the findings of this study. The current Chapter discusses the literature that fits within the parameters of this study on the implementation, challenges, and critical aspects of the new antiretroviral therapy drug Tenofovir, Lamivudine and Dolutegravir.

Literature review refers to a critical and analytical review of research related to the research topic, researchers must demonstrate sufficient familiarity with the existing literature on the topic to justify the study (De Vos, Strydom, Fouche and Delport, 2011; McCombes, 2023). The literature review provides a background to the issues under the study, describe current knowledge of practice, issues and identify gaps in this knowledge base and how the reported research contributes to the development of knowledge in this field (Burns and Groove, 2015).

In this study, the researcher reviewed the literature using scientific books, the internet, research reports and dissertations, articles in a professional journal and standard reference material including presentation at conferences and workshops relevant to proposed topic. The inclusion and exclusion criteria were done for literature to be relevant and will contain sources published in English and published from 2011-2023.

2.2. OVERVIEW OF HIV/ AIDS IN DEVELOPED AND DEVELOPING COUNTRIES

The statistics of people living with HIV/AIDS are staggering the world over (Mangal et al., 2019). Many people are being diagnosed with HIV/ AIDS. For example, in 2017 alone, it was reported that approximately 160 000 people were diagnosed with HIV, for the first time, in Europe and over half of those were diagnosed at the advanced stage of infection (WHO, 2018). In 2019, there was an estimate of 20 000 new infections discovered across the Middle East and North African region (Population Reference Bureau, 2013). According to Cousins (2018) 300 000 people were infected with HIV, for the first time, in Asia and the Pacific Region. According to UNAIDS (2019) in East and Southern Africa there were 800 000 new HIV infections, just under half of the global total number of people infected with HIV/AIDS in 2018. This high number of people infected with

HIV/AIDS in the East and Southern Africa raises an alarm regarding the prevention measures and containment strategies available for people.

HIV/AIDS endemic is driven by sexual transmission among individuals (Vearey, 2018). Cousins (2019), observed that men who have sex with other men, people who inject drugs and clients of sex workers in Asia and the Pacific Region are the groups most vulnerable to HIV infection. The World Bank (2020) found that the most affected groups in the Middle East and North Africa region are female sex workers, people injecting drugs, migrants, the migrant populations, and men who have sex with men.

2.3. THE HISTORY AND DEVELOPMENT OF HIV/AIDS ANTIRETROVIRAL THERAPY

According to the National Institute of Allergy and Infectious Diseases (NIAID, 2018), Zidovudine was the first drug to gain approval for treating AIDS in 1987 March by the United States Food and Drug Administration. In 1990, a combination therapy was introduced, and it showed more effectiveness than Zidovudine alone (NIAID, 2018). In 1996, triple therapy, also known as highly active antiretroviral therapy (HAART) was introduced which included protease inhibitors (Arun, 2020). The triple-drug therapy reduced viral loads to low levels up to a year (Arun, 2020). Globally, HIV was managed by two drugs from one group of Nucleoside Reverse Transcriptase Inhibitors; namely, Tenofovir and Emtricitabine, as well as a Non-Nucleoside Reverse Transcriptase Inhibitor named Efavirenz as a First-line Regimen (Schaecher, 2013).

Dolutegravir was approved by the United States Food and Drug Administration (NIAID, 2018) in 2013. However, this drug has high barriers to the development of HIV drug resistance (NIAID, 2020). In response, a new drug (TLD) was launched as the first combination antiretroviral therapy for people living with HIV. The dolutegravir is also contained in the drug which is an integrase inhibitor that lessens the side effects and greater efficacy for viral suppression (WHO, 2016). In August 2017, the United States Food and Drug Administration approved the use of the generic antiretroviral and asked suppliers from India for TLD drug (USAID,2019).

2.4. THE NEW ANTIRETROVIRAL THERAPY DRUG TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR

The new antiretroviral therapy drug Tenofovir, Lamivudine and Dolutegravir (TLD), is the new fixed dose combination antiretroviral therapy drug that is taken once per day by individuals living with the Human Immunodeficiency Virus (HIV) (Villa et al., 2021). Through this new therapy drug, the current trends in the literature about the treatment of HIV seem to be effective and show improvements in controlling viral replication through the combination of single-tablet regimens (Zhao et al., 2021).

2.4.1 Implementation of the TLD drug

Botswana was one of the countries that implemented the transition to TLD drug in 2018 and the response was tremendous because TLD drug is not restricted by age or weight. TLD drug is also available at a value affordable to countries with small and median incomes (WHO, 2016).

The United States PEPFAR states that populations that are recommended for transition to TLD drug include all new juveniles aged 10 years and weighing over 30 kg, as well as first-line adult populations. All existing adolescents and adult first-line populations who are currently failing or have failed first-line based regimen on the non-nucleoside reverse transcriptase (NNRTI), an NNRTI-containing regimen in the past and are currently on a PI-based second-line regimen in programs that can confirm virology suppression 3-6 months after transition to TLD drug (PEPFAR, 2018).

WHO (2018) observed that Brazil has recommended TLD drug as a first-line regimen for ART-naïve patients from the beginning of 2017. The study shows that more than 50, 000 people living with HIV are currently using TLD drug in the first-line therapy, while 30, 000 are using DTG-containing therapy in the third-line therapy. Additionally, approximately 8, 000 new patients were initiated at TLD drug each month.

In May 2018, Botswana introduced the DTG-based a first-line ART for all adults, including pregnant women (WHO, 2018). In September the same year, Botswana transitioned to TLD drug, as the preferred first-line therapy for managing HIV. Furthermore, patients with tuberculosis, using the Rifampicin treatment, pregnant women and breastfeeding women are using TLD drug in Botswana. More than 90% of individuals living with HIV on TLD drug achieved full viral load suppression in 6 months, with less than 6% reporting adverse events of gastro-intestinal

disturbances. In Botswana, integrase mutations were found in only 3 patients after being introduced to TLD drug (WHO, 2018). The decision to switch to TLD drug was influenced by the need to reduce the pill burden, rapid viral load suppression, achieve fewer side effects and for greater efficacy, as TLD drug reduces the possibility for drug resistance (Glintborg et al., 2019). In Kenya, approximately 13 000 people are using TLD drug since 2017 (WHO, 2018).

In Zimbabwe, Pembere (2020), observed that Zimbabwe transitioned to TLD drug in May 2018; and of the 1,3 million people living with HIV in Zimbabwe as per the records in 2018, 1,1 million on ART. South Africa has the highest HIV endemic levels in the entire world with 7,7 million people and the government is planning to switch them to TLD drug (UNAIDS, 2019).

2.4.2 Advantages of TLD Drug

Tenofovir, Lamivudine and Dolutegravir (TLD) drug has demonstrated dominance over efavirenz and antiviral agent (PI) dependent regimens, with greater tolerability, rapid viral load (VL) suppression and a high genetic-resistance barrier (Gholami et al., 2020). The TLD drug has proven to have the practicality and cost-saving factors and availability for both adolescents and adult populations, makes it regimen of choice for patients receiving first-line antiretroviral therapy (World Health Organization, 2016).

The study by Atkin, Scannell and Nicholas (2019) examined the use of Dolutegravir for Antiretroviral Therapy in Women of Childbearing Age. The study observed that from the perspective of registered nurses, the use of dolutegravir seems to have the potential safety aspects relating to neural tube defects in the fetuses of women who are using the dolutegravir during the conception period. The processes of determining the implementation and assessing the safety of the antiretroviral therapy drug tenofovir, lamivudine and dolutegravir is imperative (Black and Schwartz, 2018). Atkin, Scannell and Nicholas (2019) observed that registered nurses and other healthcare professionals are essential to be involved in collaborative decision-making processes regarding reproductive life planning with women of childbearing age at risk of and living with HIV. If Dolutegravir is used thereafter, consistent, and reliable contraception is essential as it is not recommended in the first trimester of pregnancy (Atkin et al., 2019). In most developed countries with high-income, dolutegravir-based regimens demonstrated superior efficacy, durability and tolerability compared to existing first-line regimens. The study observed that most of these developing countries use a mixture of tenofovir, lamivudine and efavirenz (TEE). However, the integrase inhibitor dolutegravir (DTG) has been shown to have an improved safety

profile compared to EFV (drew Hill et al., 2018; Taramasso et al., 2018). Similar to the study by Dorward et al., (2018), the study by Victoria et al., (2018) indicated that there is a high barrier to the development of drug resistance.

2.4.3 Challenges of TLD Drug

The trends and patterns in the introduction of the new antiretroviral therapy drug tenofovir, lamivudine and dolutegravir have shown different challenges and indicated that there is no smooth transition from context to context. The study by O'Kelly, Murtagh and Lambert (2020) indicated that there are many benefits to be experienced with the therapeutic drug monitoring in the management of pregnant HIV patients on highly active antiretroviral therapy. There are many drugs that are used during pregnancy, and this can result to pharmacokinetic changes and the decreasing of exposure to these agents when the pregnancy progresses. From the healthcare perspective, this is risk in viral escape at the time of pregnancy and consequently the increased risk of mother-to-child transmission of HIV. The TLD drug has been effectively established for highly active antiretroviral therapy.

The perception towards the adoption and uses of new antiretroviral therapy drug tenofovir, lamivudine and dolutegravir in developing nations is experienced differently from the developed nations. For example, the study by Dorward and Hamers (2019) examined the adoption and use of the new low-cost generic fixed-dose combination antiretroviral therapy containing tenofovir, lamivudine, and dolutegravir in sub-Saharan Africa and discussed the two concerns connected to the rollout of this regimen. The study observed that the use of tenofovir, lamivudine and dolutegravir strategies are optimal for improving viral suppression and reducing mother-to-child transmission of HIV. The advantage included the cost-saving of more than 20 years-time frame when compared with the continuation of efavirenz-based first-line ART policy. In general, the multiple benefits of dolutegravir use are offsetting the small increases in predicted neural tube defects.

The study by Dorward et al. (2018) observed that the rolling-out of the new first-line antiretroviral therapy (ART) regimen containing dolutegravir is highly done in most low-income and middle-income countries (LMICs). However, the challenge remains on LMICs and the rolling out of the dolutegravir where most of the women of reproductive age are HIV. Access to viral load and HIV drug resistance testing remains limited while tuberculosis prevalence can be high. The study by Dorward et al. (2018) observed that dolutegravir is safe to start during pregnancy. However, the

study demonstrates the need for further investigation into the risk of adverse birth outcomes when dolutegravir-based regimens are started before conceptions. Increasing access to viral load testing to assess the efficacy of dolutegravir is imperative for developing countries and the effective approach to manage patients with viremia is crucial for developing countries. In developing countries, there is also a challenge of scarcity when the dolutegravir is given with tuberculosis treatment.

The study by Vitoria et al. (2018) investigated the contemporary issues with the introduction to dolutegravir drug and other new antiretroviral to low-income and middle-income countries. The study indicated that in low-income and middle-income countries there were approximately 16 million people taking NNRTI-based first-line treatment by the year 2018. There is an inherent observation by different studies showing the high risk of neural tube defects associated with dolutegravir use in women with early pregnancy. The challenge with the new dolutegravir and other new antiretroviral in LMICs is that few patients (less than 50%) have access to routine Viral Load Testing and extremely limited genotypic resistance testing. From the clinical perspective, there is no adequate clinical data to support switching patients from TEE directly to TLD when the viral load is either undetectable or unknown. Thus, there is a need for more new clinical trials and observational studies with the healthcare professionals to ensure an understanding of the consequences of this transition of treatment especially in the LMICs (Caniglia et al., 2020). There is also the need for new clinical trials of new antiretroviral drugs in key populations should be conducted earlier to ensure that these new therapies are introduced in LMICs immediately after their launch in both high and low-income countries (de Miguel, Montejano, Stella-Ascariz and Arribas, 2018).

2.5. BARRIERS TO THE NEW ANTIRETROVIRAL THERAPY DRUG TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR

The dolutegravir demonstrated a high barrier to resistance, especially when used in a two-drug regimen (2DR) with lamivudine (3TC). The study by Boffito et al. (2020) indicated that virological suppression could be maintained at 48 weeks after switching to DTG + 3TC from a tenofovir alafenamide (TAF)-based regimen compared with continuing a TAF-based regimen.

The study by Kouamou et al. (2020) examined the drug resistance among 74 adolescents and young adults with virological failure of first-line antiretroviral therapy and response to second-line treatment at Newlands Clinic in Zimbabwe. The study observed that their drug resistance

mutations (DRMs) are one of the barriers to sustainable virological suppression (VS) and the limited treatment options. The limited treatment options are another barrier that affects the outcome of second-line antiretroviral therapy. Through the sequencing of plasma viral RNA from 74 young adults and adolescents, the first-line ART failed between October 2015 and December 2016. The authors also evaluated first-line nucleoside reverse transcriptase inhibitor susceptibility scores to first- and second-line regimens, boosted protease inhibitor-based ART provided with the viral load monitored for 48 weeks.

Furthermore, Kouamou et al. (2020) further evaluated the factors associated with VS on second-line regimens, Fisher's exact test was employed. After switching to a second-line PI regimen, 88% suppressed to <1,000 copies/mL and 76% to <50 copies/mL at 48 weeks. The findings indicated that these 74 young adults and adolescents failing first-line ART portends high levels (97%) of DRMs, despite effective adherence to counselling. The same study identified that the switching to new NRTIs in second-line improved virological suppression. The genotyping to determine NRTI susceptibility is justified towards the widespread adoption and implementation of generic dolutegravir, lamivudine and tenofovir drug in most developing countries and Africa at large (Kouamou et al., 2020). Perceptions from the nurses regarding the adoption of the new antiretroviral therapy drug (TLD) is essential to expand the knowledge and understanding of both scientific and practical socio-cultural factors that might act as barriers towards an effective transition.

The study by Kagan et al. (2019) observed that the patterns and characteristics in resistance to antiretroviral drugs for HIV-1 are important to inform drug development and clinical support. The study investigated the drug resistance mutation (DRM) trends for nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, protease inhibitor (PI), and integrase strand transfer inhibitor (INST) (Kagan, et al., 2019). The findings of the study indicated that the prevalence of DRMs associated with earlier treatment regimens declined compared to the DRMs associated with the newer regimens which increased. These trends inform the need for baseline genotypic resistance testing (Kagan et al., 2019).

The study by master's et al. (2019) observed the challenges accompanied by the shift to one pill a day on the antiretroviral therapy management among patients. The study indicated that antiretroviral therapy has revolutionized the HIV/AIDS treatment among people living with HIV/AIDS. The efficacy of the ART regimens is well-tolerated scientifically, proclaimed safe and diminishing the pill burden that was also a constraint for people to take-up treatment of HIV/AIDS.

However, the study critically revealed that there are still challenges that persist with the management of ART in persons with HIV. These challenges include the drug-drug interactions, side effects, women with pregnancy, co-morbidities, and adherence. These are the challenges that are associated with the initiation of the ART and maintaining therapy. Importantly, the study observed the socio-cultural factors that are pervasive towards the effective initiation of the ART. There is also the challenge of the coexisting medical factors. The continued development of the new therapeutic approaches to ART needs to respond to these challenges. This could also be achieved through exploring the underrepresented clinical trials from the perspective of the professional nurses.

2.6. VIEWS REGARDING TLD DRUG

Adherence to antiretroviral drugs is important to prevent drug resistance and prevention of mother to child transmission among HIV positive women (Boateng, Kwapong and baffour, 2019).

2.6.1 Availability of TLD Drug

According to Alhassan et al (2020) stakeholders of South Africa and Uganda are optimistic about adequate supply of dolutegravir-based regimen during the transition. Both countries planned to use generic fixed dose dolutegravir regimen, TLD, which has received regulatory approval at the national level. With support from development partners Uganda have procured enormous quantities of TLD drug from the international market which the MOH staff noted would be sufficient in the medium term of the transition. South Africa have a relatively well-developed pharmaceutical industry compared with Uganda, and policymakers expected it to be able to meet domestic demand for TLD drug (Alhassan et al., 2020).

2.6.2 Weak stock management system

Regimen change requires an effective stock management system to minimize drug shortage and wastage. In South Africa, poor stock management at sub-national levels is reported to often create stock out of ARVs in health facilities. Stakeholders emphasised the need for efficient systems to ensure proper forecasting and availability of ART and contraceptive commodities in health facilities (Alhassan et al., 2020).

2.6.3 People's desire for a regimen change

Uganda and South Africa identified that there is greater desire among women living with HIV for a regimen change due to the side effects of the current non-nucleoside reverse-transcriptase inhibitor-based regimens. They noted that this would promote greater community uptake of TLD drug, being a better tolerated and more effective regimen, when it is rolled out (Alhassan et al., 2020).

2.6.4 Limited knowledge about TLD drug among women

According to Alhassan et al. (2020) community awareness about TLD drug is deemed to be essential for acceptability and uptake. However, not only was awareness about TLD noted to be low in both countries, but participants also reported of widespread misinformation in communities about TLD drug due to publicity around the possible association with neural tube defects. High illiteracy among women is a key concern among stakeholders, which is noted to hinder women's ability to make optimal treatment choice. Many activists thus stressed the need for greater access to information about the risks and benefits of TLD drug to engender better decision making on ART among women.

2.6.5 Potential resistance to TLD drug use in pregnancy.

Activists and development partners are concerned that the potential risk of neural tube defects would discourage vulnerable groups with limited information from using TLD drug. They feared that most men would prevent their spouses from using dolutegravir-based regimens due the potential risks in pregnancy. Further, they recognised that most health workers involved in HIV care did not have the required skill set for dolutegravir-based treatment (Alhassan et al., 2020). Knowledge of current ART regimens and treatment protocols are deemed to be insufficient due to the potential risks of TLD drug and the need for nuanced care for women of childbearing potential. The need for comprehensive training (rather than the usual orientation), including training in contraception for ART providers is suggested. They also suggested the need for dolutegravir-based treatment guidelines to be simplified to enable lower cadre health workers to implement.

2.6.6 Uncertainty about TLD drug use in pregnancy.

A major challenge to developing ART guidelines for the transition in both countries was uncertainty about TLD drug use in pregnancy (and among women of childbearing potential) due to potential association with neural tube defects. There was reported long delay in revising ART

guidelines due to disagreement over how to balance the public health risks and individual benefits of TLD drug use among women of childbearing potential. Several guidelines' members noted that the debate presented ethical conundrums which they lacked adequate information to deal with (Alhassan et al., 2020).

2.7. CONCLUSION

The amble of the literature in this study shows that the trends in the transition from the ARV to the new antiretroviral therapy drug Tenofovir, Lamivudine and Dolutegravir (TLD), is discussed from the lenses of the experts and mainly through scientific laboratories and reports. Apparently, there are extremely limited studies that portray the perceptions of the professional nurses regarding the transition of patient with HIV/AIDS to the new antiretroviral therapy drug Tenofovir, Lamivudine and Dolutegravir (TLD). This excludes the perspectives and the actual experiences of this transition based on context. The professional and practical experience of the nurses through direct interaction with the patients is critically important towards gaining perspectives regarding the nature of the transition of patient with HIV/AIDS to the new antiretroviral therapy drug Tenofovir, Lamivudine and Dolutegravir (TLD). This is the focus of this study. To gather and gain perspective from the nurses, on the selected public health institution, regarding this new therapy drug on the transition and adoption to people living with HIV/AIDS in South Africa.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1. INRODUCTION

The previous chapter discussed the available and reviewed literature related to the study. This chapter focuses on research design and methods which was used to conduct the study.

3.2. RESEARCH APPROACH

A qualitative approach was used. According to Burns and Grove (2011); Mohajan (2018), qualitative research is a scientific, analytical approach which is accustomed to explaining and giving meaning to life experiences. This research used this approach to determine the views of professional nurses regarding TLD drug in selected clinics in Sekhukhune district, Limpopo Province. This approach provided in-depth, detailed information, and encouraged researchers to expand on their responses and became possible to understand the views and attitudes of people.

3.3. RESEARCH DESIGN

Research design refers to the researcher's structured approach followed to answer specific questions (Ehrlich and Joubert, 2014). The descriptive and explorative design were used in this study to determine the views of professional nurses regarding TLD drug in selected clinics in Sekhukhune District, Limpopo Province. The researcher chose these designs to gain insight and understanding of views and attitudes displayed by professional nurses.

3.3.1. Descriptive design

According to Jansen Van Rensburg (2020), the descriptive design is a design within which phenomena are described or the relationship between variables is examined. The descriptive style was used to describe views of professional nurses regarding TLD drug at selected clinics in Sekhukhune District, whereby professional nurses were interviewed. The design was chosen because it involves a method of observing and describing the behavior of a particular subject without influencing it in any way.

3.3.2. Explorative design

The explorative design refers to a design which aims to achieve more insight about phenomenon studied (De Vos, Strydom, Fouche and Delport, 2011; George, 2021). The explorative design was used to explore the views of professional nurses regarding TLD drug in selected clinics in Sekhukhune District, Limpopo Province whereby professional nurses were interviewed, and probing questions followed to find out more.

3.4. STUDY SETTING

The study took place at selected clinics at Driekop area, next to Burgersfort town, in Fetakgomo-Tubatse Sub-district in Sekhukhune District. The researcher is a professional nurse, working in one of the selected clinics in Sekhukhune District. Sekhukhune District is one of the five districts in Limpopo Province. The others are Vhembe, Capricorn, Waterberg, and Mopani. Sekhukhune District comprises of four sub-districts: namely, Fetakgomo-Tubatse, Makhuduthamaga, Ephraim Mogale and Elias Motswaledi, with two hospitals, one health center and twenty-seven clinics. There are one hundred and thirty-seven professional nurses who have undergone training in Nurse Initiated Management of Antiretroviral Therapy(NIMART). Furthermore, there are thirty-seven clinics in the Fetakgomo-Tubatse sub-district that comprises of seven local areas; namely, Motsepe, with six clinics; Apel with four clinics; Ikageng, with five clinics; Leboeng, with five clinics; Penge, with six clinics; Bochkloof, with five clinics and the Mandaagshoek local area, with six clinics, known as the MK Umbrella, that provides health services with lay counsellors. It helps in providing counselling and testing to people with HIV, as part of the support structure. The population in this study are African community that mostly follow traditional ways of life. The study area is surrounded by mines, where most people work to make a living, and the educational level is low. Most HIV patients in this area are youths. The professional nurses working in the area believe more in religious and traditional healing. Figure 2.1 below shows a map indicating the location of some of the clinics and the three selected in the Fetakgomo-Tubatse sub-districts.

Figure 3.1. *The selected clinics in the Fetakgomo-Tubatse sub-district, Sekhukhune District.*

3.5. POPULATION AND SAMPLING

3.5.1. Population

A population is the whole community of individuals that are of interest to the researcher and that fulfill the study requirements that the researcher be interested in (Brink, Van der Walt, and Van Rensburg, 2018). The study population was all the professional nurses working in selected clinics in the Fetakgomo-Tubatse sub-district, Sekhukhune District.

3.5.2. Sampling

According to Brink et al (2018) sampling refers to a process of choosing a population sample to obtain information about how the population of interest is represented. Non-probability sampling was used in this study. Non-probability sampling is a technique in which a researcher chooses a sample, based on his/her subjective judgement. Not all members of the population have an equal opportunity to participate in the study. Convenience sampling technique was used. Convenience sampling involves the choice of available participants or objects of the study (Brink et al, 2018). Professional nurses that were available at selected clinics around Sekhukhune District participated in this study.

3.5.2.1 Sampling of health facilities

Non-probability sampling was used as discussed above. Riba, Motlolo and Selala clinic were chosen and many of the patients are from the mines. Riba Clinic's infection rate is 52%; Selala is at 59% and Motlolo is at 46%.

3.5.2.2 Sampling of participants

Fourteen professional nurses participated in the study until saturation occurred, seven were from Selala Clinic: four from Riba Clinic and three of Motlolo Clinic. The number of participants was chosen based on the number of professional nurses available in each facility. Participants who were on duty participated in the study.

Inclusion criteria

All professional nurses working with people living with HIV and had more than six months working were considered and participated in this study.

Criteria for exclusion

Professional nurses with less than six months working with people living with HIV were excluded.

3.6. MEASUREMENT INSTRUMENT

An unstructured interview guide (see annexure 5) was used to collect data, as it produces a high response rate and allows the researcher to clarify questions that are ambiguous and confusing. The researcher asked one central, open-ended question in English, as the participants' proficiency of the language is adequate. The interview was followed by probing questions, until saturation was reached. The central question was "Can you *describe your view on the new art drug(TLD)*." This was followed by probing questions; the number of probing questions depended on the responses.

3.7. PRETEST

Pretest is a preliminary test of measure in research used on small sample of population to be studied to evaluate the practicability of instrument prior true study. (Bille, 2010; Noviana et al, 2019). The researcher conducted pretests with four participants to evaluate the usefulness, investigate for possible flaws in the instrument and as well as attaining reliability and rigor in qualitative inquiry and analysis. The pretest helped the researcher in estimating the length of time

for full interview delivery. It also helped maximise methodological skills and achieving quality standards for qualitative data collection. The results of pretest are included in the main study.

3.8. PLAN FOR DATA COLLECTION

Data Collection is defined as gathering of data to address research problems and evaluate outcomes (Polit and Beck, 2014). The data was gathered through an unstructured interview and interview guide was used. The researcher conducted the interview in English. The voice recorder was used for capturing all the data and produced the exact words of participants, without missing a point. Fields notes were captured, to include non-verbal signs that a voice recorder cannot catch. Furthermore, the participants were interviewed in a quiet, conducive room, where there were no disturbances. The interview took 30-40 minutes. The data were collected during lunchtime, to avoid disrupting the respondents' work schedules. The interview centered on the views of professional nurses in relation to the new art drug(TLD) at selected clinic clinics in Sekhukhune District. Data collection continued and there were no longer new information emerging and saturation was reached. Covid-19 precautionary measures, such as social distancing, the wearing of masks and hand washing/hand sanitizing were observed and maintained.

3.9. PLAN FOR DATA MANAGEMENT AND DATA ANALYSIS

According to Polit and Beck (2014) the analysis of data is defined as a systematic arrangement and synthesis of research data. The following Tesch's Open Coding Steps for data analysis were followed (Creswell, 2014):

Step 1: Data recording

The data recorded was transcribed in order to access it easily and organized carefully. The researcher jotted down all the data from the voice recorder, to avoid misinterpretation.

Step 2: Reading of data

By reading all transcripts carefully, the researcher obtained the sense of whole data. This highlighted the ideas that came to mind.

Step 3: Data meaning

One piece of information was selected, and the researcher went through it, asking 'What was that about?' to produce meaningful information.

Step 4: Data clustering

A list of all topics was made, where similar subjects were grouped and formed into big subject tables, with special subjects.

Step 5: Data coding,

The researcher abbreviated the formulated subject matter as codes and reviewed to check if new codes emerged or could be re-classified.

Step 6: Data findings

Narrative passage approaches were used to convey the findings.

Step 7: data analysis

The data were analyzed, asking, 'what was the lesson learned?' This captured the essence of the idea.

3.10. MEASURES TO ENSURE TRUSTWORTHINESS

According to Suzan, Groove, and Gray (2015) trustworthiness refers to the strength of qualitative study determined by evaluating all study aspects. It is a moral value considered as virtue. This improves and gives the degree of confidence in data, interpretation and methods used to ensure quality of data (Polit and Beck, 2014). The following criteria were adhered to, to ensure trustworthiness:

Credibility

Credibility refers to the data and interpretation truth (Brink et al, 2018). In this study credibility was ensured by the researcher staying in the field during data collection until data saturation occurred. In addition, participants were interviewed until fresh data no longer introduced new insights or revealed new properties. Triangulation technique was used to ensure that the findings are comprehensive and well-developed. Field notes and a voice recorder were used to collect the data.

Transferability

Transferability refers to whether the study findings can be transferred from one specific situation to another (De Vos et al, 2011; Korstjens and Moser, 2018). Transferability was ensured by providing a thick description of the data analysis using a voice recorder as well as writing field notes.

Dependability

According to Babbie and Mounton (2011); Korstjens and Moser, (2018), dependability refers to the consistency of the qualitative research findings. In the proposed study, the researcher sent the document, interview notes and voice recorder data to an independent coder who is an

experienced qualitative researcher. Afterwards, a meeting was held between researcher and independent coder, to get feedback on coding, for better analysis and to summarize the results.

Confirmability

Confirmability refers to the degree to which the researchers could confirm the findings of the research study (Korstjens and Moser, 2018). An audit trail was used to ensure confirmability, where the researcher provided a complete set of notes on decisions made during research process, by using themes to code related topics.

3.11. ETHICAL CONSIDERATIONS

The researcher adhered to research ethics when conducting the proposed research. Ethics refers to a set of principles that govern a person's behavior (Lo, 2013; Resnik, 2020). Recruitment processes were done on merit considering ethical principles and bias was avoided. Subjectivity bias was avoided by the researcher, by not involving the researcher experiences and expectations in the interview.

Permission

The researcher presented the proposal to the Department of Public Health, School of Health Sciences, the Higher Degree Committee, Executive School Higher Degree Committee, and the University Ethics Committee, for ethical clearance. Thereafter, the researcher sent it to the University Higher Degrees Committee, for approval. Permission was obtained from the Limpopo Department of Health and operational managers of the selected clinics (see annexures 1 and 2).

Informed consent

A subject voluntarily agrees to participate within the research study before commencing the study (Brink et al, 2018). Participants were informed via an information letter (see annexure 4) about the study aim and objective of the study, as well as what the study entails. Informed consent was obtained prior to commencement of the study. The participants were told they have the right to withdraw from the study at any time, without giving a reason for doing so. They were also informed that participation in the study is voluntary.

Principle of justice

According to Lisa and Jacqueline (2013; Resnik, 2020) the principle of justice refers to an obligation to treat people equally and fairly. Participants were not discriminated against by the researcher. Instead, the researcher was transparent to all participants.

Principle of autonomy

It is also known as the principle of human dignity (Motloba, 2019). Participants' decisions were respected at all times, and the researcher did not interfere in the decisions made by participants. Finally, the researcher did not judge the participants in any manner.

Principle of nonmaleficence

Nonmaleficence is defined as non-harming or inflicting the least harm possible to reach a beneficial outcome (Lisa and Jacqueline, 2013; Korstjens and Moser, 2018). Participant were not harmed in any manner by researcher. Participant information is safe and accessible with only authorized people.

Respect for privacy

Refers to persons and to their interest in controlling the access of others to themselves (Lisa and Jacqueline, 2013; Resnik, 2020). Participants were not forced to reveal information that they did not wish to reveal to the researcher. Furthermore, the interview was conducted in a secure room, free from noise and people listening in.

Anonymity and Confidentiality

The researcher should at all times ensure that all aspects of the study are kept confidential (Brink et al, 2018). The researcher did not divulge the information collected from participants and the data remained private and confidential. To this end, the researcher used codes to identify participants, to ensure anonymity.

3.12. DELIMITATIONS OF THE STUDY

The researcher focused on the views of professional nurses regarding the new ART drug (TLD), as it is currently new and is regarded as the best drug of choice in first-line regimen among people living with HIV.

3.13. CONCLUSION

This chapter described the research design of the study, the study setting, population sample and sampling method. It also described the data collection instrument, data analysis method, trustworthiness, and ethical consideration.

CHAPTER 4

RESULTS

4.1. INTRODUCTION

The purpose of this chapter was to present the findings of the study as deduced from the data collected from participants' interviews. The findings were presented in narrative form and are based on the objectives of the study and research questions as indicated in the first chapter. The purpose of this study was to explore and describe the views of professional nurses regarding TLD drug at selected clinics in Sekhukhune District, Limpopo Province. The study population was all the professional nurses working in selected clinics in the Fetakgomo-Tubatse sub-district, Sekhukhune District.

In this chapter, the demographic profiles of the participants were laid out and themes were generated from the responses of the participants and corroborated by quotes from the interviews.

4.2. DEMOGRAPHIC PROFILE OF PARTICIPANTS.

This section provides participants' demographic data which was requested during the interview.

The participants in this study were predominantly female. 14 interviews were conducted and 10 of the interviewees were females whilst 4 were male. The participants were of the ages of 28 to 49. Seven participants had Bcur in Nursing and two with post graduate Diploma in Primary Health Care and seven with Diplomas in Nursing.

Below is the table presenting demographic data of participants.

Table 4.1: Demographic profile of the participants

Participants	Sex	Age	Qualifications
1	Female	28	Bcur in Nursing
2	Female	41	Bcur in Nursing; diploma PHC
3	Female	28	Diploma in nursing
4	Female	47	Diploma in nursing
5	Female	37	Bcur in Nursing; diploma PHC
6	Female	49	Diploma in nursing

7	Male	43	Diploma in nursing
8	Male	30	Bcur in Nursing
9	Female	40	Bcur in Nursing
10	Female	35	Bcur in Nursing
11	Male	36	Diploma in nursing
12	Male	30	Bcur in Nursing
13	Female	40	Diploma in nursing
14	Female	44	Diploma in nursing

4.3. THEMES EMERGING FROM DATA.

Three themes were generated from the participants' interviews namely: Implementation of the TLD drug, Explanation of the benefits of the new TLD drug and Challenges observed after implementing the TLD drug. For the sake of giving a better coherent flow to the data, sub themes and categories were created. The themes give a thorough description of the views of the nurses as stipulated in the purpose of the study.

Table 4.2: Themes, sub-themes and categories

THEMES	SUBTHEMES	Categories
Implementation of the TLD drug	Initial view of the professional nurses involved in ART	1. Reluctance to initiate or shift patients on TLD drug 2. Factors affecting the implementation of the new drug
	Current view of the professional nurses involved in ART	1. Changed view by professional nurses regarding the new drug 2. Facilitators of the new attitude

		• Existing policy and guidelines • Positive feedback from patients
Explanation of the benefits of the new TLD drug	• It is time convenient • Can be used in conjunction with other medication. • Reduced pill burden • Quick viral load suppression • Suitability of the drug to all patients • Low default rate and resistance build-up	
Challenges observed after implementing the TLD drug	• Insomnia and Tiredness • Gaining weight • Congenital abnormalities	

4.3.1. THEME 1: IMPLEMENTATION OF THE TLD DRUG

Under this theme, two sub-themes emerged: Initial views of professional nurses involved in ART and current views of professional nurses involved in ART.

Sub-theme 1: Initial view of the professional nurses involved in ART.

Two categories were identified namely: Reluctance to initiate or shift patients to TLD drug and Factors affecting the implementation of the new drug.

Category 1: Reluctance to initiate or shift patients to TLD drug.

Majority(Nine) of participants said they were reluctant to switch patients to TLD drug especially to childbearing age and pregnant women due to side effect that will occur to the baby. Due to this

there was a negative effect on the implementation of the drug. Patients were also refusing the drug.

Participant said: "yes, it was boring because they were saying you can give them but once they become pregnant you must switch them to Atroiza and it was frustrating, not only us as health providers but also to patients and most ended up refusing this TLD drug" (participant 4, Female, 47 years)

"... we were told that it has the negative impact on the baby, they say there is a chance that the baby can be born with neural tube defects" (Participant 11, Male, 36 years)

"...when you give those women at child-bearing age you must explain to them that the moment they want to be pregnant they must tell you so that you can put them back at their old treatment..." (participant 10, Female, 35 years)

Another patient added: *"... because TLD drug was introduced with negative effect, some of us were reluctant and being afraid to switch" (participant 9, Female, 40 years)*

Category 2: Factors affecting the implementation of the new drug

The study participants revealed that there were factors affecting the implementation of the TLD drug. Some participants said there was no document to show who to give the drug and the neural tube defects to the baby was also the other factor.

"When we started using this TLD drug I remember clearly, they said we must not give to pregnant women and younger ones, these youths. After a couple of months, after researcher I do not know then there comes again that we give even the pregnant women. But because we are fearful and there is no support document, we continue giving Atroiza for pregnant woman" (participant 3, Female, 28 years).

The other participant also added by saying: "there was no documentation to support the statement" (participant 6, Female, 49 years)

"When it came, we were told that it has the negative impact on the baby, they say there is a chance that the baby can be born with congenital abnormalities" (participant 12, Male, 30 years)

"At first they told us that it has a side effect on the baby, the baby will have congenital abnormalities" (participant 6, Female, 49 years)

"...TLD drug is bad because it is not supposed to be given to pregnant women..." (participant 1, Female, 28 years)

Sub-theme 2: Current view of professional nurses involved in ART

This sub-theme comprises of two categories, changed view by professional nurses regarding the new drug and facilitators of the new attitude.

Category 1: Changed view by professional nurses regarding the new drug

Most of the participants mentioned that they are no longer reluctant to switch patients and initiating them to TLD drug. This is followed by updates regarding TLD drug. Most of the participants see TLD drug as a good drug. It does, however, seem that initially this was not the case. There were initially concerns that TLD drug could possibly be harmful to pregnant women or women at childbearing age. One of the participants reiterated that the change in mandate of whom to give TLD drug happened after research was done and they were later instructed to give TLD drug.

"Yes, there was a workshop that was attended, and that report said it is safe to give the pregnant women" (participant 1, Female, 28 years)

"...when you put or switch patient on TLD drug within 6 months the viral load will be low, and the adherence is good." (Participant 1, female,28 years)

"TLD drug is a new drug that is essential to us because you can use it during the day or during the night depending on how you can manage to use it. It is the best and effective". (Participant 2, Female, 41 years)

Other participant added: "TLD drug is very good because firstly is one pill a day, at your preferred time which reduces stress" (participant 5, Female, 37 years)

Category 2: Facilitators of the new attitude

Participants raised existing policy and guidelines, and positive feedback from patients as facilitators for change of attitude toward the drug.

- **Existing policy and guidelines**

Some of the participants said while they were still having doubts about giving TLD drug to child-bearing age women and pregnant women, the guideline was brought forward to make the assurance that TLD drug is good for everyone. Below are the participant's comments:

> *"TLD drug is good because you can take it while on other medication without interfering with one another like mental health treatments or TB treatments and now with the MEMO in place, almost everybody on regimen one is taking TLD drug" (participant 12, Male, 30 years)*

"There is an SOP (standard operating procedure) that says in 2023 everybody should be on TLD, so we are switching them to TLD drug and those who are starting we give them TLD drug. And I think because they saw how quickly it reduces the virus and the less reported side effects" (participant 7, Male, 43 years)

The other participants expressed their views on the new attitude that made them to initiate and switch patients as follows:

"Thank God, while we were still in the dilemma the guideline came stating that the risk of neural tube defect is low and it gave us assurance then we started giving to pregnant women and child-bearing age women and by God's grace no baby is born with neural tube defects that made me happy and now I highly recommend it to my patients" (participant 5, Female, 37 years)

"Eh.... after some time, the guideline came that gave us the assurance that it is safe to give pregnant women and child-bearing age women that is where we started switching them and initiating in big numbers and fortunately since we started giving them TLD drug no one who gave birth to a disabled child" (participant 10, Female, 35 years)

- **Positive feedback from patients**

Some of the participants' reported that in most cases patients are incredibly happy about TLD drug and the reception is often welcoming especially when the patients are told that the new treatment regimen is just one pill which can be taken at any time of day or night and that it has limited side effects. Patients are also happy to hear that the new drug suppresses the viral load a lot quicker.

"Most of the patients were extremely happy when we introduced it to them because we told them that it reduces viral load extremely fast. Because with other drugs when we interview patients, we

can see they are taking it well, but the viral load is not going low, so we see that patients are taking it well" (Participant 1, Female, 28 years)

The other participant also added that:

"...Adolescents are happy that they also take one pill like others and the bonus for them is time because most came saying it is better now because I take it in the morning and I don't have to stress about time when I'm out with friends" (participant 3, Female, 28 years)

"Well..... patients love it because we told them it suppresses virus quickly and is not easy to have resistance because TLD drug has high barrier to resistance, so they love it. Most of them come back saying with this TLD drug they are able to sleep with no difficulties or having nightmares..." (participant 14, Female, 44)

4.3.2. THEME 2: EXPLANATION OF THE BENEFITS OF THE NEW TLD DRUG

The participants revealed that there are a lot of benefits of TLD drug. Six sub-themes emerged: It is time convenient, can be used in conjunction with other medications, reduced pill burden, quick viral load suppression, suitability of drug to all patients and low resistance build up.

Sub-theme 1: It is time convenient.

One of the most common themes that could be extracted from the majority of the participants' interviews is the fact that TLD drug can be taken at any time of the day or night. So, the client is in a better position to manage their doses because of this advantage. According to the majority of the participants, this is perceived as a great advantage. This was confirmed by the following quotes:

"TLD drug is a new drug, and it is essential because you can use it during the day and during the night. Depend on how you can manage to use it…." (Participant 3, Female, 28 years)

"I think TLD drug is a better anti-retroviral drug because it is a fixed dose combination. You only take one pill per day and then you are sorted. You take it at the time that you feel you are convenient with." (Participant 8, Male, 30 years)

Some of the participants corroborate the narrative that TLD drug is more convenient by highlighting the fact that unlike tenofovir, Emtricitabine and Efavirenz(TEE), it can be taken during

the day as well and if a patient was to miss a dose during the day, then they can just ensure that they take it at night. The participant said:

"Ok TLD drug has lesser, few side effects if any. And also, you can take it at any time unlike TEE..." (Participant 6, Female, 49 years)

Sub-theme 2: Can be used in conjunction with other medication.

Some of the participants reiterated the narrative that TLD drug can be used while the patient is on some other medication. This also included women who were on some form of contraceptive or family planning. One of the participants also further highlighted that patient could take it while on hypertension medication.

"The other thing is that it is less likely to interject with other drugs or other medication that you might be taking… Most people can take TLD drug without having to worry some of their other medication." (Participant 11, Male, 36 years)

"If you are having psychiatric condition, some ARV are not allowed because they trigger mental illness that can make you hallucinate like TEE but with TLD drug there is no such, you take them both which is good" (Participant 9, Female 40 years)

Few of the participants went further to explain that in comparison to TEE, it is much better because it does not contradict other drugs or nullify their effectiveness.

"This one you can take it anytime. Even if you are using contraception, you cannot use TEE because they limit each other's effectiveness if you have implant in you." (Participant 14, Female, 44 years)

Sub-theme 3: Reduced pill burden

Participants reported that one of the key advantages of TLD drug is the fact that it is a fixed dose drug, so this makes the experience of using TLD drug more pleasant and convenient to the patient.

"I think TLD drug is a better anti-retroviral drug because it is a fixed dose combination. You only take one pill per day and then you are sorted." (Participant 8, Male, 30 years)

"Is good for those teenagers because it is only one pill a day because most of them were taking lot of medication and sometimes, they will tell you that it is too much for them but now they are happy..." (Participant 10, Female, 35 years)

"Lots of tablets will cause a lot of pressure on them so if it's one then its life and it doesn't give you the stress of saying you must take three." (Participant 7, Male, 43 years)

"... One pill once a day is equal to less problems..." (Participant 11, Male, 36 years)

One participant also further highlighted that though a drug like TEE is a single pill dose as well, however it is trumped by TLD drug because it has numerous side effects which TLD drug does not have.

"Another reason is that you do not have to take too many pills at one time because it is one pill. Although we have EFE which is one pill, but it has many side effects compared to TLD drug." (Participant 6, Female)

Sub-theme 4: Quick viral load suppression

The majority of the participants' report that one of the most important advantages of the use of TLD drug is that it speedily suppresses viral load. This means that the patient can quickly recover. This is one of the advantages of TLD drug that patients greatly emphasized. The majority of the participants also emphasized that the suppression of viral load occurs faster with TLD drug than with TEE.

"It lowers viral load very quickly. Much quicker. Which means it is much stronger than TEE. So, I would encourage someone to take TLD drug as long as they qualify because we check the weight of the person and any underlying conditions if the person has the average weight." (Participant 6, Female, 49 years)

"On my side, TLD drug is very good for patients living with HIV because it suppresses the virus faster..." (Participant 3, Female, 28 years)

A few of the participants again went further to explain that the suppression of viral load means that the patients are able to fight opportunistic infections much quicker.

"Isn't it when a patient comes, they are not good; they can have opportunistic infections if they are initiated on TLD drug they no longer have opportunistic infections." (Participant 2, Female, 41 years)

Sub-theme 5: Suitability of the drug to all patients

Some of the participants emphasized the fact that TLD drug can be given to young people, which seemed to have not always been the case. This is confirmed by the following quote:

"Like most youth mostly we give them this TLD drug. It is good for them. They like it because it can be taken any time of the day" (Participant 4, Female, 47 years)

The majority of the participants also reported that TLD drug can be given to pregnant women as well. One of the participants even emphasized that TLD drug can even be given to patients who suffered from TB.

"TLD drug can be given to anyone including pregnant mothers as long as they are not underweighting..." (Participant 6, Female, 49 years)

".....TLD drug is also suitable for all working classes, whether you work during the day or during the night" (Participant 1, Female, 28 years)

"...after a couple of months, after researcher, I don't know then there comes again that we give even the pregnant women..." (Participant 3, Female, 28 years)

"Well, it is also good because even adolescents can take it, this one is good..." (participant 1, Female, 28 years)

"Psychiatric patients are also happy as they can now take a single dose combination pill like everyone because TLD drug does not have psychiatric effects like hallucinations" (Participant 5, Female, 37 years"

Sub-theme 6: Low default rate and resistance build-up

The majority of the participants emphasized that TLD drug has a lower default rate when compared to other drugs. Few of the participants attributed this to the fact that the dose is only

one tablet which therefore makes it simpler and more convenient for the patient. Few of the participants also attributed its low default rate to the fact that it was not easy to develop resistance to TLD drug to an extent that even if a patient defaulted, they can still get back to the treatment and it will still be effective.

Participants said:

"*The risk of defaulting is extremely low. Because someone is taking a number of tablets and they are annoyed sometimes…..*" *(Participant 7, Male, 43 years)*

"...so, most adolescents no longer default..." (Participant 1, Female, 28 years)

"it's just that it is effective to patients and most of them are no longer defaulting because they say they don't have nightmares and dizziness" (Participant 2, Female, 41 years)

"...and is not easy to have resistance because TLD drug has a high barrier to resistance, so they love it" (Participant 14, Female, 44 years)

"The other thing is that TLD drug has a higher barrier to resistance, so it gives patients time not to change regimen unlike TFE. Since we started giving TLD drug, no one has been resistant to it." (Participant 9, Female, 40 years)

"TLD drug has a high barrier to resistance which means is more powerful, within 6 months a person can achieve undetectable viral load..." (Participant 13, Female, 40 years)

4.3.3. THEME 3: CHALLENGES OBSERVED AFTER IMPLEMENTING THE TLD DRUG

Sub-theme1: Minor side effects

One participant reported that the patients that they have seen complain of insomnia and not being able to sleep if they take TLD drug at night. This however was not widely reported by other participants.

"...and the side effects are very few and I remember only few that mentioned that they were unable to sleep since they started this TLD drug, but it didn't last more than two weeks..." (Participant 1, Female 28 years)

A minority of the participants reported that other patients complain about gaining weight.

"...but the terrible thing is gaining weight for patients who do not want to gain weight. It will be a problem to them..." (Participant 5, Female, 37 years)

"... like any medication TLD drug also have side effects but they are minor once, patients report slightly headache and weight gain, weight gain to many especially adults are not a problem but young once some don't like it, so I encourage them to live a healthy lifestyle like exercising and eating healthy to maintain their body weight" (Participant 9, Female, 40 years)

Sub-theme 2: Psycho-social problems

There were few participants however whose view was that the low default rate on TLD drug cannot necessarily be attributed to the nature of the drug, but rather is primarily caused by emotional, cognitive, and social factors. One of these participants emphasized that some patients default treatment because they are in denial and have not accepted their status and the stigma related to being HIV positive is a great hindrance to this acceptance. Another participant who attributed default rate to social factors reiterated that many of the patients default because they do not want their partners or their family members to find out that, they are positive.

"When it comes to the issue of defaulting treatment, I do not usually attribute it to medication per se. With most of my patients who defaulted treatment it is different from saying they defaulted because of treatment regardless of which drug they were taking. It is usually because of denial. It is usually when patients have not accepted because of the stigma that is out there. Or patients who did not disclose their status to family members. Those are the people who usually default treatment." (Participant 8, Male, 30 years)

"...some people default because of social problems. They will tell you "I did not want my partner to find out that I was on ARVs. I fear that she will leave me due to my status and I do not want to lose her..." (Participant 11, Male, 36 years)

"...The most people who are living with HIV don't want to be seen by other people just because they are afraid of discrimination and be judged by other people..." (Participant 3, Female, 28 years)

Sub-theme 3: Packaging

A few participants also highlighted the fact that there was confusion with regards to patients who had problems with the pill coming in blue containers whilst sometimes it comes in white containers. This was particularly the case with patients who cannot read. They were reported to complain or suspect that they were not being given the same drug as they got before because perhaps, they are used to it in a blue color and then they see it in a different color.

"The minor problem is that it is similar to TEE so many patients could not differentiate it. If it could have its own color that would be good. It should not be white then at other times it is blue. Because other patients cannot read. If they first saw it being white when it is now blue, they refuse to take it" (Participant 2, Female, 41 years)

"This TLD drug comes with different colours, so the patients are worried because today they get blue color next month is white that other month is pink and remember most do not even read the name of the medication. You will hear some saying this blue one makes me feel tired, I need the pink one and others vice versa. Even if you try to tell them that is one thing, they do not get it so that is the bad part about it" (Participant 4, Female, 47 years)

4.4. CONCLUSION

This chapter presented the data collected from the participants through interviews. Themes and sub-themes emerged on views of professional nurses regarding TLD drug. The next chapter focus on discussion of the results.

CHAPTER 5

DISCUSSION, LIMITATION OF THE STUDY, RECOMMENDATIONS AND CONCLUSION

INTRODUCTION

The previous chapter presented the data collected from the participants. In this chapter, the researcher discusses and compares the results of the data to those of other studies and highlight both corroborations and contradictions.

The demographic profile in this study included gender, age, and qualifications.

The findings showed that most participants were female, ten females and four males. This significant different in gender could be that nursing is seen as female profession. These findings are in line with study findings conducted by Ndou (2019) that had more female participants than males.

The findings showed that majority of participants were 30 years and above. This is in line with national statistic, which indicate that less than 6% of nurses in South Africa were younger than 30 years (South African Nursing Council, 2022).

The findings also indicated that participants were highly qualified. Seven participants hold degree in nursing with two having advance diploma in primary health care and seven have diploma. This is in line with the study findings conducted by Ndou (2019) that had more qualified professional nurses.

The participants mentioned that the reluctance to initiate or shift patients to TLD drug was due to the negative effect when given to pregnant women. It was mentioned that the baby would be born with congenital abnormalities and the fact that you must switch back child-bearing age women when they become pregnant.

The study by Govathson (2022) also concurs with the study as they stated that the challenge includes the hesitancy of clinicians to initiate and switch patients to TLD drug is due to initial drug safety. The study by Zipursky and Loufty (2020) is congruent with this study as they stated that though WHO said that TLD drug can be given to pregnant women, Health Canada has yet to reconsider which create dilemma for health providers whether to prescribe TLD drug to pregnant women or not.

The findings revealed that the factors affecting the implementation of the TLD drug was that there was no document to show who to give the drug and that it must not be given to pregnant women because the baby will be born with the neural tube defects. USAID Global Health Supply Chain program (2019) also concur with the study by stating that also WHO raised a concern on preliminary studies from Botswana that showed increased risk of neural defects and the fact that the health providers need guidance when giving pregnant women because there is no clear documentation.

The study findings revealed that participants have changed views regarding TLD drug because there are guidelines and policies on who to give TLD drug and assurance on pregnant women and women of child-bearing age. These changed views were also encouraged by positive feedback received from patients on TLD drug stating that TLD drug is good for them due to lesser side effects and because is one pill that is taken once a day. The 2019 ART clinical Guideline is in line with the study findings as it states that TLD drug is recommended to pregnant women and women of child-bearing age. WHO (2019) also concurs with the study as it recommends TLD drug to all people living with HIV. The study by Mehari, Muche, Gonete and Shiferaw (2021) also concurs with the study as they stated that patients are highly satisfied with TLD drug treatment.

The participants revealed that there are a lot of benefits of TLD drug. One of the recurring views that participants reiterated was that they believed that the most benefits aspect of the use of TLD drug for their patients was that it is time convenient meaning it could be taken anytime during the day or night which enables the patient to manage their doses in a manner that is convenient to them and their lifestyle. The press release by The South African National AIDS Council (2020) also concurs with the study as they stated TLD drug as best solution for people living with HIV by its time convenient. Study conducted by Taha and Das (2019) also concurs with this current study.

This study found that most professional nurses believed and celebrated that TLD drug could be used in conjunction with other medication. The groups they specifically mentioned were patients who were taking medication for Diabetes and contraceptives. Kandel and Walmsley (2015) seem to agree with this notion in their reiteration that 'dolutegravir has few drug-drug interaction'. they did however have to acknowledge that there is evidence for disruptive interaction with antimicrobial agents (Kandel & Walmsley, 2015). The notion that TLD drug has no interaction with contraceptives is however refuted by Tittle, Bull, and Nwokolo (2015) and again by Patel, Song and Boland (2011). However, one may argue that these studies are all carried out in the very early stages of the introduction of TLD drug.

The study found that majority of the professional nurses were of the belief that TLD drug suppresses the viral load quicker and thus helps the patients recover quicker and helps them fight off opportunistic infections. The study by Kandel and Walmsley (2015) postulate that Dolutegravir based treatments were superior if not at least equivalent to existing treatment regimen due to its tolerability and less adverse side effects. The study by Nicholas, Peytavin, Bitilinyu-Bangoh et al. (2022) also concur with the study as revealed that of 1892 who transitioned to TLD drug who were viraemic, 1762 had less than 50 copies viral load within 12 months.

Majority of the professional nurses in the study reiterated that they were generally of the view that TLD drug is suitable to anyone including adolescents and girls of childbearing age. The WHO (2018) official recommendations on this issue corroborate the validity of the opinions of the participants in that the recommendations do clearly state that adolescent girls and women of childbearing potential who do not currently want to become pregnant can receive TLD drug together with reliance contraception. There was a contradiction in a few of the participants' opinions regarding the guidelines for giving pregnant women TLD drug. Upon analysis, it is clear however that the initial instruction was that they should not give TLD drug to pregnant women or adolescents in childbearing age. The study conducted by National Institutes of Health (2020) showed that TLD drug is the most effective and safest drug during pregnancy. The study conducted by Alcorn (2019) reported TLD drug as safe to use in pregnancy. This seemed to have been changed at a later stage through a circular and a series of briefings in which the nurses were told that it was now recommended by the government that they could give TLD drug to pregnant women as well.

The study found that Professional nurses believed that the default rate when TLD drug was used was low and few of them postulated that it was also advantageous because even if a patient defaulted, their body would not easily build up resistance to TLD drug. Inzaule, Harners, Doherty, Shafer, Bertagnolio and De Wit (2019) give a narrative on the use of ARV drugs in public health that explained the foundation of the necessity of the use of Dolutegravir in first line treatment. There are other studies that corroborate the perspectives of the nurses or at least give credence to the notion that TLD drug was indeed superior in dealing with resistant variants. These include the studies done by Walmsley, Antela and Clumeck (2013) and Orrel, Hagins and Belonosova (2017).

The study found that one of the side effects that nurses reported from the patients was unwanted weight gain in patients who did not desire to gain weight. The truthfulness of this notion is corroborated by the study by Menard, Amélie; Meddeb, Line and Tissot-Dupont et al (2017); in which they analysed the reasons for the discontinuation of TLD drug in 2260 HIV-infected patients. The Mernard et al (2017) study found that 7 percent of patients who defaulted from TLD drug were due to what they termed abnormal weight gain. Upon further investigation, they found that patients reported a range between 4 to 12 kg of weight. They also found that the data was statistically significant in women and showed a tendency towards significance in men though not statistically significant (Mernard et al, 2017)

According to this study other common side effects that some of the participants reported from their patients' included tiredness and insomnia. Parant, Miailhes, Brunel and Gagnieu (2018) corroborate this notion by highlighting that though TLD drug are highly effective integrase inhibitors with 'excellent tolerability', there are still considerable amounts of patients who experience neurological adverse effects due to them and many eventually default on treatment. The reports from the professional nurses are also corroborated by the study by Campbell, Amamilo, Nabitaka et al (2018) which reported that the most common side effect reported by patients from Uganda and Nigeria were Increased appetite, tiredness, headache, muscle ache, and insomnia. Two of these side effects (insomnia and tiredness) are like what was reported by the professional nurses in this study.

The study revealed that the other challenge was that patients do not disclose their status to partners because they are afraid to lose them, and others do not want to be discriminated against due to their condition. The study by Ndou (2019) concurs as it revealed that most HIV positive results led to conflicts, denial, and quarrels among couples. Halkitis et al (2016) also supported the findings by stating that many patients do not seek HIV testing services in public sectors due to fear of stigmatization.

The study showed packaging with different color containers as a challenge to some patients. This is however not supported. The study by Muiruri, Jazowski, Semvua et al (2020) does not concur with the study as they stated that most patients do self-repackaging to make pill less conspicuous.

LIMITATIONS OF THE STUDY

The study was conducted at selected clinics in Sekhukhune District. Generalizability in this study was the limited number of professional nurses who participated in the study. The views of the patients are not considered though are indirectly involved to the study.

RECOMMENDATIONS

Based on the results of this study, these are the recommendations that might be made to the Department of Health as the custodian of Health services especially of HIV drug distribution in South Africa and to the patients.

Department of Health

- Provide guidelines and policies to facilities before implementing changes for health providers to be well informed.
- Conduct workshops for professional nurses to impart knowledge on current changes of treatments.

Recommendation to patients

- Patients and supervisors for patients who cannot read should be encouraged to know the treatments by names to avoid confusion due to packaging. Attendance of adherence counselling sessions would help.
- Continuous Health education about HIV and its management to break the stigma and to support each other in times of illness.

Recommendations to other researchers

- Future researchers should assess the views of professional nurses regarding TLD drug in South Africa using quantitative study.
- Perceptions or satisfaction of patients regarding TLD drugs

CONCLUSION

In conclusion, the professional nurses have a positive perception of TLD drug based on the reports they received from their patients. The consensus is that the introduction of TLD was a much welcome breakthrough not only because it is seen as more effective at suppressing viral load but also because the patients report it to be more convenient for their lifestyle. The results from the study showed more positive views regarding TLD drug and is chosen as the first-line drug due to its efficacy and rapid viral load suppression. Though results showed more positive views, there are negative effects that comes with TLD drug such as weight gain, insomnia as well as packaging. Professional nurses support TLD drug hundred percent.

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Annexure 1: Interview guide

Section A: Demographic data

Please tick the appropriate box.

1. Age ……
2. Gender
   - Female □
   - Male □
3. Educational Qualification
   - Diploma □
   - Degree □
   - Honors □
   - Masters □
   - Doctorate □

Section B: Interview Questions

May you please share with me your views regarding the new ART drug, TLD?

Probing question

- Describe the reactions of patients to the new drug

.

Annexure 2: Univen informed consent

LETTER OF INFORMATION

Title of the Research Study: VIEWS OF PROFESSIONAL NURSES REGARDING THE NEW ANTIRETROVIRAL THERAPY DRUG TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR IN SELECTED CLINICS OF LIMPOPO PROVINCE.

Principal Investigator/Researcher : RAMUSILEI FHULULEDZANI INNOCENTIA, Professional nurse.
Co-Investigator/s/Supervisor/s : Dr Mabunda J.T., PhD & Dr Tshivhase S.E., PhD

Brief Introduction and Purpose of the Study: Tenofovir, Lamivudine and Dolutegravir, also known as TLD, is a new fixed-dose combination antiretroviral therapy drug that is taken once daily by individuals living with the Human Immunodeficiency Virus (HIV). The purpose of the proposed study is to explore and describe the views of professional nurses regarding TLD in selected clinics in Sekhukhune District, Limpopo Province.

Outline of the Procedure: Participants will be interviewed in a quiet conducive room, where there will be no interruptions; the interview will take 30-40 minutes. The participants will be given time to answer and seek clarity, where such is required. Professional nurses who will be on duty will participate in the study and those on leave will be excluded. Notes will be taken during the interview and a voice recorder will capture the data. All the information captured will be analysed.

Risks or Discomforts to the Participant: In cases where the participant does not feel comfortable in expressing their views, he/she will be comforted.

Benefits: The researcher will gain more knowledge and understanding on how participants view the new ARV drug and their attitudes towards it. This knowledge will help improve healthcare provision, as the information provided by the participants will be published.

Reason/s why the Participant, when they feel uncomfortable or when they are no longer willing to participate in the study. They will not be punished for so doing, as the study is voluntary.

Remuneration: There will be no payment for participation in the study.

Costs of the Study: Participant will not pay anything towards the study. All costs will be borne by the researcher.

Confidentiality: The researcher will ensure that all the transcripts and voice recorder are kept safe and participants' names will not be used as identification; codes will be used, instead.
Research-related Injury: No compensation will be provided in case of any injury.

CONSENT
Statement of Agreement to Participate in the Research Study:

- I..... hereby confirm that I have been informed by the researcher Ramusilei Fhululedzani Innocentia about the nature, conduct, benefits, and risks of this study. Research Ethics Clearance Number: .....
- I have also received, read, and understood the above written information (*Participant Letter of Information*) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerized system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during this research which may relate to my participation will be made available to me.

Full Name of Participant Date Time Signature

I, ……. …… …… ……..
(*Name of researcher*) herewith confirm that the above participant has been fully

Informed about the nature, conduct and risks of the above study.

Full Name of Researcher

…… Date……. Signature……

Full Name of Witness (If applicable)

…… Date ……. Signature……...

Full Name of Legal Guardian (If applicable)

…… Date…… Signature……..

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

Department of Health

Ref : LP_2021-10-011
Enquires : Ms PF Mahlokwane
Tel : 015-293 6028
Email : Phoebe.Mahlokwane@dhsd.limpopo.gov.za

Ramusilei fhululedzani innocentia

PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES

Your Study Topic as indicated below;

Views of professional nurses regarding the new antiretroviral therapy drug tenofovir, lamivudine and dolutegravir in selected clinics of Limpopo Province

1. Permission to conduct research study as per your research proposal is hereby Granted.
2. Kindly note the following:
   a. Present this letter of permission to the institution supervisor/s a week before the study is conducted.
   b. In the course of your study, there should be no action that disrupts the routine services, or incur any cost on the Department.
   c. After completion of study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
   d. The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
   e. The approval is only valid for a 1-year period.
   f. If the proposal has been amended, a new approval should be sought from the Department of Health
   g. Kindly note that, the Department can withdraw the approval at any time.

Your cooperation will be highly appreciated

pp **Head of Department** **Date** 11/11/2021

Private Bag X9302 Polokwane
Fidel Castro Ruz House, 18 College Street. Polokwane 0700. Tel: 015 293 6000/12. Fax: 015 293 6211.
Website: http/www.limpopo.gov.za

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Annexure 3: Department of Health approval letter

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

SEKHUKHUNE DISTRICT

Enquiries: Makgoga M.T

Contact: 0763982622

Date: 07 march 2022

Dear Ramusilei FI

Subject: Approval letter to conduct a study

This letter acknowledges that I have received and reviewed a request to conduct a research project titled: **VIEWS OF PROFESSIONAL NURSES REGARDING TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR (TLD) IN SELECTED CLINICS OF LIMPOPO PROVINCE** and I approve of this research to be conducted at our clinics.

Wishing you all the best in your studies

Ntsie M.S

Acting Sub-manager FTLM

Annexure 4: Sub-district Approval letter

ETHICS APPROVAL CERTIFICATE

RESEARCH AND INNOVATION
OFFICE OF THE DIRECTOR

NAME OF RESEARCHER/INVESTIGATOR:
Ms FI Ramusilei

STUDENT NO:
11605855

PROJECT TITLE: **Views of professional nurses regarding the new antiretroviral therapy drug tenofovir, lamivudine and dolutegravir in selected clinics of Limpopo Province.**

PROJECT NO: SHS/21/PH/07/1008

SUPERVISORS/ CO-RESEARCHERS/ CO-INVESTIGATORS

NAME	INSTITUTION & DEPARTMENT	ROLE
Dr TJ Mabunda	University of Venda	Supervisor
Mrs SE Tshivhase	University of Venda	Co - Supervisor
Ms FI Ramusilei	University of Venda	Investigator – Student

Type: **Masters Research**
Risk: **Minimal risk to humans, animals or environment (Category 2)**
Approval Period: **August 2021 – August 2023**

The Human and Clinical Trails Research Ethics Committee (HCTREC) hereby approves your project as indicated above.

General Conditions
While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, please note the following.

- The project leader (principal investigator) must report in the prescribed format to the REC:
  - Annually (or as otherwise requested) on the progress of the project, and upon completion of the project
  - Within 48hrs in case of any adverse event (or any matter that interrupts sound ethical principles) during the course of the project.
  - Annually a number of projects may be randomly selected for an external audit.
- The approval applies strictly to the protocol as stipulated in the application form. Would any changes to the protocol be deemed necessary during the course of the project, the project leader must apply for approval of these changes at the REC. Would there be deviated from the project protocol without the necessary approval of such changes, the ethics approval is immediately and automatically forfeited.
- The date of approval indicates the first date that the project may be started. Would the project have to continue after the expiry date; a new application must be made to the REC and new approval received before or on the expiry date.
- In the interest of ethical responsibility, the REC retains the right to:
  - Request access to any information or data at any time during the course or after completion of the project,
  - To ask further questions; Seek additional information; Require further modification or monitor the conduct of your research or the informed consent process.
  - withdraw or postpone approval if:
  - Any unethical principles or practices of the project are revealed or suspected.
  - It becomes apparent that any relevant information was withheld from the REC or that information has been false or misrepresented.
  - The required annual report and reporting of adverse events was not done timely and accurately,
  - New institutional rules, national legislation or international conventions deem it necessary

ISSUED BY:
UNIVERSITY OF VENDA, RESEARCH ETHICS COMMITTEE
Date Considered: July 2021

Name of the HCTREC Chairperson of the Committee: Dr NS Mashau

Signature:

UNIVERSITY OF VENDA
OFFICE OF THE DIRECTOR
RESEARCH AND INNOVATION
2021 -08- 10
Private Bag X5050
Thohoyandou 0950

PRIVATE BAG X5050, THOHOYANDOU, 0950, LIMPOPO PROVINCE, SOUTH AFRICA
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Annexure 5: Ethical clearance

Annexure 6: Interview transcript

Participant 1

R- Good morning, my name is Ramusilei Innocentia. I am a master student at the University of Venda. Thank you for granting me the opportunity to interview you. Note that the information will be recorded and is used for research purposes only. I will name you participant one for privacy.

P- good morning to you too

R- how are you today?

P- well...., I am good just a bit nervous.

R- ok, that is normal my dear, just relax and feel free. Can I offer you water?

P- no, thanks ey

R- So, may you please describe your views regarding TLD.

P-mmmh..... TLD is good and also bad at times because when they first introduced it, they said we must not give it to pregnant women, but it suppresses viral load fast.

R- can you please elaborate on that?

P- the good thing about this TLD is that it suppresses viral load in no time, but it is bad because it is not supposed to be given to pregnant women whereas most pregnant women you find that they have high viral load because they don't condomise and it was going to help them to suppress the virus.

R-what is the reason for not giving it to the pregnant women?

P- ok the reason for not giving it to pregnant women is that they said it could have adverse side effects on the baby. The child could be born disabled but now everybody drinks it.

R- disabled? In which way?

P- they say baby can be born with spinal problem that will also affect the brain, they call it neural tube defects.

R- I heard you saying now everybody drinks it.

P- yes, there was a workshop that was attended, and that report said it is safe to give the pregnant women.

R- safe? In which way?

P-okay.... that side effects of the baby to be born with disability is no longer there or is very minimal chance for baby to be disabled.

R-are you giving them?

P-eish at first, I personally was afraid due to the side effect mentioned before but because I am at work I had to do that.

R- when you say you had to, are you forced?

P-noooo....., you know when things change neh, it is not easy to adjust especially when you heard the bad side of it. I was just fearing for my life.

R- what do you mean, fearing for your life.

P- if I give her and the baby comes with that side effects, I will feel guilty even though they said chances are very low.

R- I hear you, how did other professional nurses take this new information.

P_ majority where happy that it will help because some of those pregnant women their virus is high because they do not condomise.

R- do you see it helping?

P- very much, more of them are virally suppressed and on top of that, thank God not even one whom we have given TLD gave birth to child with defects, which means it is true that the chances are very low. Now I give them with confidence.

R-ok, you mentioned that it suppresses viral load fast, what can you say about that?

P- okay.....when you put or switch the patient on TLD within 6 months the viral load will be low, and the adherence is good.

R-what are the reactions of patients to this new drug?

P- Most of the patients were extremely happy when we introduced it to them because we told them that it reduces viral load very fast. Because with other drugs when we interview patients, we can see they are taking it well, but the viral load is not going low, so we see that patients are taking it well. wow, patients love it a lot you know, they love it.

R- what could be the reason?

P-some says it doesn't give them nightmares and they sleep peacefully unlike the previous drug and the side effects are very few and I remember only few that mentioned that they were unable to sleep since they started this TLD, but it didn't last more than two weeks, and most do not have a single side effect and it is also suitable for all working classes.

R- suitable for all working classes?

P- yes, whether you work during the day or at night with TLD you are good to go.

R- what do you mean?

P- TLD is a single dose combination drug that is taken any time of the day which means you can choose the best suitable time for yourself unlike that TEE which was strictly taken at night, and it was a disadvantage to night shifters.

R- why?

P- TEE is having this drug called efavirenz that is compulsory to be taken at night due to its side effects which are nightmares, so you see, if you work at night and those nightmares start is a disgrace but with TLD you are covered because it does not give hallucinations and is time convenient.

R- what else can you say about this drug.

P-well, it is also good because even adolescents can take it, this one is good. With that one you were supposed to be 15 years with weight of above 40kg to be given single dose combination, but TLD when you are above 10 years and 35 kg you can have it and is very possible for that weight in adolescents.

R- what do you mean by that one?

P- oh..... I mean TEE is a single dose combination pill with lot of disadvantages, but TLD is the best.

R- what is single dose combination.

P- oh...I mean three drugs in one pill, so most adolescents no longer default, and their virus are now suppressing which shows that a pill burden was also a factor for defaulting.

R- you mean that the default rate is decreasing.

P- yes, since we started switching them to TLD they comply, and the viral load results are much improved most have achieved undetectable viral load. Others also comment that this one is better because it is only one pill.

R- what do you mean by pill burden.

P- with those ones you find that they have to take three tablets twice a day which is not convenient for them because they are adolescents so most were just stopping it or take treatment at their preferred time and the boring part was that sometimes they will come at the clinic and find that one pill is not available and you need to refer patient to hospital and they will tell you that they don't have money and they won't go, so it was a disadvantage on its own.

R- you mean there is shortage of treatment.

P- Yes with those ones not with TLD, TLD is available at all times and is working in miraculous way. The financial constraints are also reduced because when they come, they have the treatment they are no longer referred to hospital.

R- ok, is there anything you would like to add.

P-no, I think I have said enough.

R-ok, thank you for your time and response. Much appreciated.

P-you are welcome.

EDITOR'S CERTIFICATE FOR RAMUSILEI FHULULEDZANI INNOCENTIA

11 May 2023

To whom it may concern

Dear Sir/Madam

This is to confirm that I, Zitha Innocent have proofread and edited a mini-dissertation for the degree of Master of Public Health in the Faculty of Health Sciences at the University of Venda, titled '**VIEWS OF PROFESSIONAL NURSES REGARDING THE NEW ANTIRETROVIRAL THERAPY DRUG TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR IN SELECTED CLINICS OF LIMPOPO PROVINCE**

RAMUSILEI FHULULEDZANI INNOCENTIA

STUDENT NUMBER: 11605855

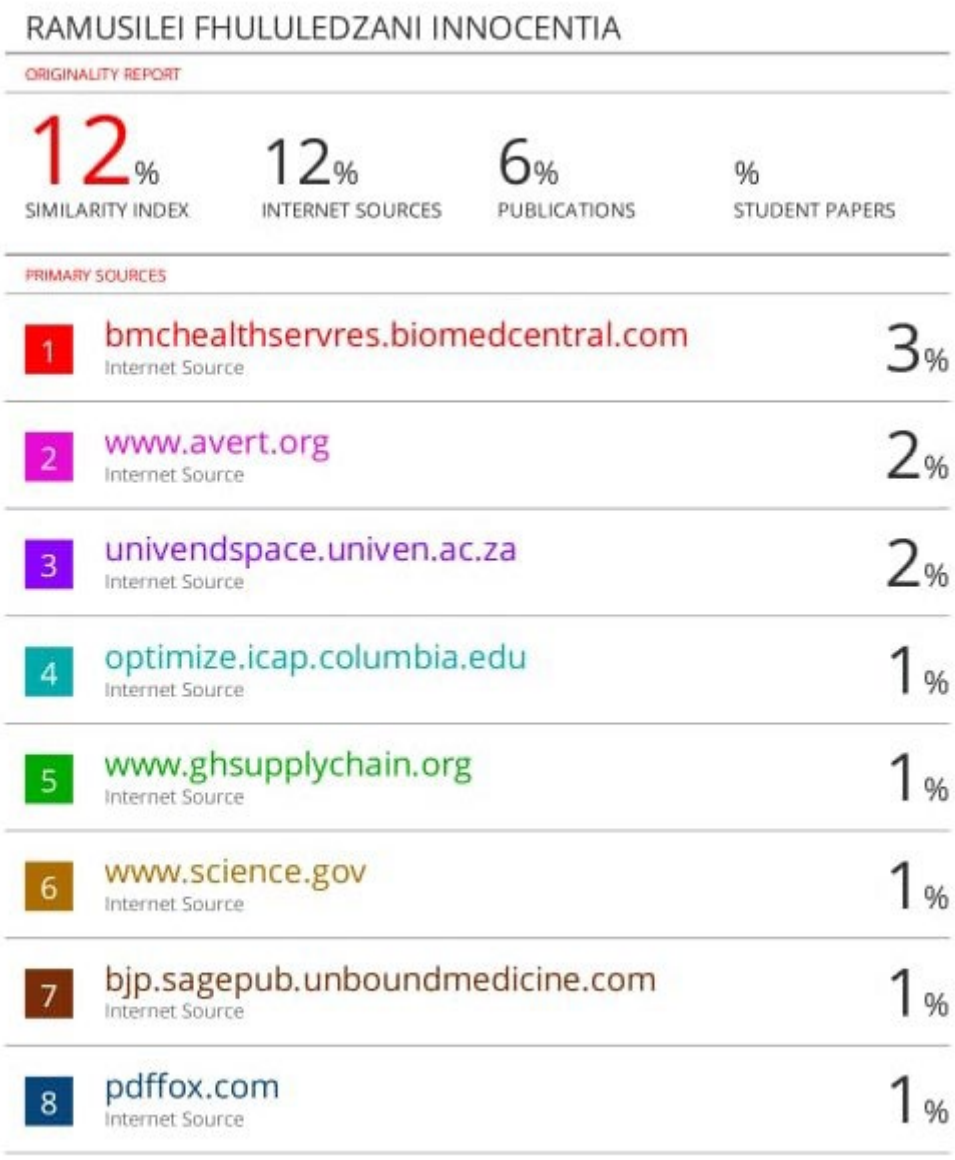
I have further suggested several amendments that the student has undertaken to effect before this research is finally submitted: spelling, grammar, structure, and format of chapters. This mini-dissertation was inspected meticulously for consistency and correctness in grammar usage, coherence, cohesion, and citations. Should there be any inquiry, please do not dither to contact me.

Best Regards

Zitha I
***Cell Phone**:* 0715430998/ 015 962 8922
Email:Innocent.Zitha@univen.ca.za

BA (English), BA (Hons) in English, MA in English
Lecturer (English) at Science Foundation
University of Venda

Annexure 7: Proof of editing letter



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