PREVALENCE AND DETERMINANTS OF DIABETIC RETINOPATHY IN MARULENG HEALTHCARE FACILITIES, MOPANI DISTRICT IN LIMPOPO PROVINCE

by

MALULEKE KHISIMUSI DEBREE

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SUPERVISOR: Dr. E Maimela

CO-SUPERVISOR: Dr TS Ntuli

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DEDICATION

I dedicate this mini-dissertation in memory of my late uncle, Sikheto Samson Maluleke (Nicknamed: Dulu-ra-mumu). To the God Almighty.

DECLARATION

I declare that the mini-dissertation titled "**PREVALENCE AND DETERMINANTS OF DIABETIC RETINOPATHY IN MARULENG HEALTHCARE FACILITIES, MOPANI DISTRICT IN LIMPOPO PROVINCE**", hereby submitted to the University of Limpopo, for the degree of Master of Public Health has not previously submitted by me for a degree at this or any other university; that it is my work in design and in execution, and that all materials contained herein has been duly acknowledged.

Maluleke KD (Mr) **09 September 2021**

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ABSTRACT

Background: Diabetes mellitus (DM) is a major public health problem, and it remains one of the global epidemics of non-communicable diseases. Diabetic retinopathy (DR) is a micro-vascular complication of DM due to a prolonged hyperglycaemia, and it is the most common cause of a visual loss in people living with DM. The global increase in the prevalence of DM has led to an increase in prevalence of diabetic complications, such as DR. The primary aim of this study was to investigate the prevalence and determinants of DR among the DM patients receiving treatment from Maruleng public healthcare facilities, Mopani District in the Limpopo Province.

Methodology: A quantitative cross-sectional survey was used as a primary source data from the DM patients who were readily available at the selected public healthcare facilities to collect a chronic treatment during the time of the study. Selection of eligible DM patients was done through a convenient sampling technique for those who were readily available or willing to take part of the study after receiving all information about the study for them to consent freely without any form of coercion by researcher or any other person. All selected respondents had undergone face-to-face interviews and basic clinical screening for DR to collect a primary source data using piloted structured researcher-administered questionnaire to record data collected from respondents, and calibrated medical equipment were used to measure a clinical variables during clinical screening. Data analysis was carried out using Statistics and Data Analysis (STATA) version 15 software for windows. The characteristics of DM patients were summarised and analysed using a descriptive statistics. Inferential statistics were performed on dependent variable and independent variables using a logistic regression analysis to determine the strength of association between variables, where a potential predictors of DR among DM patients were identified at significant level of less than 0.05 ($p<0.05$).

Results: Out of the 416 DM patients who participated in the study, the majority were females (n=315; 76%) and all DM patients were above the age of 18 years, with a mean age of 61 years (standard deviation [SD] =11.5). The overall prevalence of DR was 35.4% comprising 32% mild non-proliferative DR (NPDR) and 3.4% moderate NPDR. DR was found to be slightly more prevalent in females, at 35.9%, than in males, at 34.6%; particularly in those females with type 2 DM, at 35.1%, comprising 32.1%

mild NPDR and 3% moderate NPDR. DR was more prevalent in older females, at 77.8%, comprising 55.6% mild NPDR and 22.2% moderate NPDR. The DM patients aged 55 years and above were found to be 2.7 times more likely to develop DR, at *p<0.001*, and DM patients with higher systolic blood pressure of 140 mmHg or more were found to be 1.4 times more likely to develop DR as compared to DM patients with a systolic blood pressure of 139 mmHg or less (≤139 mmHg), at *p<0.05*. Employed DM patients were 1.4 times more likely to develop DR as compared to unemployed DM patients, at *p<0.001*. Age of the DM patients, high systolic blood pressure (SBP) or a hypertension of 140 mmHg or more (≥ 140 mmHg), and employment status were significantly associated with higher risk of developing DR among DM patients. Gender, hyperglycaemic state, poor glycaemic control, smoking and high BMI were found to be associated with DR but this association was not statistically significant.

Conclusion and recommendations: Slightly more than one third of the DM patients receiving treatment during the study period from the public healthcare facilities in the Maruleng sub-district had some form of DR, which means that nearly four in ten DM patients had some form of DR. Diabetic retinopathy was more prevalent in females, and in older DM patients. Age of the DM patient, employment status, and high systolic blood pressure were significantly associated with an increased risk of developing DR among the DM patients. There is an urgent need to implement a health promotional programmes to educate people about the complications of a diabetes mellitus such as DR, and also to establish a coordinated screening programme for DR among DM patients receiving a chronic treatment, which must be supported by the Department of Health in all public healthcare facilities.

Keywords: Diabetes Mellitus, Diabetic Retinopathy, Prevalence, Determinants.

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DEFINITIONS OF KEY CONCEPTS

Determinants are many factors combine together to affect the health of individuals and communities (WHO, 2020). Determinants include the social, economic and physical environments, as well as individual characteristics, such as biological and behavioural factors (WHO, 2020). In this study, *determinants* refers to the associated risk factors influencing the rapid development of diabetic retinopathy among diabetes mellitus patients, such age of patient, duration of diabetes mellitus, poor glycaemic or diabetic control, high systolic blood pressure, high body mass index and smoking.

Diabetes mellitus, commonly known as diabetes, is a chronic metabolic disease that occurs as a result of high blood sugar (hyperglycaemia), when the body's cells cannot utilise insulin effectively, leading to a type 2 diabetes, or when the pancreas produces inadequate insulin, leading to a type 1 diabetes (IDF, 2020; WHO, 2020).

Diabetic retinopathy is a complication of diabetes mellitus that occurs as a result of hyperglycaemia, leading to visible vasculature damage of the small blood vessels (capillaries) in the retina of the eye, causing a blockage of capillaries, or leakage of blood fluids from the retinal blood capillaries (Bowling, 2016; IDF, 2020).

Prevalence is a statistical concept referring to the number of disease cases present in a specific population in particular area at a given time, which could be referred to as period prevalence at specific time interval, for example, the month of June (Gordis, 2014). Prevalence could be referred to point prevalence, meaning prevalence in a specific area at a specific time (Gordis, 2014). In this study, *prevalence* refers to point prevalence, which means the proportion of diabetes mellitus patients having diabetic retinopathy in Maruleng public healthcare facilities in relation to the total number of diabetes mellitus patients in Maruleng public healthcare facilities during the time of study.

LIST OF ABBREVIATIONS AND ACRONYMS

BMI	Body mass index
CI	Confidence interval
DM	Diabetes mellitus
DR	Diabetic retinopathy
IDF	International Diabetes Federation
NPDR	Non-proliferative diabetic retinopathy
OR	Odds ratio
PDR	Proliferative diabetic retinopathy
STATA	Statistics and Data Analysis
STDR	Sight-threatening diabetic retinopathy
WHA	World Health Assembly
WHO	World Health Organization

CHAPTER ONE: OVERVIEW OF THE STUDY

1. INTRODUCTION AND BACKGROUND

Diabetic retinopathy (DR) is the most common cause of vision impairment or blindness in people living with a diabetes mellitus (Hartnett, Baehr & Le, 2017). It occurs as a direct result of sustained or prolonged high blood sugar, commonly known as hyperglycaemia, causing visible damage to small blood vessels or blood capillaries in the retina of the eye, leading to a blockage of capillaries or leakage of blood fluids from the retinal blood capillaries (American Academy of Ophthalmology [AAO], 2020; International Diabetes Federation [IDF], 2020). Other associated risk factors influencing rapid development or pathogenesis of DR in diabetic people include the age of diabetic person, duration of diabetes mellitus (DM), poorly controlled diabetes, high body mass index (BMI), hypertension, type of DM, pregnancy, lipidaemia, nephropathy and smoking (AAO, 2020; Bowling, 2016).

Diabetic retinopathy is also the leading cause of legal blindness in working-age diabetic adults between 20 and 65 years, particularly in the developed world, because of unhealthy lifestyles such as physical inactivity and bad eating habits (IDF, 2020). In 2010, at least 0.8 million diabetic people were considered blind, while 3.7 million diabetic people were considered visually impaired because of DR, with an alarming increase of 27% and 64%, respectively, spanning the two decades from 1990 to 2010 (Leasher, Bourne, Flaxman, Jonas, Keeffe & Naidoo et al., 2016). DR accounts for 2.6% of all cases of blindness and 1.9% of all cases of vision impairments, globally. This represents an increase of 2.1% in blindness and 1.3% in vision impairments. These figures were lower in regions with younger populations, with blindness occurring in less than 2% of the population, particularly in East and South East Asia and Oceania, compared to high-income regions, such as North America, Western Europe and Australasia (Leasher et al., 2016).

The global prevalence of diabetic retinopathy is currently estimated to be between 27% and 28.1% prevalence of any DR, according to the two recent systematic reviews and meta-analyses reported for the period 2015 to 2019 by Hashemi, Pakzad, Heydarian, Pakbin, Yekta and Aghamirsalim et al. (2019) and Thomas, Halim, Gurudas, Sivaprassad and Owens (2019). The regional prevalence of DR is 20.6% in Europe, in South East Asia it is 12.5%, in the Western Pacific it is 36.2% and in Africa

and Middle East region it is 33.8% (Thomas et al., 2019). There is a continuous increase in diabetes mellitus (DM), especially in type 2 DM cases, because of unhealthy lifestyles, such as physical inactivity and bad eating habits, leading to the increase in the prevalence of diabetic complications, such as DR, in low-income and middle-income countries (Vujosevic, Aldington, Silva, Hernàndez, Scanlon & Peto et al., 2020).

In Africa, the overall regional prevalence of any DR is 33.8% (Thomas et al., 2019). The other associated factors contributing to this prevalence of DR include socio-economic factors, such as poor access to care, poor infrastructures, low gross domestic product (GDP) and inadequate healthcare funding (WHO, 2020). In 2016 diabetes country profile of South Africa shows that the overall prevalence of DM is 9.8%, comprising a 7.7% DM prevalence in males and an 11.8% DM prevalence in females. There are several studies on the prevalence of any DR, which were carried out in some parts of the country such as the one in Bloemfontein at the National District Hospital by Cairncross, Steinberg and Labuschegne (2017) showing the prevalence of any DR is 10.8%, in Tshwane District by Webb, Rheeder and Roux (2016) showing prevalence of any DR at 24.9%, in KwaZulu-Natal Province by Abdool and Mahomed (2017) at 42%, and another similar study in KwaZulu-Natal Province at the McCord Provincial Hospital by Verwey and Mahomed (2020) shows the prevalence of any DR at 71.8%. Associated risk factors that influence a rapid development of DR for people living with DM include overweight, obesity and physical inactivity. An examination of the fundus or retinal examination is commonly used to detect any abnormalities on the retina of the eye including a retinal abnormalities caused by the presence of any DR among DM patients. However, this examination is currently not available at the primary healthcare level in South Africa, and it is only available at the secondary and tertiary healthcare level (WHO, 2020).

2. RESEARCH PROBLEM

Diabetic retinopathy (DR) has been identified by the World Health Organization (WHO) as one of the leading causes of distance or near vision impairment and blindness in diabetic people, particularly in working-age diabetic adults in developed countries (IDF, 2020; WHO, 2020). Diabetes mellitus (DM) remains one of the global epidemics of non-communicable diseases (NCDs) (Sube et al., 2020). The World Health Assembly (WHA) in WHO, comprising all the member states, including South Africa,

has adopted resolution WHA42/R36 as a global action or strategy aimed at preventing and controlling NCDs, such as DM, including its complications, such as DR (WHO, 2020). An increase in the prevalence of DM in a global population, particularly type 2 DM, leads to an increase in DM complications, such as DR (Vujosevic et al., 2020).

Through observation by the researcher, the prevalence and associated risk factors (or determinants) of diabetic retinopathy among diabetes mellitus patients receiving treatment from the public healthcare facilities or government healthcare facilities in the Maruleng Sub-district were not known because almost 91% (10/11) of these facilities do not have a single optometrist to initiate and implement a DR screening programme among diabetes mellitus patients. The most important step in any epidemiological investigation is to establish the magnitude of a disease by determining the prevalence rate of the disease in an area at a specific point in time (Gordis, 2014).

3. LITERATURE REVIEW

A review of the literature on DR, its prevalence and the determinants of DR was conducted by the researcher using library materials, such as scholarly journals and books, including accredited databases in consultation with a subject librarian of the Faculty of Health Sciences, University of Limpopo. This review will be comprehensively dealt withs in Chapter 3.

4. PURPOSE OF THE STUDY

4.1. Aim of the study

The aim of the study was to investigate the prevalence and the determinants of a diabetic retinopathy among diabetes mellitus patients receiving treatment from the Maruleng public healthcare facilities, Mopani District in Limpopo Province.

4.2. Objectives of the study

The objectives of the study were;

- To describe the socio-demographic characteristics of diabetes mellitus patients receiving treatment from the Maruleng public healthcare facilities during the time of study.
- To determine the prevalence of diabetic retinopathy among diabetes mellitus patients receiving treatment from the Maruleng public healthcare facilities during the time of study.

- To identify the determinants of diabetic retinopathy among diabetes mellitus patients receiving treatment from the Maruleng public healthcare facilities during the time of study.

5. RESEARCH QUESTION

What are the prevalence and the determinants of diabetic retinopathy among diabetes mellitus patients receiving treatment from Maruleng public healthcare facilities, Mopani District in Limpopo Province?

6. RESEARCH METHODOLOGY

The research methodology used to conduct the present study included the research method; research design; site sampling; data collection and data analysis; internal and external validity of the study; bias and confounding effect will be fully discussed in Chapter 3.

7. ETHICAL CONSIDERATIONS

The Turfloop Research and Ethics Committee (TREC) of the University of Limpopo granted the researcher an ethical clearance certificate (TREC/28/2020: PG), which was applied for because the respondents (the DM patients) in the study were human beings, see Appendix 4. Details of the ethical considerations related to sampling and data collection will be discussed in Chapter 3.

8. SIGNIFICANCE OF THE STUDY

The study results will increase the existing body of knowledge on the prevalence and determinants of DR among DM patients. The results of the study will also increase knowledge of DR among DM patients receiving treatment and the other healthcare benefits, such as the prevention and treatment options available. The authority in the Department of Health may use the results to make policy regarding the prevention and treatment strategies; while serving healthcare professionals may also use results to provide an evidence-based practice, improve diabetic healthcare services and motivate authorities to improve resource allocations.

9. OUTLINE OF THE CHAPTERS

In the next chapter, the researcher will discuss a review of the literature on the study. In Chapter 3, the researcher will outline the methods and materials used to conduct the study, including study design, sampling and data collection. In Chapter 4, the

researcher will present the results of this study, including summarised and analysed quantitative data. In Chapter 5, the researcher will discuss the results of the study and link the results to other published studies.

10. CONCLUSION

This is the end of chapter one, in which the researcher provided an overview of the present study.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

In the previous chapter, the researcher introduced the study by providing an overview of the study. A literature review is very important as it prevents duplication of work that has been before, identifies knowledge gaps and helps researchers to compare their own ideas to existing ideas, including a bibliographic management compiled to acknowledge the work of others (Brink et al., 2018; De Vos et al., 2017). In this chapter, therefore, the researcher focuses the discussion on other studies relating to the present study. The scope of this literature review includes diabetes mellitus, diabetic retinopathy (DR), prevalence and determinants of DR, socio-demographic characteristics, consequences and the public health importance of diabetes.

2.2. Literature search strategy

Science Direct and Google Scholar were the search engines used to locate published studies and other literature for this review. The websites of credible organizations, such as World Health Organization (WHO), International Diabetes Federation (IDF) and the others, were also used to locate the health databases. This search was restricted to English-language publications not older than five (5) years.

2.3. Natural history of diabetes mellitus

Diabetes mellitus (DM), commonly known as diabetes, is a chronic metabolic disease characterised by high blood sugar or plasma glucose (hyperglycaemia). It occurs when the pancreas produces insufficient insulin or when body's cells cannot effectively utilise the insulin produced (IDF, 2020; WHO, 2020). The two most common types of DM are type 1 DM and type 2 DM. A less common type of DM is gestational diabetes, which occurs during pregnancy in women (Learned & Pieramici, 2018).

2.3.1. Type 1 diabetes mellitus

Type 1 DM presents in childhood or early adulthood as a direct result of inadequate insulin produced by the pancreas because of destructed beta (β) cells in the pancreas, leading to low levels of insulin, resulting in blood sugar elevation (IDF, 2020; Learned & Pieramici, 2018). An estimated of 1 in every 430 to 530 people under the age of 19 years live with type 1 DM, and out of 3.7 million people with DM, diabetes UK estimates

that 10% have type 1 DM, which translates to 400, 000 people with 29,000 of those living with type 1 DM are children (Beyond Type 1, 2020).

2.3.2. Type 2 diabetes mellitus

Type 2 DM is characterised by the body cells becoming resistant to insulin, leading to elevated blood sugar levels. The most important risk factors associated with a type 2 DM include physical inactivity and bad eating habits. However, a family history of DM, or genetics, and maternal diabetes also play a major role in the rapid development of type 2 DM (IDF, 2020; Learned & Pieramici, 2018).

2.3.3. Gestational diabetes mellitus

Gestational diabetes during pregnancy occurs as a direct result of hormonal changes in pregnant women which happen to ensure that a foetus receives sufficient nutrients and insufficient insulin is produced by the mother, leading to excessive blood sugar level (IDF, 2020; Learned & Pieramici, 2018).

2.3.4. Prevalence of diabetes mellitus

In 2020, at least 422 million people globally were living with DM, particularly in the low-income and middle-income countries, and 1.6 million deaths of people are directly attributed to DM each year (WHO, 2020). The global prevalence of DM in adults above the age of 18 years rose from 4.7% in 1980 to 8.5% in 2014. The prevalence of DM has risen more rapidly in low-and middle-income countries than in the high-income countries (WHO, 2020). The determinants of DM include obesity or overweight and/or physical inactivity. DM is the main contributor to blindness, kidney failure, heart attacks, strokes and lower limb amputation (IDF, 2020; WHO, 2020). Increased prevalence of DM leads to an increase in complications of DM, such as a diabetic retinopathy (DR), which is a micro-vascular complication of DM in the retina of the eye as a result of sustained hyperglycaemia (AAO, 2020; Bowling, 2016; IDF, 2020).

2.4. Natural history of diabetic retinopathy

Diabetic retinopathy (DR) is a complication of diabetes mellitus that occurs as a result of sustained hyperglycaemia, causing a visible damage to small blood vessels (or retinal capillaries), and leading to a blockage of retinal blood capillaries, or leakage of blood fluids from the retinal blood capillaries of the eye (AAO, 2020; Bowling, 2016; IDF, 2020). The process of the pathogenesis of DR starts with sustained or prolonged

hyperglycaemia, causing visible damage to vasculature, which includes the endothelia thickening, and pericytes dysfunction or loss (AAO, 2020). DR is divided into two main forms, namely, a non-proliferative DR (NPDR) and proliferative DR (PDR).

2.4.1. Non-proliferative diabetic retinopathy

Non-proliferative DR (NPDR) is the early progressive stage of DR, comprising mild NPDR, moderate NPDR and severe NPDR (AAO, 2020; Bowling, 2016). In mild NPDR abnormalities, DM patients do not present any visual symptoms and this stage is characterised by the presence of micro-aneurysm. Moderate NPDR abnormality is characterised by the presence of more than just micro-aneurysms but also micro-aneurysms plus haemorrhages, while severe NPDR, sometimes called pre-proliferative DR abnormality, is characterised by the presence of all the mild NPDR and moderate NPDR abnormalities, plus cotton wool spots and venous beading in more than 2 quadrants or all 4 quadrants of the retina (AAO, 2020; Bowling, 2016).

2.4.2. Proliferative diabetic retinopathy

Proliferative DR (PDR) is the advance or late stage of DR, characterised mainly by the presence of a new small blood vessels (or neovascularisation) growing on the optics disc, or elsewhere on the retina of the eye, and vitreous or pre-retinal haemorrhages (AAO, 2020; Bowling, 2016).

2.5. Overall prevalence of diabetic retinopathy in all perspectives

Thomas et al. (2019) reported a systematic review and meta-analysis conducted on international databases of studies published from 2015 to 2019 on the prevalence of DR and diabetic macular oedema (DME). They reported that the global prevalence of any DR was 27%, comprising 25.2% non-proliferative DR (NPDR), 1.4% proliferative DR (PDR), and 4.6% of DME (Thomas et al., 2019). Europe had a DR prevalence of 20.6% compared to 12.5% in South East Asia, 33.8% in Africa and Middle East, and 36.2% in the Western Pacific region (Thomas et al., 2019). Hashemi et al. (2019) also reported on a systematic review and meta-analysis conducted on publications from a published database, which started in November 2018. They estimated the global prevalence of any DR at 28.4% in the general population, broken down into 26.1% in females and 28.9% in males.

Yasir, Hassan and Rajiv (2019) reported on a survey conducted in the Riyadh district of Saudi Arabia between 2014 and 2017 that aimed to determine the prevalence and determinants of DR. They reported that the age-adjusted prevalence of any DR was 44.7% among 890 participants who participated in a survey. This study found that DR was significantly higher in males than in females among those participants above 60 years. The study also found that the crude prevalence of a sight-threatening diabetic retinopathy (STDR) was 12.4% (Yasir et al., 2019).

Keel, Xie, Foreman, van Wijngaarden, Taylor and Dirani (2017) reported on a survey conducted in Australia using self-reported previous diagnosis. The study aimed to determine the prevalence and related associated risk factors of DR among 431 non-indigenous Australian adults and 645 indigenous Australian adults. They reported a 28.5% weight-adjusted prevalence of any DR in non-indigenous population, and a 4.5% prevalence of DR in the indigenous population (Keel et al., 2017). Among adults who were 40 years or older had 39.4% prevalence of DR with 9.5% prevalence of STDR, while a longer duration of diabetes was associated with STDR in indigenous population (Keel et al., 2017). Liu, Song, Tao, Qiu, Lv and Jiang (2017) reported on a study conducted in six provinces in China that aimed to describe the prevalence and severity of DR and STDR among Chinese adults with DM. They reported that the overall prevalence of any DR was 34.1%, and that the prevalence of STDR was 13.1%, which was associated with the age of participants (Liu et al., 2017).

Martinell, Dorkhan, Stàlhammar, Storm, Groop and Gustavsson (2016) reported on a study conducted on 2174 DM patients diagnosed with a type 2 DM. The study aimed to research DR at diagnosis, and to estimate contributing risk factors by the sociodemographic, cardiovascular and metabolic characteristics present among patients who were recently diagnosed with a type 2 DM. They reported that the prevalence of DR at diagnosis was 12%, comprising mild NPDR prevalence at 7% and moderate NPDR at 5% (Martinell et al., 2016). Valizadeh, Moosazadez, Bahaadini, Vali, Lashkari and Amiresmaili (2016) reported on a study that aimed to determine the prevalence of diabetic retinopathy and its associated factors in diabetic patients referred to a diabetes centre in an Iranian city. They reported a 45.1% prevalence of any diabetic retinopathy (Valizadeh et al., 2016).

Lòpez, Cos, Alvarez-Guisasola and Fuster (2017) reported on a cross-sectional study conducted in Spain that aimed to investigate the prevalence of DR and the other risk factors. They reported that the prevalence of any DR was 14.9%, with the condition being more prevalent in females (*p=0.0087*) and older patients; while duration of DM and high blood pressure had a positive association with the development of DR, more so in patients using insulin (Lòpez et al., 2017). Tan, Gan, Sabanayagam, Tham, Neelam and Mitchell et al. (2018) reported on a study that aimed to evaluate the prevalence and risk factors for DR among participants in the Singapore Epidemiology of Eye Diseases (SEED) programme. They reported that an overall age-standardised prevalence of any DR of 28.2% and that the independent risk factors included ethnicity, duration of DM, serum glucose and systolic blood pressure (Tan et al., 2018). Shiferaw, Akatu, Desta, Kassie, Petrucka and Assefa et al. (2020) reported on systematic search conducted using the PubMed, African Journals, Google Scholar, Scopus and Wiley Online Library for observational studies addressing association of haemoglobin A1c (HbA1c) levels with DR. Poor glycaemic control of HbA1c>7% was recorded to be associated with DR.

Magan, Pouncey, Gadhvi, Katta, Posner and Davey (2019) reported on an observational cross-sectional study conducted at the Mulago Hospital, Kampala in Uganda in April 2016. The study aimed to determine the prevalence of diabetic eye disease and the authors reported that mean age of patients was 50.4 years, that 14.6% had VA<6/18, and the overall prevalence of any DR was 85.7%, of which 14.6% had STDR with a maculopathy. The study also found that DR was more prevalent in females and in older patients (Magan et al., 2019). Bobb-Semple, Ruvuma and Onyango (2017) also reported on a study conducted at the Mbarara Regional Referral Hospital in South Western Uganda. The study aimed to determine the sensitivity and specificity of smartphone fundoscopy in diagnosing and staging DR. They found a 13.5% prevalence of any DR among 207 patients (Bobb-Semple et al., 2017).

Cleland, Burton, Hall, Hall, Courtright and Makupa (2016) reported on a study conducted in the Kilimanjoro region of Tanzania that aimed to investigate the prevalence of DR and its risk factors. They reported that the prevalence of any DR was 27.9%, comprising a 19.1% prevalence of background DR, a 6% prevalence of pre-proliferative DR and a 2.9% prevalence of proliferative DR among 3187 patients. The authors also found that DR was associated with duration of DM, and systolic blood

pressure (Cleland et al., 2015). Ahmed, Elwali, Awadalla and Almobarak (2017) reported on a cross-sectional study conducted among 316 individuals with diabetes in Sudan. The mean age of participants was 58±10 years old, where 39.8% of females and 60.2% of males had DR and hypertension was identified risk factor (Ahmad et al., 2017).

Lartey and Aikins (2018) reported on a study conducted at the Komfo Anokye Teaching Hospital Eye Unit in Ghana that aimed to determine the prevalence of DR. They found a 22.3% prevalence of any DR, comprising a 13.7% prevalence of mild NPDR and moderate DR, a 1.8% prevalence of severe NPDR and a 6.8% prevalence of maculopathy (Lartey & Aikins, 2018). Sube et al. (2020) reported on a study conducted at the Malakia Health Centre in South Sudan that aimed to determine the prevalence and risk factors of DR. They found 13% prevalence of any DR, comprising of 11.6% prevalence of NPDR and a 0.5% prevalence of PDR associated with duration of DM, uncontrolled blood glucose, hypertension and obesity (Sube et al., 2020).

Lewis, Hogg, Chandran, Musonda, North and Chakravarthy (2018) reported on a study that aimed to estimate the prevalence of DR and visual impairment in Zambia. They reported a 52.0% prevalence of any DR, a 36.0% prevalence of STDR and a 7.0% prevalence of PDR (Lewis et al., 2018). Duration of DM; random blood glucose; systolic and diastolic blood pressure; the use of insulin; and, oral treatment were strongly associated with DR (Lewis et al., 2018). Another study conducted in Zambia was reported on by Bellemo, Lim, Lim, Nguyen, Xie and Yip (2019). The study aimed to identify and reduce blindness due to diabetes. A total of 1574 Zambians were recruited to participate in the study and the authors found that 22.5% of Zambians had referable DR, 5.5% had STDR and 8.1% had DME (Bellemo et al., 2019).

Chisha, Terefe, Assefa and Lakew (2017) reported on a cross-sectional study conducted at the Arbarminch General Hospital in Ethiopia. The study aimed to determine the prevalence of DR and factors associated with DR. The authors found that the prevalence of any DR was 13%. Shibru, Aga and Boka (2019) reported on a study conducted at the Tikur Anbessa Hospital in Ethiopia that aimed to assess prevalence of DR and associated factors among type 2 diabetes patients. They found that the prevalence of any DR was 51.3%. Agroiya, Alrawahi, Pambinezhuth and Al-Busaidi (2020) reported on a retrospective study that aimed to describe the

prevalence, severity and clinical profile of DR among Omani diabetic patients at a tertiary care hospital. They found that the prevalence of any DR was 31%, comprising a 21.3% prevalence of mild DR, a 4.5% prevalence of moderate-to-severe DR and a 5.2% prevalence of PDR (Agroiya et al., 2020).

Hall, Tambekou, Penn, Camara, Balde and Sobngwi (2017) reported on a study conducted in Cameroon that aimed to determine association between depression and glycaemic control; and to record the prevalence of DR. They recorded a prevalence of DR at 27.2%, comprising a 23.4% prevalence of NPDR, a 2.5% prevalence of pre-proliferative DR and a 3.2% prevalence of PDR, associated with poor glycaemic control, educational level and use of insulin (Hall et al., 2017).

In the South African context, Webb, Rheeder and Roux (2016) reported on a study conducted in the Tshwane district that aimed to determine the prevalence of DR, maculopathy and visual loss in primary care patients; and to identify associated risk factors. They reported that there was a 24.9% prevalence of DR, comprising a 19.5% prevalence of NPDR and a 5.5% prevalence of PDR, which was associated with a high BMI, high systolic blood pressure, being on insulin treatment, high HbA1c, and the presence of neuropathy (Webb et al., 2016). Cairncross et al (2017) reported on study conducted at the National District Hospital in Bloemfontein, aimed at determining the prevalence of eye pathology in a group of diabetic patients have reported that the prevalence of any DR was at 10.8%. Verwey and Mahomed (2020) have reported the prevalence of any DR at 71.0% among 2250 DM patients from an analytical cross-sectional study on a posterior segment of the eye, which was carried out at the McCord Provincial Hospital in KwaZulu-Natal Province, aimed at describing an epidemiology of presenting eye conditions. Abdool and Mahomed (2017) reported on a retrospective cross-sectional analytic study conducted in KwaZulu-Natal that aimed to determine the prevalence and associated risk factors of DR among type 2 DM patients and they reported a 42% prevalence of any DR.

2.6. Determinants of diabetic retinopathy

The primary instigator of DR is a sustained, prolonged or chronic high blood sugar level, commonly known as hyperglycaemia, leading to visible damage to the vasculature (AAO, 2020; IDF, 2020). The associated risk factors of DR (or determinants of DR) that influence a rapid development or pathogenesis of DR

include, the age of DM patient, duration of DM, poor glycaemic or diabetic control, hypertension or high systolic blood pressure, type of DM, nephropathy, pregnancy, smoking, lipidaemia and a history of eye surgery (AAO, 2020; Bowling, 2016).

2.6.1. Age of diabetes mellitus patient

The age of diabetes mellitus (DM) patients influences the rapid development of DR (AAO, 2020; Bowling, 2016). Studies reported on by Chisha et al. (2017) in Ethiopia, and by Agroiya (2020) in Omani tertiary hospital have shown that increasing age of DM patients was significantly associated with increased risk of developing DR.

2.6.2. Duration of diabetes mellitus

The duration of DM influences the rapid development or pathogenesis of DR (Bowling, 2016). Studies reported on by Lòpez et al. (2017) in Spain; by Tan et al. (2018) in the SEED programme; by Lewis et al. (2018) and Bellemo et al. (2019) in Zambia; by Cleland et al. (2015) in Tanzania,;by Sube et al. (2020) in South Sudan; by Hall et al. (2017) in Cameroon, by Keel et al. (2017) in Australia; and, by Webb et al. (2016) in the Tshwane district of South Africa have all shown that the longer a person lives with DM the higher or increased risk of developing DR.

2.6.3. Poor glycaemic or diabetic control

Poor glycaemic or diabetic control in DM patients influences the rapid development or pathogenesis of DR (AAO, 2020; Bowling, 2016). Studies reported on by Shiferaw et al. (2020); by Lewis et al. (2018) in Zambia; by Hall et al. (2017) in Cameroon; and, by Webb et al. (2016) in the Tshwane district of South Africa have all shown that poor glycaemic control was significantly associated with DR.

2.6.4. High systolic blood pressure or hypertension

Hypertension, or a high systolic blood pressure of 140 mmHg or more (≥ 140 mmHg), influences the rapid development or pathogenesis of DR among DM patients (AAO, 2020; Bowling, 2016). Studies reported on in Tanzania (Cleland et al., 2015); in Spain (Lòpez et al., 2017); in Singapore (Tan et al., 2018; Shiferaw et al., 2020); in South Africa in the Tshwane district (Webb et al., 2016); in South Sudan (Sube et al., 2020); and, in Zambia (Lewis et al., 2018) have all shown that a high systolic blood pressure or hypertension was significantly associated with DR among DM patients.

2.6.5. High body mass index

High body mass index (BMI) influences the rapid development or pathogenesis of DR amongst DM patients (AAO, 2020; Bowling, 2016). Studies reported on by Martinell et al. (2016) and by Webb et al, (2016) in the Tshwane district of South Africa have both shown that a high BMI was significantly associated DR among DM patients.

2.7. Socio-demographic characteristics

2.7.1. Age

Age is an independent characteristic or variable that influences the rapid development of DR, but it increases the chances of developing DR in DM patients, as described in the reviewed literature above (AAO, 2020; Bowling, 2016; Chisha, 2017).

2.7.2. Gender

Gender is an independent characteristic or variable that influences the rapid development of DR in DM patients, as described in the reviewed literature above (AAO, 2020; Bowling, 2016) and in studies reported on by Hall et al. (2017) and by Sunita, Singh, Rogye, Sonawane, Gaonkar and Srinivasan (2017).

2.7.3. Employment

Employed people living with DM have increased risk of developing DR due to the bad eating habits caused by abundant of food sometimes with saturated fats, particularly in meat according to a study carried out by Soleimani, Jafroudi, Kazem, Nejad, Sedighi and Paryad (2017).

2.8. Consequences of diabetic retinopathy

The presence of uncontrolled diabetic retinopathy among diabetic people leads to visible damage of the retinal vasculature, particularly the retinal capillaries of the eye, causing a blockage or leakage from retinal capillaries (AAO, 2020; Bowling, 2016; IDF, 2020). Daily activities, such as driving, reading and other activities that need a perfect vision get affected by DR (AAO, 2020; AOA, 2020; Soleimani et al., 2017).

2.9. Public health importance

Screening for diabetic retinopathy is essential to detect referable cases of DR that need timeous intervention in order to a visual loss due to DR (Vujosevic, Aldington, Silva, Hernàndez, Scanlon & Peto et al., 2020). DR has been identified by the World

Health Organization (WHO) as one of leading causes of vision impairment or blindness in people living with diabetes mellitus (WHO, 2020).

2.10. Conclusion

This is the end of Chapter 2. In this chapter, the researcher dealt with a discussion on the prevalence and determinants of DR among DM patients from the point of view of the literature; a condition that represents a substantial global health burden.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. INTRODUCTION

In the previous chapter, the researcher presented a review of the literature similar to the topic of the present study. In this chapter, the researcher will outline the materials and research methodology used in conducting this research and in analysing the results obtained from of the present study.

3.2. RESEARCH METHOD

The present study followed a quantitative research method to quantify the variables, in other words, the systematic investigation of a defined phenomenon by collecting a quantifiable data to perform a statistical techniques (de Vos et al., 2017). The data were converted into numeric form in order to perform a statistical analysis using the Statistics and Data Analysis (STATA) version 15 software for windows.

3.3. RESEARCH DESIGN

The study was a cross-sectional study, with a survey design, which was conducted on a public healthcare facility-based DM population. The study aimed to investigate the prevalence and determinants of DR among DM patients receiving treatment in the Maruleng, Mopani District of Limpopo Province. A cross-sectional study is a type of the observational study used to collect data at a specific point in time (Gordis, 2014). This design was appropriate to this study because it allowed researcher to collect once-off primary source data from a convenient sample of DM patients receiving treatment in the Maruleng public healthcare facilities, using a structured researcher-administered questionnaire and calibrated medical equipment to collect clinical data through the clinical screening for DR.

3.3.1. Sampling

Sampling is the process of selecting a part or subset of a population to participate in the study so that the results can be used to make assumptions about a target population of interest (Brink et al., 2018; Singh & Masuku, 2014).

3.3.1.1. Study sites

The study was conducted in all the selected public healthcare facilities in Maruleng in the Mopani District of the Limpopo Province, South Africa. The facilities include 10

community clinics, namely; Bismark, Calais, Hoedspruit, Lorraine, The Oaks, Sekororo, Sofaya/Sopihia, Turkey, Mabins, and the Willows clinic; and in one local hospital, called the Sekororo District Hospital. These are public healthcare facilities under the control of the Limpopo Department of Health, situated within Maruleng Sub-district. These healthcare facilities provide primary healthcare services to the community, including diabetic healthcare at the community clinic level; and secondary diabetic healthcare services at the hospital. A physical locations of these selected public healthcare facilities in Maruleng are presented in Figure 3.1 below, which is the map adapted from the Maruleng local municipality website (Maruleng Municipality, 2020).

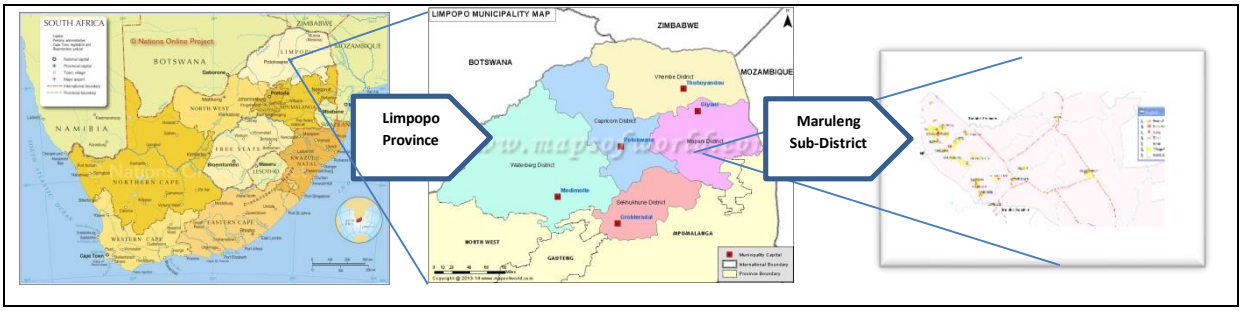


Figure 3.1: Maps of South Africa and the Limpopo Province showing the 5 districts of Limpopo Province and Maruleng Sub-district located in the Mopani District
Source: https://www.maruleng.gov.za/index.php?page=sitemap

3.3.1.2. Study population

The study population was all DM patients, with either with type 1 DM or type 2 DM, receiving treatment during the study period from all the selected public healthcare facilities in Maruleng.

3.3.1.3. Sampling method and size

Convenient sampling (also known as *accidental or grab sampling*) method was applied by the researcher during the time of the study to select a sub-set or part of the DM patients who already arrived at the selected healthcare facilities, and waiting for review and collection of a chronic diabetic treatments. The researcher approached these DM patients who were waiting in the reception areas to give them all information about the present study, and also to asking them to give the researcher a consent to be included without any form of coercion by researcher or any other person in the facilities. All DM patients who were present during the time of the study, and also meeting the inclusion

criteria set of sampling gave the researcher a written consent to be included in the present study. However, two (2) of the DM patients with a gestational diabetes due to pregnancy were excluded. These patients were found in 2 different clinics, where one patient was from the Oaks clinic and the other one was from Turkey clinic.

The Yamane's (1967:886) statistical formula has been used to determine the desired sample size of DM patients because the population size of all DM patients was known during the study from register book of the patients. In the formula below, n=desired sample size, N=population size and e=precision level or margin of error resulting from poor attendance or any other limitations that may have occurred during the study.

$$n = \frac{N}{1 + N(e)^2}$$

The desired sample size of a prospective respondents was calculated per facility, as presented on the last column of **Table 3.1** below. However, the overall sample size from all selected public healthcare facilities was **423** DM patients in order to estimate the prevalence of DR among DM patients receiving treatment in all selected Maruleng public healthcare facilities, Mopani District of the Limpopo Province.

Table 3.1: Distribution of respondents proportional to healthcare facilities

Name of facility		Diabetic Population size (N)	Calculated sample size (n) using Yamane formula: $n = \frac{N}{1+N(e)^2}$
Community clinics in Maruleng	Bismark	22	**21**
	Calais	25	**24**
	Hoedspruit	33	**30**
	Lorraine	24	**23**
	Mabins	51	**45**
	The Oaks	21	**20**
	Sekororo	59	**51**
	Sofaya/ Sophia	35	**32**
	Turkey	43	**39**
	Willows	50	**44**
Hospital	Sekororo	123	**94**
TOTAL		**486**	**423**

3.3.1.4. Ethics issues related to sampling

- **Informed consent**

The respondents signed adapted TREC consent forms after receiving all the necessary information about the study (see Appendix 9a, 9b & 9c). A consent form was also translated by the researcher to Sepedi and Xitsonga language versions, so that all respondents understood the content of form before signing it. For those patients who were unable to write or read, the researcher took their right hand thumb print, after reading and explaining the content using a language that they understood. Witnesses signed along with these participants, for future reference.

- **Voluntary participation**

Participation in the present study was completely voluntary and the researcher did not used any form of coercion to persuade participants to participate. The respondents were given all the necessary information about their rights to participate in, or withdraw from, the study at any time if they felt that they wanted to do so.

- **Autonomous participation**

The respondents were allowed to make a self-determination about whether to enter the study or not because they were above the age of 18 years and were without mental

illness, in accordance with the inclusion and exclusion criteria set of sampling, Participants were not coerced into participating in the study.

- **Justice**

The principle of justice refers to the respondents` right to fair selection and treatment (Brink et al., 2018; de Vos et al., 2017). The selection of the study respondents was done in a fair and just manner, by using inclusion criteria set for sampling from an approved research protocol, which will be fully discussed below.

3.3.1.5. Sample

A convenient sample of **416** respondents was achieved, which was 8 participants less than the calculated desired sample size. This was because of limitations caused by the national lockdown as a result of the Covid-19 pandemic.

3.3.1.6. Inclusion and exclusion criteria set of sampling

The inclusion criteria are the characteristics that prospective respondents need to have to qualify to participate in the study (Gordis, 2014). The exclusion criteria are the characteristics disqualify the respondents to participate in the study (Gordis, 2014).

- Inclusion criteria

The present study only included diabetes mellitus (DM) patients either with type 1 DM and type 2 DM above the age of 18 years; and who had given the researcher their consent to participate, in writing or using right thumb print, on the adapted TREC consent form, with a witness signing alongside.

- Exclusion criteria
    - Pregnant women with gestational diabetes as a result of pregnancy were excluded because gestational diabetes usually disappear after delivery of a baby.
    - DM patients with a history of eye surgery were excluded because some surgical procedures, like laser surgery, leave marks on the fundus.
    - DM patients with known mental illness were excluded because of incompetent autonomy in terms of Mental Health Care Act 17 of 2002 that regulates the mental healthcare services and users (Department of Justice SA, 2020).

3.3.2. Data collection

Data collection is a systematic process of gathering and measuring information on the variables of interest in an attempt to answer any queries, address research questions and test hypotheses, and to evaluate the outcomes (Brink et al., 2018; de Vos et al., 2017).

3.3.2.1. Data collection approach and method

A structured researcher-administered questionnaire containing closed-ended survey questions was used in the study. The questionnaire was administered by researcher to the prospective respondents who were readily available at the selected facilities during the study; and had consented to participate in the present study. One-on-one (or face-to-face) interviews and basic clinical screening of DR were performed by the researcher who is a licensed optometrist by profession to collect a primary source data using piloted structured researcher-administered questionnaire and calibrated medical equipment such as ophthalmoscope to assess the integrity of the retina and Snellen`s charts to measure visual acuities (VA) at 6 meters distance from a convenient sample of the DM patients who came for review and collection of a diabetic chronic treatment. However, the vital signs such as plasma glucose level at pre-prandial or postprandial state of the individual patient, systolic blood pressure (SBP), body weight (BWT) and height (HT) were measured at the reception areas of the selected public healthcare facilities by the designated nursing personnel as a norm used in all public healthcare facilities under the Limpopo Department of Health.

3.3.2.2. Development and testing of the data collection instrument

Following in-depth literature review, the instrument (or questionnaire) to collect primary source data was not available. The researcher developed a structured questionnaire by taking into account the research goal, writing and reviewing the questions, aligning the questions and operationalizing central concepts. Basic principles of clear, brief and simple questions first were used to construct the questionnaire (de Vos et al., 2017). The newly developed questionnaire was pre-tested during a pilot study conducted at Van Velden Hospital and Tzaneen community clinic on limited number of respondents to identify the flaws that would compromise the integrity of upcoming main study so that necessary adjustments (or amendments) could be made prior main study.

3.3.2.3. Characteristics of the data collection instrument

The researcher in the present study used a piloted structured researcher-administered to record primary source data, and this questionnaire was designed on one-sided page (see Appendix 10a, 10b & 10c) comprised of 4 sections; namely *Section A, Section B, Section C,* and *Section D*. This questionnaire was administered to the selected DM patients by the researcher during the time of the study. Section A of the questionnaire has a socio-demographic profile of the patients such as age, gender, educational level, employment status, and alcohol drinking and cigarette smoking assessment habits in a checkboxes format. Section B has DM background information such as age of onset, diabetic treatment compliance, and family history of DM in a multiple choice format. Section C has a vision-related information such as visual screening history, and visual state of the DM patients completing in a dichotomous format. Lastly, Section D of the questionnaire has the clinical assessment parameters in a fill-in format such as plasma glucose level (in mmol/L) at a pre-prandial or postprandial state of the individual DM patient during the time of the study, systolic blood pressure (SBP) measured in mmHg, body weight (BWT) and height (HT) measured in meters, calculated body mass index (BMI) including classification of BMI such as underweight, normal, overweight, and obese. However, the above vital signs were measured and recorded at the reception areas of selected facilities by designated nursing personnel. Other clinical assessment parameters measured by the researcher include eye or vision assessment parameters such as unaided distant visual acuities (DVA) measured at 6 meters distance using Snellen`s reading chart, pinhole test with DVA, habitual DVA, and diabetic retinopathy (DR) results after performing an indirect ophthalmoscopy including classifications of DR such as no DR, mild non-proliferative DR (NPDR), moderate NPDR and severe NPDR, and causes of vision impairment (VI) or blindness on affected DM patients.

3.3.2.4. Data collection process

The study took place between July and September 2020, during the weekdays (Monday to Friday) from 07h30 to 16h30. All information about the study was given to the respondents, including their right to grant or refuse consent. The respondents who granted the researcher consent signed the adapted TREC consent form, with the witness signing alongside them. For those who could not write, the right thumb print was taken using an ink stamp pad. However, participation in the study was completely voluntary and the researcher did not used any form coercion. The respondents who

participated were debriefed after the study to maintain and protect their social wellbeing, while those with DR signs were referred to the hospital.

3.3.2.5. Ethical considerations related to data collection

- **Approval**

The Provincial Health Research and Ethics Committee (PHREC) and the Mopani District office in the Limpopo Department of Health granted the researcher approval (see Appendix 5 & Appendix 6 respectively) to collect primary source data from the selected public healthcare facilities, following ethical approval granted by the Turfloop Research and Ethics Committee (TREC/28/2020: PG) of the University of Limpopo (see Appendix 4). Further arrangements were made with the operational managers and chief executive officers (CEOs) of the public healthcare facilities concerned at pilot and main study sites.

- **Privacy**

The interviews and basic clinical screening for DR took place between the researcher and respondent inside an allocated consultation room in the selected public healthcare facilities. During the data collection session, the researcher put a visible notice on the outside door of the consulting room stating that an interview was in progress to ensure that no one entered the room to interrupt the session.

- **Anonymity**

Information that could identify the individual respondents during or after data collection was not recorded on the questionnaire. The data captured on the Microsoft Excel 2013 spreadsheet and STATA15 software used research numbers or identity numbers, instead of respondents` names.

- **Confidentiality**

All respondents were given assurance by the researcher that the information provided during data collection would not be shared anyone, including on social media platforms, with the exception of the supervisor of the study, for the purpose of the study. Computer passwords were be used to lock captured data, while the questionnaires used during data collection were locked in a lockable cabinet in the office of the researcher.

- **Respect for person**

The researcher honoured the agreement about when to start the study and when to finish the study, including cultural or traditional aspects, because the respondents came from the communities with their own cultural or traditional beliefs.

- **Avoid harm**

The study was a non-invasive but had a potential to do psychological or emotional harm. However, the respondents who participated in the present study were briefed by the researcher before engagement in the study and they were debriefed after the study, especially those who felt affected by a DR positive result., They were referred to the hospital for further management.

- **Beneficence**

All respondents gained knowledge about DR and the other health benefits (such as prevention and treatment options). The study results have increased body of knowledge on the prevalence of DR among DM patients receiving chronic treatment from Maruleng public healthcare facilities. The authorities in the Department of Health may also use the results of this study to make policy decisions, while serving healthcare professionals may use the results to provide an evidence-based practice, improve a diabetic care and to motivate for the allocation of resources, when need arises.

- **Scientific and other responsibilities**

Ethical research was conducted by the researcher, based on the approved research protocol and on the other stated conditions in the approval letter received from the PHREC in the Limpopo Department of Health. There was no research design manipulation or fabrication, falsification, forgery or selective retention of data and/or plagiarism, to ensure that the reputation of the research community, the university and/or Department of Health was protected during and after the study.

3.3.3. Data analysis

The researcher double checked questionnaires used for correctness and then coded the variables, assigning the identity (ID) numbers (also called *research numbers*) on the questionnaires used to collect data from the convenient sample of the DM patients instead of using their names to maintain a principle of anonymity as outline under the

section of ethical considerations. The data were captured and stored on the Microsoft Excel 2013 spreadsheet by the researcher, and then cleaned using a pivot tables of the spreadsheet to eliminate corrupted or duplicated data. The quantitative data were then imported into the STATA version 15 for a windows (STATA Corporation, College Station, Texas) computer software to commence with a statistical analysis processes. The Microsoft Excel 2013 spreadsheet was also used to make the graphs or pie charts and/or tables for a visual presentations of the study results, depending on the type of variable and levels of measurement.

Descriptive statistics were used to summarise, explain and analysis quantitative data, which were also displayed on the tables, charts and graphs. The characteristics of the DM patients in the present study have been summarised and analysis by performing descriptive statistics. Inferential statistical analyses were performed on the dependent variable and independent variables using logistical regression analysis. The following statistical techniques were computed by the researcher to summarise and analyse the quantitative data with the aid of STATA version 15 software for windows:

- *Frequency distribution*

Frequencies were used to describe the distribution of dataset containing one variable to give a reader good picture of large dataset. The characteristics of the DM patients were summarised and analysed using frequency distribution, aimed at determining the prevalence of DR presented which was presented as proportions at 95% confidence interval. Categorical variables were presented as the percentages, while continuous variables were presented as means.

- *T-test*

The independent t-test was performed by the researcher on the variables having two categories to assess whether there was statistically significant between the means of two groups, which was tested at 95% confidence level with a p-value of less than 0.05 ($p<0.05$) for test results to be considered statistically significant.

- *Logistic regression analysis*

A simple logistic regression analyses were performed on the categorical variables to assess the strength of association between dependent variable (DR) and independent variables such as the age of the DM patients, gender, educational level, employment

status, drinking alcohol, smoking cigarette, type of DM, hyperglycaemic state, family history of DM, systolic blood pressure, and body mass index (BMI).

- *Odds ratios*

Odds and relative odds were computed by the researcher using the information in the cross-tabulation (2X2 table) in which one dimension of the table was DR (outcome of interest) to determine the odds of the probability of the measured variables against the exposure variables such as age, gender, educational level, and employment status. Odds ratio (OR) of 1 implied that DR was equally likely in two groups, while OR greater than 1 implied that DR was more likely to have occurred in two groups, and OR less than 1 implied that DR was less likely to have occurred in two groups.

3.4. INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

3.4.1. Pilot study

The pilot study of the present study was carried out at the Van Velden District Hospital, and Tzaneen community clinics (in Bus-stop & Tzaneen Municipality facility), prior to the main study, on a limited number of the respondents, using the approved research protocol of the main study to evaluate the feasibility of upcoming main study and to pre-test the newly developed questionnaire to identify flaws that would compromise the integrity of the main study, thereby increasing the validity and sensitivity of the instrument. Following results evaluation of pilot study, researcher made some necessary amendments to the instrument by rephrasing questions to eliminate the ambiguity and leading questions. A Xitsonga language version was also added to the original questionnaire to ensure that all respondents understand the language. The respondents that took part in the pilot study did not take any part in the main study.

3.4.2. Validity

Internal and external validities were assessed in the present study to ensure that the questionnaire and the medical equipment measured what they were supposed to measure in order for the results to be true. Instrument validity is the extent to which the research instrument measures what it is supposed to measure for the results to be true (Brink et al., 2018; de Vos et al., 2017). Internal validity was ensured by adequate implementation of the approved research protocol using a piloted questionnaire and calibrated medical equipment. External validity was ensured by not generalising the results to the broader population of the Maruleng Sub-district.

3.4.3. Reliability

The internal consistency of the questionnaire was measured using the Cronbanch Alpha Correlation Coefficient (CACC) from the STATA15 computer software, while the medical equipment was fully functioning and calibrated. Instrument reliability is the degree to which a measuring instrument yields a consistent result over time when repeated (De Vos et al., 2017). The statistical test results from the CACC were within a range of $0.8>\alpha\geq0.7$, which were considered acceptable.

3.5. BIAS AND CONFOUNDING

3.5.1. Bias

The present study was susceptible to selection (sampling) bias and information bias to distort the results and conclusion. Study bias is the distortion or flaws leading to a spurious conclusion (Gordis, 2014). The researcher undertook the measures outlined below to prevent bias in the present study.

3.5.1.1. Measures to prevent sampling bias

The inclusion criteria were used to prevent selection or sampling bias by not allowing volunteers or not allowing people without DM to participate.

3.5.1.2. Measures to prevent information bias

The approved research protocol, the piloted questionnaire and calibrated medical equipment were used to prevent the information bias.

3.5.2. Confounding effect

The present study was susceptible to the confounding effect influencing study results. The confounding effect is when a well-known risk factor (confounder) influences the results, leading to spurious a conclusion to the study (Gordis, 2014). However, the researcher used restriction techniques during a study design phase, and stratification techniques during data analysis phase, to eliminate confounders as outlined below.

3.5.2.1. Restriction technique

The restriction technique was used during research design phase by not allowing respondents who were below the age of 18 years, by not allowing those with known mental illness, by not allowing pregnant women with gestational diabetes due to the

pregnancy, and by not allowing those that had undergone laser surgery to participate in the study.

3.5.2.2. Stratification technique

The stratification technique was used during the data analysis phase of the study by regrouping the research variables into various strata (groups) during data analysis. For example, the data were stratified by the age group, gender group, educational group, employment group and the selected associated risk factors of DR.

3.6. CONCLUSION

This is the end of chapter 3 where the researcher outlined all materials, and research methodology used in conducting the present study.

CHAPTER FOUR: RESULTS PRESENTATION AND INTERPRENTATION

4.1. INTRODUCTION

In the previous chapter, the researcher outlined the methodology used to conduct the present study. In this chapter, the researcher will present and interpret the results obtained from the present study by focusing on data management and analysis, research results and an overview of the research findings.

4.2. DATA MANAGEMENT AND ANALYSIS

The data for the present study were collected by the researcher using the piloted structured researcher-administered questionnaire to record primary source data; and calibrated medical equipment to measure clinical variables during clinical screening for DR. All questionnaires were double checked by researcher for correctness and completeness, coded and assigned a unique identity number. This data was then captured in a Microsoft Excel 2013 spreadsheet for the cleaning process, using a pivot tables to eliminate duplicated data. Cleaned data were imported into STATA15 software for statistical analysis. Microsoft Excel 2013 was also used to create a visual display of analysed data in a form of tables or graphs and/or pie charts, depending on the type of the variable and level of measurement.

4.3. RESEARCH RESULTS

4.3.1. Sample of the respondents

The sample of the present study comprised of already diagnosed DM patients aged 18 years and above who came to public healthcare facilities for review and collection of the monthly chronic treatment during the time of the study. A total of 418 prospective DM patients were present in all 10 selected public healthcare facilities in the Maruleng Sub-District, of which 2 patients with a gestational diabetes due to pregnancy were excluded to participate which implies that 416 DM patients remained in the present study. The excluded patients were from 2 different selected public healthcare facilities (1 patient was from the Oaks clinic and other one patient was from Turkey clinic). None of the remaining 416 DM patients meeting the inclusion criteria set of sampling have refused to grant the researcher consent after receiving all information about the study for them to consent freely without any of coercion.

4.3.2. Socio-demographic information

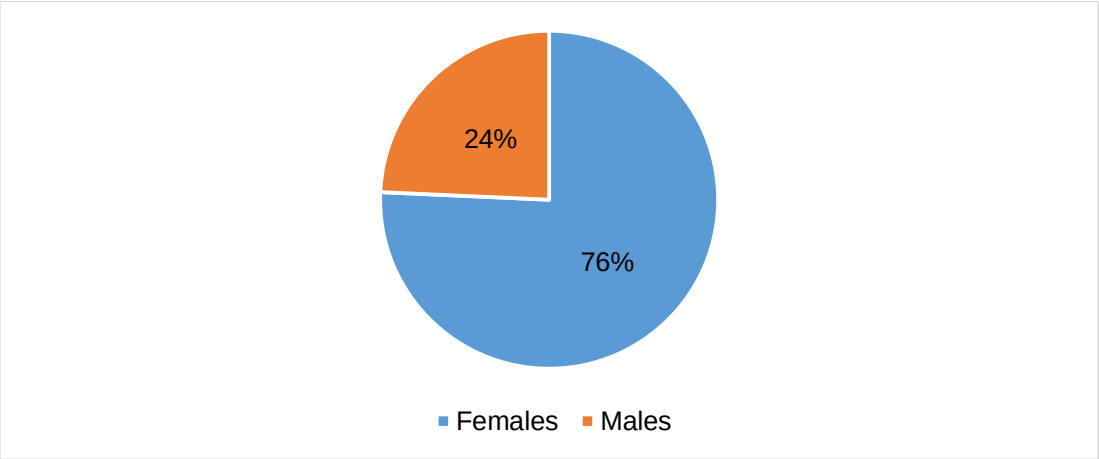
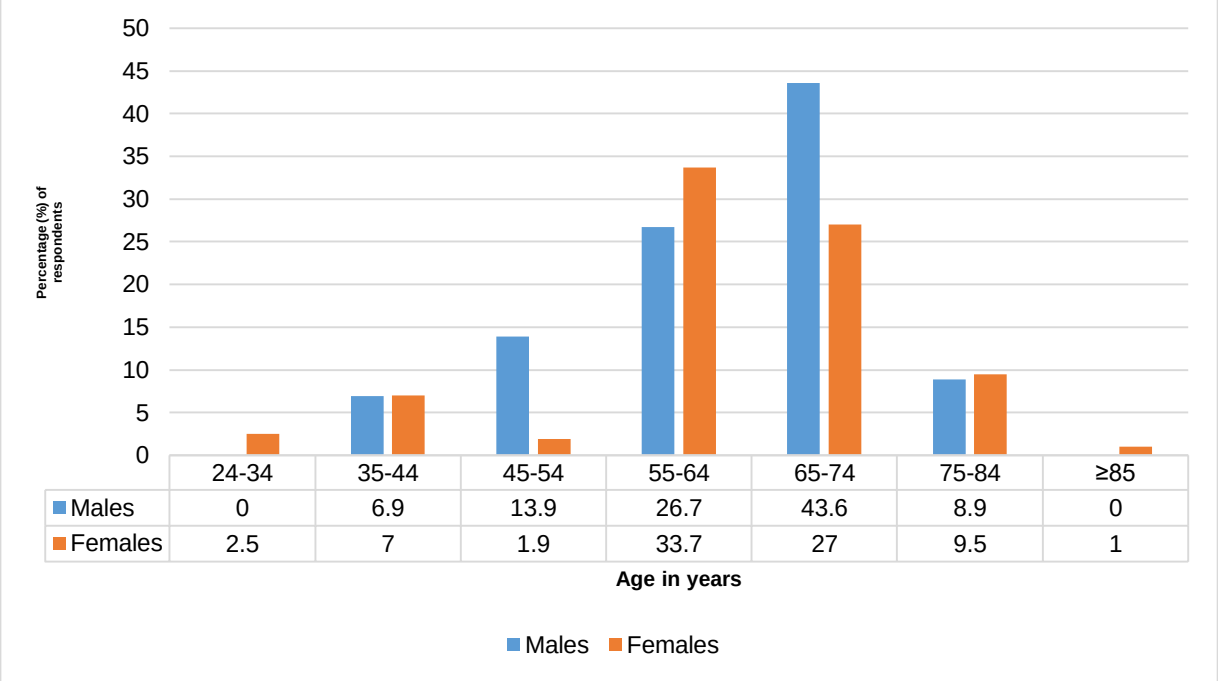


Figure 4.1: Gender distribution of respondents

Figure 4.1 above presents the gender distribution of 416 respondents who participated in the present study, where the majority of respondents were females, at 76%, compared to 24% males.



	24-34	35-44	45-54	55-64	65-74	75-84	≥85
Males	0	6.9	13.9	26.7	43.6	8.9	0
Females	2.5	7	1.9	33.7	27	9.5	1

Figure 4.2: Age distribution of respondents

Figure 4.2 above presents the age distribution of the 416 respondents who participated in the present study, where males show increasing trends as the age increases, from 6.9% in age group 35-44 years; to 13.9% in age group 45-54 years; to 26.7% in age group 55-64 years; to a maximum of 43.6% in age group 65-74 years; dropping to 8.9% in age group 75-84 years. However, females show fluctuating trends

with an increase in age from 2.5% in age group 24-34 years; to 7% in age group 35-44 years; then dropping to 2% in age group 45-54 years, and increasing again to a maximum of 33.7% in age group 55-64 years; then dropping to 27% in age group 65-74 years; until to the lowest of 1% in the age 85 years or older.

Table 4.1: Socio-demographic profile of 416 respondents stratified by gender

Socio-demographic profile		Males (n=101)	Females (n=315)	p-values
		n (%)	**n (%)**	**p-value**
Age Mean =61.04 SD=11.58	24 - 34	0	8 (2.5)	0.0541
	35 - 44	7 (6.9)	22 (7)	
	45 - 54	14 (13.9)	6 (1.9)	
	55 - 64	27 (26.7)	106 (33.7)	
	65 - 74	44 (43.6)	85 (27)	
	75 - 84	9 (8.9)	30 (9.5)	
	≥85	0	3 (1)	
		n (%)	**n (%)**	**p-value**
Educational level	No matric	86 (85.2)	268 (85.1)	0.7341
	Matric	8 (7.9)	26 (8.3)	
	Post matric	8 (7.9)	21 (6.7)	
		n (%)	**n (%)**	**p-value**
Employment status	Unemployed	17 (16.8)	101 (32.1)	0.0059
	Employed	13 (12.9)	36 (11.4)	
	Self-employed	2 (2)	5 (1.6)	
	Pensioner	69 (68.3)	173 (56.5)	
		n (%)	**n (%)**	**p-value**
Alcohol drinking	No	79 (78.2)	309 (98.1)	<0.0001
	Yes	22 (21.8)	6 (1.9)	
		n (%)	**n (%)**	**p-value**
Drinking habits	Daily	1 (1)	0	<0.0001
	Weekly	2 (2)	0	
	Less often	20 (19.8)	6 (1.9)	
		n (%)	**n (%)**	**p-value**
Cigarette smoking	No	97 (96)	314 (99.7)	0.0034
	Yes	4 (4)	1 (0.3)	
		n (%)	**n (%)**	**p-value**
Smoking habits	Daily	3 (3)	1 (0.3)	0.0051
	Less often	1 (1)	0	

Table 4.1 above presents a summary of the socio-demographic profiles of the 416 respondents who participated in the present study. The mean age of all respondents was ± 61.04 years with standard deviation (SD) of 11.58. The majority of respondents were females (76%; n=315). The profile shows that the majority of respondents had no matric, at 85.2% for males compared to 85.1% for females. This is followed by 8.3% of females with matric compared to 7.9% of males, and finally, 6.7% of females had a post matric education. The majority of respondents were dependant on pension money (either a government old-aged grants or post labour pension money) at 68.3% of males compared to 56.5% of females; followed by 32.1% of unemployed females compared to 16.8% of unemployed males; but only 12.9% of males were employed compared to 11.4% of females. There was a statistically significant difference (*p-value 0.0059*) between the groups. The majority of males, at 21.8%, consumed alcohol compared to 1.9% of females. Nineteen point eight percent of males drank alcohol less often compared to 1.9% of females, and there was a statistically significant difference (*p-value <0.001*). Lastly, at least 4% of males smoked cigarettes compared to 0.3% of females, with a significant difference of *p-value 0.017* between groups. Three percent of males smoked cigarettes daily compared to 0.3% of females and there was a statistically significant difference (*p-value 0.0034*) between the groups.

4.3.3. Diabetes mellitus background information

Table 4.2 below presents the DM background information of the 416 respondents who participated in the present study. The results show that majority of females, at 94.6%, had DM at the age of 31 years or older compared to 93.1% of males. The majority of males, at 97.1%, had a type 2 DM compared to 96.8% of females, while only 3% of males had a type 1 DM compared to 3.2% of females. The majority of males, at 69.3%, were compliant with the treatment, and there was a significant difference (*p-value 0.0176*) between groups. Males also had no family history of DM compared to 56.5% of females, while fewer males, at 30.7%, were non-compliant and also had a family history of DM compared to 43.5% of females. There was a significant difference (*p-value 0.0225*) between these groups. Ninety-three percent (93%) of females had hyperglycaemia compared to 88.1% of males. The majority of males, at 48.5%, were overweight compared to 35.9% of females. However, 37.5% of females had obesity compared to 16.8% of males, and there was a significant difference (*p-value 0.0082*) between the groups. Lastly, 58.4% of males had hypertension or stage 1 as compared

to 49.5% of females, while fewer males, at 11.9%, had hypertension crisis compared to 12.7% of females. Fewer males, at 16.8%, had a pre-hypertension compared to 20.3% of females.

Table 4.2: Diabetes mellitus background information of respondents.

Diabetes mellitus (DM) background information	Males (n=101)	Females (n=315)	Significant level at 0.05 (p<0.05)
Age of onset (in years)	**n (%)**	**n (%)**	**p-value**
11-20	2(2)	8(2.5)	0.8087
21-30	5(5)	9(2.9)	
≥31 or older	94(93.1)	298(94.6)	
Type of DM	**n (%)**	**n (%)**	**p-value**
Type 1 DM	3(3)	10(3.2)	0.9185
Type 2 DM	98(97.1)	305(96.8)	
Diabetic treatment compliance	**n (%)**	**n (%)**	**p-value**
Compliant	70(69.3)	178(56.5)	0.0176
Non-compliant	31(30.7)	137(43.5)	
Family history of DM	**n (%)**	**n (%)**	**p-value**
Had family history	31(30.7)	137(43.5)	0.0225
No family history	70(69.3)	178(56.5)	
Level of glycaemia	**n (%)**	**n (%)**	**p-value**
Normal (5.7-6.4 mmol/L	5(5)	11(3.5)	0.1943
Hypoglycaemia (≤3.9 mmol/L)	7(6.9)	11(3.5)	
Hyperglycaemia (≥6.5 mmol/L)	89(88.1)	293(93)	
Level of body mass index (BMI)	**n (%)**	**n (%)**	**p-value**
Normal (18.6-24.9 kg/m^2)	32(31.7)	79(25.1)	0.0082
Underweight (≤ 18.5 kg/m^2)	3(3)	5(1.6)	
Overweight (25.0-29.9 kg/m^2)	49(48.5)	113(35.9)	
Obesity (≥ 30 kg/m^2)	17(16.8)	118(37.5)	
Level of systolic blood pressure	**n (%)**	**n (%)**	**p-value**
Normal (≤120 mmHg)	0	17(4.1)	0.2166
Elevated (120-129 mmHg)	10(9.9)	38(12.1)	
Pre-hypertension (130-139 mmHg)	17(16.8)	64(20.3)	
Hypertension or stage 1 (≥140 mmHg)	59(58.4)	156(49.5)	
Hypertension crisis or stage 2 (≥140 mmHg)	12(11.9)	40(12.7)	

4.3.4. Prevalence of any diabetic retinopathy

Table 4.3: Prevalence of any diabetic retinopathy stratified by gender

Diabetic retinopathy (DR)	Overall prevalence of DR	Males (n=101)	Females (n=315)
	% (95% CI)	**% (95% CI)**	**% (95% CI)**
No DR	64.7 (59.9 – 69.1)	66.3 (56.4 - 75)	64.1 (58.4 – 69.2)
Mild NPDR	32 (27.6 – 36.6)	28.7 (20.6 – 38.4)	33 (28 – 38.4
Moderate NPDR	3.4 (2-5.6)	5 9 (2-38.4)	2.9 (1.5 -5.4)

Table 4.3 above presents the overall prevalence of DR among the 416 respondents who participated in the present study. The study results reveal that nearly two-thirds of the 416 respondents, at 64.7%, had no DR. However, 32% of the respondents had mild NPDR compared to 3.4% of respondents with moderate NPDR, of whom 28.7% of males had mild NPDR compared to 33% of females, while 5.9% of males had moderate NPDR compared to 2.9% of females. Therefore, the overall prevalence of any DR was **35.4%** among the respondents who participated in the present study.

Table 4.4: Prevalence of diabetic retinopathy stratified by type of diabetes mellitus

Type of diabetes mellitus (DM)		
Diabetic retinopathy (DR)	**Type 1 DM**	**Type 2 DM**
Males (n=101)		
	% (95% CI)	**% (95% CI)**
No DR	100	65.3 (55.2 – 74.1)
Mild NPDR	-	29.6 (21.3 – 39.5)
Moderate NPDR	-	5.1 (2.1 – 11.8)
Females (n=315)		
	% (95% CI)	**% (95% CI)**
No DR	40 (14.9 – 71.8)	64.9 (59.4 – 78.1)
Mild NPDR	60 (28.2 – 85.1)	32.1 (27.1 – 37.6)
Moderate NPDR	-	3 (1.5 – 5.6)

Table 4.4 above presents the prevalence of DR among the respondents who participated in the present study. The results revealed that 32.1% of females with type 2 DM had mild NPDR compared to 29.6% of males, while 60% of females with type 1 DM had mild NPDR, and 5.1% of males with a type 2 DM had moderate NPDR

compared to 3% of females. Therefore, the highest prevalence of mild NPDR, at 61.7%, combined together for both males (29.6%) and females (32%) with a type 2 DM compared to 60% of mild NPDR in type 1 females, while the prevalence of moderate NPDR was only in type 2 DM for both males (5.1%) and females (3%).

Table 4.5: Prevalence of diabetic retinopathy stratified by age group

Age in years							
DR	**24-34 years**	**35-44 years**	**45-54 years**	**55-64 years**	**65-74 years**	**75-84 year**	**≥85 years**
Males (n=101)							
	% (95% CI)	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**
No DR	-	100	85.7 (55.5 – 96.7)	66.7 (46.7 – 82)	63.6 (48.3 – 76.6)	22.2 (5 – 60.7)	-
Mild NPDR	-	-	14.3 (3.3 – 44.5)	29.6 (15.2 – 49.7)	31.8 (19.6 – 47.2)	55.6 (23.4 – 83.7)	-
Moderate NPDR	-	-	-	3.7 (0.5 – 23.2)	4.5 (1.1 - 16.9)	22.2 (5.0 - 60.7)	-
Females (n=315)							
	% (95% CI)	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**
No DR	87.5 (42.5 - 98.5)	90.9(69.2 - 97.8)	70.5 (57.8 – 80.7)	59.4 (49.8 – 68.4)	62.4 (51.5– 72.1)	50 (32.5 – 67.5)	33.3 (2.5 – 90.5)
Mild NPDR	12.5 (1.5 – 57.5)	9.1 (2.2 – 30.8)	26.2 (16.6 – 38.8)	36.8 (28.1 – 46.4)	35.3 (25.8 – 46.1)	46.7 (29.6 – 64.5)	66.7 (9.5 – 97.5)
Moderate NPDR	-	-	3.3 (8.0 -12.4)	3.8 (1.4 - 9.7)	2.4 (0.6 – 9)	3.3 (0.4 – 20.9)	-

Table 4.5 above presents the prevalence of DR stratified by age group among the respondents who participated in the present study. In males, the prevalence of any DR shows increasing trends with an increase in age, where the prevalence of mild DR increased from 14.3% in age group 45-54 years; to 29.6% in age group 55-64 years; to 31.8% in age group 65-74 years; and to 55.6% in 75-84 years. The same increasing trends in prevalence of moderate NPDR as the age increases from 3.7% in age group 55-64 years; to 4.5% in age group 65-74 years; to 22.2% in 75-84 years, was observed. However, the prevalence of any DR in females shows fluctuating trends as the age increases, where the prevalence of moderate NPDR, at 12.5%, in age group 24-34 years dropped to 9.1% in age group 35-44 years, then increased to 26.2% in age group 45-54 years. Prevalence continues fluctuating with age, and the prevalence of moderate NPDR shows the same fluctuating trends with increased in age from 3.3% in 45-54 years; to 3.8% in age group 55-64 years, then dropping to 2.4% in age group 65-74 years and increasing again to 3.3% in age group 75-84 years.

Table 4.6 below presents the prevalence of DR stratified by selected associated risk factors among the respondents who participated in the present study. The results show that females had a high prevalence of mild NPDR with hyperglycaemia, at 33.8%, compared to 29.2% in males, while a high prevalence of moderate NPDR with hyperglycaemia, at 5.6%, was seen in males compared to 2.4% in females. A high prevalence of mild NPDR with pre-hypertension, at 31.3%, was seen in females compared to 17.6% in males. The high prevalence of mild NPDR with hypertension (stage 1 hypertension), at 32.2%, was seen in males compared to 31.4% in females. The highest prevalence of mild NPDR with hypertension crisis (stage 2 hypertension), at 52.5%, was seen in females compared to 33.3% in males but prevalence of moderate NPDR at 5% was only seen in females. A high prevalence of mild NPDR with overweight, at 32.7%, was seen males compared to 29.2% in females. A high prevalence of mild NPDR with obesity, at 38.1%, was seen in females compared to 17.6% in males. Lastly, the highest prevalence of mild NPDR at 100% was seen in females smoking cigarettes compared to 50% in males.

Table 4.6: Prevalence of diabetic retinopathy stratified by Selected associated risk factors

Selected associated risk factors of diabetic retinopathy (DR)							
	Hyperglycaemia (≥ 6.5 mmol/L)	**Pre-hypertension (130-139 mmHg)**	**Hypertension or stage 1 (≥140 mmHg)**	**Hypertension crisis or stage 2 (≥180 mmHg)**	**Overweight (25.0-29.9 kg/m^2)**	**Obesity (≥30 kg/m^2**	**Cigarette smoking**
Males (n=101)							
DR	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**
No DR	65.2 (54.6 – 74.5)	70.6 (44.7 – 87.7)	64.4 (51.2 – 75.7)	66.7 (36 – 87.7)	63.3 (48.7 – 75.7)	70.6 (44.7 – 87.7)	50 (56.9 – 75.8)
Mild NPDR	29.2 (20.6 – 39.7)	17.6 (5.5 – 44)	32.2 (21.4 – 45.3)	33.3 (12.3 – 64)	32.7 (20.8 – 47.2)	17.6 (5.5 – 44)	50 (9.1 – 90.8)
Moderate NPDR	5.6 (2.3 – 13)	11.8 (2.8 – 38.3)	3.3 (0.8 – 12.9)	-	4.1 (1-15.3)	11.8 (2.8 – 38.3)	-
Females (n=315)							
DR	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**
No DR	63.8 (58.1 – 69.2)	65.6 (53.1 – 76.3)	65.4 (57.5 – 72.5)	42.5 (28.1 – 58.3)	66.4 (57.1 – 74.5)	59.3 (50.2 – 67.9)	-
Mild NPDR	33.8 (28.6 – 39.4)	31.3 (21 – 43.7)	31.4 (24.6 – 39.2)	52.5 (37 -67.5)	29.2 (21.5 – 38.3)	38.1 (29.8 – 47.3)	100
Moderate NPDR	2.4 (1.1 – 4.9)	3.1 (0.7 – 11.8)	3.2 (1.3 – 7.5)	5 (1.2 – 18.3)	4.4 (1.8 – 10.3)	2.5 (0.8 – 7.7)	-

Table 4.7: Vision-related background information

Vision –related background information	Males (n=101)		Females (n=315)		p-values
	Yes	No	Yes	No	
Items	**n (%)**	**n (%)**	**n (%)**	**n (%)**	
Have you ever went for eye screening since you became diabetic?	63 (62.4)	38 (37.6)	174 (55.2)	141 (44.8)	0.1042
Have you ever experienced any blurred or cloudy vision?	77 (76.2)	24 (23.8)	237 (75.2)	78 (24.8)	0.4192
Do you experience any vision fluctuation sometimes?	39 (38.6)	62 (61.4)	145 (46)	170 (54)	0.9038
Do you see any spot or dark strings floating or dark or empty areas?	4 (4)	97 (96)	14 (4.4)	301 (95.6)	0.7420
Are you not experience any challenge when seeing colours?	89 (88.1)	12 (11.9)	288 (91.4)	27 (8.6)	0.8391
Are using spectacle?	26 (25.7)	75 (74.3)	41 (13)	274 (87)	0.0012

Table 4.7 above presents vision-related background information of the 416 respondents who participated in the present study. The majority of males, at 62.4%, had vision screening before the present study compared to 55.2% of females. More than two-third of the males, at 76.2%, had experienced blurred vision compared to 75.2% of females. Forty-six percent of females had experience vision fluctuations compared to 38.6% of males. Four point four percent of females had seen spots or dark strings floating in their eyes compared to 4% of males. The majority of females, at 91.4%, had experience challenges with colour vision perception compared to 88.1% of males. Lastly, 25.7% of males were using spectacles compared to 13% of females, and there was a statistically significant difference (*p-value 0.0012*) between the groups.

4.3.5. The predictors of diabetic retinopathy

Table 4.8 below presents the predictors of DR using logistics regression. The results of the present study reveal that the older DM patients were 2.7 times more likely to have DR than the younger patients were, with a statistically significant difference (*p<0.001*). Female DM patients were 1.1 times more likely to have DR than male patients were but this was not statistically significant. DM patients with matric or more education were 0.6 times less likely to have DR, which was statistically significant (*p<0.005*). Employed DM patients were 1.4 times more likely to have DR than unemployed patients were, with a statistically significant difference (*p<0.001*). DM patients drinking alcohol were 0.1 times less likely to have DR than patients who did not drink alcohol, which was statistically significant (*p<0.05*). DM patients smoking cigarettes were 2.8 times more likely to have DR than patients not smoking cigarettes but the difference was not statistically significant. DM patients in the hyperglycaemic state were 1.1 times more likely to have DR than patients who were in the normal glycaemic state but this was not statistically significant. DM patients with poor glycaemic control were 1.4 times more likely to have DR than patients with good glycaemic control but this was not statistically significant. DM patients with a family history of DM were 0.9 times less likely to have DR than those with no family of DM, which was not statistically significant. DM patients with systolic blood pressure (or hypertension) of 140 mmHg or more (≥140mmHg) were 1.4 times more likely to have DR than patients with systolic blood pressure of 139 mmHg or less, which was statistically significant (*p<0.05*). DM patients with a BMI of 30 kg/m^2 or more were 1.1

times more likely to have DR than patients with a BMI of 25.0-29.9 kg/m^2 or less but this was not statistically significant.

Table 4.8: Predictors of diabetic retinopathy

Predictors		Any DR	Significant level
		OR (95% CI)	p-value
Age	<45-54 years	Reference (1)	<0.001
	≥ 55 years	2.7 (1.6-4.4) *	
Gender	Males	Reference (1)	0.686
	Females	1.1 (0.7-1.8) [a]	
Educational level	< No matric	Reference (1)	0.038
	≥ Matric	0.6 (0.4-1.0) ***	
Employment status	Unemployed	Reference (1)	<0.001
	Employed	1.4 (1.2-1.6) *	
Alcohol drinking	Not drinking alcohol	Reference (1)	0.006
	Drinking alcohol	0.1 (0.03-0.6) ***	
Type of DM	Type 1 DM	Reference (1)	0.411
	Type 2 DM	0.6 (0.2-1.9) [a]	
Hyperglycaemic state	Normal	Reference (1)	0.689
	Hyperglycaemia (≥ 6.5 mmol/L)	1.1 (0.7-1.8) [a]	
Glycaemic control	Good glycaemic control	Reference (1)	0.573
	Poor glycaemic control	1.4 (0.38-5.6) [a]	
Family history of DM	No family history	Reference (1)	0.621
	Family history	0.9 (0.6-1.4) [a]	
Cigarette smoking	Not smoking cigarette	Reference (1)	0.266
	Smoking cigarette	2.8 (0.5-16.8) [a]	
Systolic blood pressure	≤139 mmHg	Reference (1)	0.006
	≥ 140 mmHg	1.4 (1.1-1.7) ***	
Body mass index (BMI)	<25.0-29.9 kg/m^2	Reference (1)	0.233
	≥ 30 kg/m^2	1.1 (1.0-1.3) [a]	

Values reported as odds ratios (95%CI); *Significant at p<0.001; **Significant at P<0.005; ***Significant at p<0.05; [a]Not significant

4.4. OVERVIEW OF RESEARCH FINDINGS

The results of the present study revealed that 416 DM patients participated in the study and that the majority of these patients were female, at 76% (n=315). A mean age of all the patients who participated in the study was 61 years (standard deviation [SD]

=11.5). The overall prevalence of any DR was 35.4%, comprising 32% of mild NPDR and 3.4% of moderate NPDR. In all of these cases, DR was more prevalent in females, at 35.9%, than in males at, 34.6%, particularly in females with a type 2 DM, at 35.1%, comprising 32.1% mild DR and 3% moderate NPDR. DR was more prevalent in the older females, at 77.8%, comprising 55.6% mild NPDR and 22.2% moderate NPDR. The age of DM patients (odds ratio [OR] =2.7; 95%CI=1.6-4.4; *p<0.001*), high systolic blood pressure hypertension of 140 mmHg or more (OR=1.4, 95%CI=1.1-1.7; *p<0.05*) and employment status were significantly associated with DR (OR=1.4; 95% CI=1.2-1.6; *p<0.001*), However, gender of the patient, hyperglycaemic state, poor glycaemic control, smoking, and a high BMI were associated with higher or increased risk of developing DR but not statistically significant.

4.5. CONCLUSION

This is the end of Chapter 4, in which the researcher presented and interpreted the results of the present study.

CHAPTER FIVE: DISCUSSION, RECOMMENDATIONS AND CONCLUSION

5.1. Introduction

In this chapter, the researcher will discuss the results of the present study in line with the current literature related to the study. This study investigated the prevalence and determinants of DR among DM patients receiving treatment from the Maruleng public healthcare facilities, Mopani District in the Limpopo Province. The study focus was to determine the prevalence and determinants of DR among DM patients. In this chapter, the researcher will discuss the results and conclusions, as well as make recommendations.

5.2. Research design and method

The research methodology used in this study was a quantitative cross-sectional survey of the selected public healthcare facility-based diabetic population in Maruleng, using a piloted structured researcher-administered questionnaire to record the primary source data collected from a convenient sample of DM patients receiving treatment during the study. The study aimed to investigate the prevalence and determinants of DR.

5.3. Socio-demographic characteristics

All respondents in the present study were diabetes mellitus (DM) patients, either with a type 1 DM or type 2 DM, receiving treatment from a public or government healthcare facilities in the Maruleng Sub-district. The majority of patients in this study had a type 2 DM, as was the case in reported studies by Martinell et al. (2016) in Sweden and Magan et al. (2019) in Uganda. There were more females than males in this study, as was the case in previous reported studies in Saudi Arabia (Yasir et al., 2019), Cameroon (Hall et al., 2017) and in Uganda (Magan et al., 2019), as opposed to a study reported on in Singapore (Tan et al., 2018), where the majority of patients were males.

In this study, the size of the sample was bigger than that of other reported previous studies undertaken in Uganda (Magan et al., 2019) and at the National District Hospital in Bloemfontein, South Africa (Cairncross et al., 2017). This could be due to the methodology used to collect data, including the study settings and the time-frame to

complete the study. However, the reported studies in Spain (Lòpez et al., 2017), Saudi Arabia (Yasir et a., 2019) and in Zambia (Bellemo et al., 2019) showed a sample size bigger than that of the present study, which could be as a result of the methodology used to collect data, including the settings.

The majority of the patients in this study had no matric education (or secondary education), as was the case in other reported studies in Sudan (Ahmed et al., 2017) and in Sweden (Martinell et al., 2016). This could be a result of the social background of the patients, which varies from one individual to another. Lastly, the least number of the patients who participated in this study consume alcohol and smoked cigarettes, as was the case in other reported studies (Hall et al., 2017; Martinell et al., 2016; Tan et al., 2018). These habits could be to the result of other social determinants, such as individual behaviour, that vary from one person to another.

5.4. Prevalence of diabetic retinopathy

The findings of the present study revealed that the overall prevalence of any DR among DM patients was 35.4%, comprising a 32% prevalence of mild NPDR, and a 3.4% prevalence of moderate NPDR. The prevalence of any DR in the present study was greater in type 2 DM patients, in females and in older patients, as was the case in a previous study reported on in Spain (Lòpez et al., 2017), as opposed to the other previous studies reported on in Saudi Arabia (Yasir et a., 2019) and in Ethiopia (Shibru et al., 2019), where DR was more prevalent in males; however, this previous study only agreed with this study in the area of type 2 DM and older patients who are above the age of 60 years. The findings of the present study are also comparable to the findings of the systematic review and meta-analysis on the global prevalence of any DR, which was reported to be between 27% and 28.4% by Hashemi et al. (2019) and Thomas et al. (2019). This was lower than that of the present study, which could be as a result of unequal healthcare systems around the world or year of publication (Hashemi et al., 2019; WHO, 2020).

The findings on the prevalence of any DR in the present study are also comparable to the previous findings on the regional prevalence of any DR in Europe, South East Asia and the Middle East and North Africa, which was reported to be between 12.5% and 33.8% (Thomas et al., 2019). This is lower than prevalence of any DR in the present

study, which could be as a result of unequal healthcare systems around regions of the world (WHO, 2020). However, the region of the Western Pacific has shown that the prevalence of any DR was 36.2% (Thomas et al., 2019), which is higher than the prevalence of any DR in the present study. This may provide further evidence of unequal healthcare systems.

Other previous studies reported on in Australia (Keel et al., 2017); China (Liu et al., 2017); Spain (Lòpez et al., 2017); and, in Singapore (Tan et al., 2018) have shown that the prevalence of any DR was between 14.9% and 34.1%, which is lower than the prevalence of any DR in the present study. This could be as a result of the research methodology used, including study settings or the availability of the medical technology to detect and treat DR early. A previous study reported on in Saudi Arabia (Yasir et al., 2019) showed that the prevalence of any DR was 44.7%, which is higher than the prevalence of any DR in the present study. This could be as a result of the research methodology used, including study settings or type of sample.

Previous studies reported on in Ethiopia (Chisha et al., 2017); Ghana (Lartey & Aikias, 2018); Zambia (Bellemo et al., 2019); Cameroon (Hall et al., 2017); Tanzania (Cleland et al., 2016); South Western Sudan (Bobb-Semple et al., 2017); and in South Sudan (Sube et al., 2020) have shown that the prevalence of any DR was between 13% and 31.8%, which is lower than the prevalence of any DR in the present study. This could be as a result of the methodology used to collect data, including study settings or sample. However, previous studies reported on in Uganda (Magan et al., 2019); in Zambia, in Copperbelt province (Lewis et al., 2018); in Ethiopia (2019); and, in Sudan (Ahmed et al., 2017) have shown that the prevalence of any DR was between 39.8% and 85.7%, which is higher than the prevalence of any DR in the present study. This could be as a result of the methodology used, including study settings or the type of sample.

In South Africa, previous studies reported on in Bloemfontein at the National District Hospital (Cairncross et al., 2017) and in the Tshwane District (Webb et al., 2016) have shown that the prevalence of any DR was between 10.8% and 24.9%, which is lower than the prevalence of any DR in the present study, which could be attributable to the research methodology or sample size. However, the a previously reported study

undertaken at the McCord Provincial Hospital in KwaZulu-Natal province (Vervey & Mahomed, 2020) and a study at the Vision 4 Life Clinic in KwaZulu-Natal (Abdool & Mahomed, 2017) have both shown that the prevalence of any DR was 71%, which was higher the prevalence of any DR in the present study. This could be as a result of the research methodology used to collect data or type of sample, particularly the usage of the self-reported questionnaires in the study undertaken by Vervey and Mahomed (2020), where there was a greater likelihood of over-reporting the prevalence by the participants.

5.4. Determinants of diabetic retinopathy

The findings of the present study revealed that the age of DM patient (OR=2.7; 95% CI =1.6-4.4; *p<0.001*), employment status (OR=1.4; 95%CI=1.1-1.7; *p<0.001*) and a high systolic blood pressure or hypertension of 140 mmHg (OR=1.4; 95% CI=1.2-1.6; *p<0.05*) were significantly associated with DR. The findings of the present study that indicate a significant association with DR in terms of the age of DM patients concur with the findings of the previously reported studies (Agriya, 2020; Chisha et al., 2017). The finding of the present study which indicate that DR was significantly associated with the employment status concurs with the finding of a previous study reported on by Soleimani et al. (2017) but oppose the findings of other previously reported studies (Shibru et al., 2019; Valizadez et al., 2016). Lastly, the finding of the present study that DR was significantly associated with high systolic blood pressure or hypertension of 140 mmHg or more (≥140 mmHg) concurs with the findings of the other previously reported studies (Cleland et al., 2015; Lewis et al., 2018; Lòpez et al., 2017; Tan et al., 2018; Shiferaw et al., 2020; Sube et al., 2020; Webb et al., 2016).

5.4. Conclusions

More than a third of DM patients receiving treatment during the study period from public healthcare facilities in the Maruleng Sub-district had some form of DR, which means that nearly four in ten DM patients had some form of DR. This study also found that DR was more prevalent in females, in patients with type 2 DM, and in older DM patients. The prevalence of DR in the Maruleng Sub-district, Mopani District in Limpopo Province was relatively high compared to the other recent reported studies in South Africa, as discussed above. This is worrisome since it may suggest that the public healthcare measures against a risk of DR among DM patients receiving chronic

treatment remain critical. Age of DM patients, employment status and high systolic blood pressure were significantly associated with DR among DM patients.

5.5. Recommendations

The researcher recommends that the government authority, particularly under the Department of Health, implements the public healthcare measures, such as prevention strategies through health promotion, and/or early treatment, in order to control the rapid development of DR among DM patients on treatment. There is an urgent need for educational programmes about DR to be supported by government, including a coordinated screening programme for DR through the integrated healthcare system at all levels of healthcare services. This is particularly true in primary healthcare because indigent communities, such as the Maruleng communities, depend on the public healthcare for their healthcare needs. Further scientific study is needed to evaluate these recommendations or the causal relationships between exposure (DM) and health outcome (DR) among patients being treated in the Maruleng Sub-district.

5.6. Contributions of the study and implications for healthcare

This study will contribute in the body of knowledge, and will assist the policymakers to make evidence-based decisions during allocation of the healthcare resources, including prevention and treatment strategies related to DR among DM patients. The findings will also be used by serving healthcare professionals to provide evidence-based healthcare practice to DM patients, to improve DM healthcare and to motivate for healthcare resources (human, material and financial), when need arises. DM patients will use the knowledge of DR gained during the study to improve treatment compliance and to ensure that they have a regular eye check-ups at the nearest healthcare facility providing eye care services.

5.7. Limitations of the study

The study took place during the national lockdown period imposed by the government to reduced rapid of the coronavirus disease 2019 (COVID-19), where movement of people was restricted, particularly elderly and diabetic people who were identified by the National Institute of Communicable Diseases (NICDs) and National Department of Health as belonging to a high risk group of people to contract COVID-19 virus when exposed. The study applied a convenient sampling method to select a sub-set or part

of the DM patients who were readily available in the waiting or reception areas of all selected public healthcare facilities for a review and collection of a chronic diabetic treatment during the time of the study, which had limitation in generalization the study findings to the entire diabetic population in the Maruleng sub-district. Consequently, the sample size attained is smaller than anticipated since the calculated desired sample size in the original plan was 423, which is 8 less than actual number of DM patients who participated in the study after using a convenient sampling method to select part of the DM patients who were at the selected facilities during the time of the study. Other limitations of this study include its cross-sectional design, which could not established a causal relationship between DM and DR, and structured questionnaire used also prevented the respondents from fully expressing themselves during the data collection sessions.

5.8. Concluding remarks

Diabetes mellitus is a major public health problem, and it remains a global epidemic among the non-communicable diseases (NCDs). A global increased in the prevalence of diabetes mellitus leads to an increase in the prevalence of a diabetes mellitus complications, such as diabetic retinopathy (DR). The World Health Organization (WHO) has identified DR as one of the leading causes of vision impairment (VI) or blindness, and it also a leading cause of a legal blindness in a working-adults in the developed world, as a result of unhealthy lifestyles, such as physical inactivity and a bad eating habits. WHO gave a mandate to all member states to implement Resolution WHA42/R36, adopted during the forty-second World Health Assembly (WHA), which emanated from the General Assembly of the United Nations, to prevent and control the prevalence NCDs, including diabetic complications such as DR. The resolution is used as a global strategy or action plan to achieve one of the sustainable development goals, SDG 3.4 on health, in order to prevent and control NCDs, such as DM including its complications like DR.

In public health, the most important step of investigation by any public health specialist (epidemiologist) is to determine the magnitude of the disease by measuring frequency, such as rates or ratios and/or proportions. Therefore, determining the prevalence of any DR among DM patients will mark the beginning of solving a public health problem caused by complicated DM, leading to the occurrence of DR in people living with DM.

South Africa has a mandate to implement Resolution WHA42/R36 by a virtue of its membership in WHO.

Maruleng Sub-district is one of the sub-districts in South Africa within the Limpopo Province, which is one of the rural provinces in the country. Indigenous communities, particularly in the Maruleng Sub-district, depend on the public healthcare system for their healthcare needs. The prevalence of DR among DM patients is relatively high in the Maruleng public healthcare facilities compared to other parts of the country, where the similar studies have been conducted and reported on by the other researchers. Therefore, there is a need to implement public healthcare measures in Maruleng against the risk of DR through the introduction of educational programmes or health promotion programmes about DR, supported by government, and the introduction of a coordinated screening/ treatment programme.

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APPENDICES

Appendix 1: Time schedule

ACTIVITIES	TIME FRAME																						RESPONSIBILITY
	Academic year 2019												Academic year 2020										
	January	February	March	April	May	June	July	August	September	October	November	December	January	February	March	April	May	June	July	August	September	October	
Developing a research proposal																							Researcher & Supervisor
Research approval																							Faculty Higher Degree Committee (FHDC)
Ethical clearance																							Turfloop Research and Ethics Committee (TREC)
Approval by Department of Health																							PHREC
Introduction and arrangement with the																							Researcher
Conducting pilot study																							Researcher
Data collection for main study																							Researcher
Data capturing and analysis																							Researcher
Writing the dissertation																							Researcher
Language editing																							Researcher
Report evaluation																							Internal & External examiners
Feedback report following evaluation																							Supervisor
Printing and binding																							Researcher
Submission																							Supervisor & Department of Public Health
Acceptance of dissertation																							University Central Executive Committee

Appendix 2: Expenditure per item

ITEMS	EXPENSE (R)	RESPONSIBILITY
1. All kilometres (km) travelled using own car - 6248 km @ R3.30 University rates	**20,618.40**	Postgraduate bursary by HWSETA
2. Black & white copies @ R1.50 X 1500 made for - Questionnaires - Consent forms, and - Information letters	**2,250.00**	Postgraduate bursary by HWSETA
3. Editing the report - Language editing by the University Accredited Language Editors	**2,860.00**	Postgraduate bursary by HWSETA
4. Printing & binding by - University of Limpopo printing work		Postgraduate bursary by HWSETA
TOTAL		

Appendix 3: Faculty Approval

University of Limpopo
Faculty of Health Sciences
Executive Dean
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 2149, Fax: (015) 268 2685, Email:Kgagabi.letsoalo@ul.ac.za

DATE: 09 October 2019

NAME OF STUDENT:	**MALULEKE KD**
STUDENT NUMBER:	**9911323**
DEPARTMENT:	**PUBLIC HEALTH**
SCHOOL:	**HEALTH CARE SCIENCE**
QUALIFICATION:	**MPH**

Dear Student

FACULTY APPROVAL OF PROPOSAL (PROPOSAL NO. FHDC2019/6)

I have pleasure in informing you that your MPH proposal served at the Faculty Higher Degrees Meeting on 09 October 2019 and your title was approved as follows:

Approved **Title**: "Prevalence and Determinants of Diabetic Retinopathy in Maruleng Healthcare Facilities, Mopani District in Limpopo".

Note the following:

Ethical Clearance	**Tick One**
Requires no ethical clearance Proceed with the study	
Requires ethical clearance (TREC) (apply online) Proceed with the study only after receipt of ethical clearance certificate	√

Yours faithfully

MR K.J. Letsoalo
Chairperson

UNIVERSITY OF LIMPOPO
FACULTY OF HEALTH SCIENCES
2019 -10- 09
PRIVATE BAG X1106
SOVENGA 0727

CC: Supervisor: Dr E Maimela
CO- Supervisor : Dr T.S Ntuli

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Appendix 4: Ethical clearance certificate

University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 3935, Fax: (015) 268 2306, Email: anastasia.ngobe@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE

ETHICS CLEARANCE CERTIFICATE

MEETING: **05 March 2020**

PROJECT NUMBER: **TREC/28/2020: PG**

PROJECT:

Title:	Prevalence and Determinants of Diabetic Retinopathy in Maruleng Healthcare Facilities, Mopani District in Limpopo Province
Researcher:	KD Maluleke
Supervisor:	Dr E Maimela
Co-Supervisor/s:	Dr TS Ntuli
School:	Health Care Sciences
Degree:	Master of Public Health

PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

The Turfloop Research Ethics Committee (TREC) is registered with the National Health Research Ethics Council, Registration Number: **REC-0310111-031**

Note:

i) **This Ethics Clearance Certificate will be valid for one (1) year, as from the abovementioned date. Application for annual renewal (or annual review) need to be received by TREC one month before lapse of this period.**

ii) **Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee, together with the Application for Amendment form.**

iii) **PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.**

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Appendix 5: Limpopo Department of Health Approval

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Ref : LP-202003-006
Enquires : Ms PF Mahlokwane
Tel : 015-293 6028
Email : Kurhula.Hlomane@dhsd.limpopo.gov.za

K. D. Maluleke

PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES

Your Study Topic as indicated below;

Prevalence and Determinants of Diabetic Retinopathy in Maruleng Healthcare, Mopani District in 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

Head of Department **Date** 5/06/2020

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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Appendix 6: Approval by Mopani district office in Department of Health

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
MOPANI DISTRICT

Reference No : S4/2/2
Enquiries : S Chuma
Tel Direct : 015 811 6661

To: Mr KD Maluleke
P.O Box 361
Letaba
0870

Dear Mr Maluleke

RE: PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES OF MARULENG UNDER MOPANI DISTRICT: YOURSELF

1. We acknowledge receipt of your request received on the 23 June 2020.
2. It is with pleasure to inform you that permission has been granted for you conduct the above-mentioned research as granted by Limpopo Department of Health.
3. We also note that the pilot study will be conducted at Van Velden Hospital and Tzaneen Community Clinic.
4. You are advised to furnish the CEO/Manager of the health facilities with this letter for the purposes of access and assistance.
5. You will also be expected to observe and comply with all ethical standards and acts governing the public service to keep the integrity of the health facility and the department.
6. Wishing success in your studies.

pp .....
ACTING DIRECTOR: CORPORATE SERVICES

2020/06/29
DATE

Appendix 7: Approval by Van Velden Hospital for pilot study

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

VAN VELDEN HOSPITAL

Enq: Ragolane VJ

Ref: S4/2/2

Tel: 015 307 8800

Date: 29 June 2020

To: Mr Maluleke K D

P.O Box 361

Letaba

0870

From: Van Velden Hospital

RE: REQUEST FOR PERMISSION TO CONDUCT A PILOT STUDY AT VAN VELDEN HOSPITAL BY YOURSELF

1. Acknowledgement of receipt of your authentic documents is hereby made.
2. It is a pleasure to inform you that permission is granted for you to conduct a pilot study at Van Velden Hospital.
3. During your presence at Van Velden Hospital you will be required to always wear a cloth mask and observe a social distance.
4. In line with research ethics you will provide a consent form for patients to indicate their willingness or unwillingness to participate in your study.
5. .You will be screened daily at the gate when entering the facility and offered a visitor's card.
6. Wishing a success with your research.

Signed by _____ Date 29/6/2020

Deputy Director Nursing

Appendix 8(a): Information letter (English)

Research Project

PREVALENCE AND DETERMINANTS OF DIABETIC RETINOPATHY IN MARULENG PUBLIC HEALTHCARE FACILITIES, MOPANI DISTRICT IN LIMPOPO PROVINCE

By

Research Student in Public Health Master 2020

Dear Respondent

Congratulation you have been selected to participate in this research project by Department of Public Health in University of Limpopo. The purpose of study is to investigate the prevalence and determinant of diabetic retinopathy which is a micro-vascular complication of diabetes mellitus affecting the eyes amongst patients receiving diabetic chronic treatment.

Your participation in this research is completely voluntary and you have the right to withdraw at any time if you do not want to continue with the questionnaire. Your responses are also confidential and anonymous. There is no place where we ask your name or any other information that could identify you. Nobody but project researcher will have access to the information you provided.

Your participation in this project is appreciated and will assist government in your health needs. Completing the attached questionnaire will take less than 30 minutes.

Should you have any further questions about the research you are welcome to phone me, the researcher on **083 947 3970**.

Yours sincerely

_____ _____

Maluleke KD (Researcher: 9911323) **Date**

Appendix 8(b): Information letter (Sepedi)

Dinyakišašo

BOLWETŠING BJOO BO LEGO GONA BJA MAHLO BJA GO HLOLA KE SWIKIRI MO GO TŠA MAPHELO KA MARULENG, SELETENG SA MOPANI KA LIMPOPO.

ka

Moithuti wa masitara Diphatisiso tša maphelo tša setshaba 2020

Go Motsia-karolo

Re a go lebogiša ge o kgethilwe go ba mokšia-karolo mo projekeng ya lefapha la maphelo la setshaba mo univesithing ya Limpopo, Afrika Borwa. Morero wa diphatišišo ke go lekola go ata le boikemiše tšo bja mahlo go hlola ke swikiri.

Go tšea gag ago karolo mo diphatišišong tše ke ka go ithagopa gomme ona le tokelo ya go I kgogela morago nako ege goba efe eje eba o ikwao sesa nyaka go tša gago e tlaba sephiri, ebile go ka se bolelwe gore ke tša bomang. Ga go moo swanetšego gongwala loina la gago goba go nea boitšebišo bofe goba bofe bjoo boka thušago gore o mang. Ga go motho ya mongwe yoo a tla bago le phihlelelo ya tshedimošo yeo oe neilego ka ntle le mofatišiši.

Go tjea ga gago karolo mo diphatišišong tše ke mogo re amogela karolo yeo o tlo e tšeago mo diphatišišong tše gomme dipoelo tša yona dietla thuša gore o be le tshedimošo ka a gago ebile o kgone go ba le sebaka sa go botšiša dipotšišo ka bolwetši bjo.Go tla tšea fela metsotso yeo e sa fetego ye lesometharo go tlatša foromo ye a mamareditšwego.

Ge eba o na le dipotšišo ka diphatišišo tše o ka nomorong ya ka ya mogela 083 947 3970.

Wa gago ka potego

_____ _____

Maluleke KD (Monyakiša: 9911323) **Letšatši**

Appendix 8(c): Information letter (Xitsonga)

Vulavisisi

VUKONA NA SWIVANGELO SWA VUVABYI BYA MAHLO LEBYI BYI NGA VANGIWA HI VUVABYI BYA CHUKELA EMARULENG KA XIFUNDZA-NTSONGO XA MOPANI EXIFUNDZENI XA LIMPOPO.

hi

Mudyondzi wa vulavisisi wa rihanyo ra rixaka hi lembe ra 2020

Eka mungheneri wa vulavisisi

Hankhensa ku va u nghenerile ndzavisiso lewu, laha xikhongemelo-kulu ku nga ku lavisisa vuvabyi bya mahlo lebyi byi vangiwaka hi vuvabyi bya chukela exikarhini ka vanhu lava va kumaka mitsebyani yo chungula vuvabyi bya chukela.

Ku nghenela ndzavisiso lowu, munhu wa tihlawulela a nga sindzisiwi na kona vuxokoxoko hinkwabyo byi ta va bya xihundla no hlayiseka. Munhu u na fanelo yo tihumesa loko a twa swifanerile. Ku hava munhu loyi a nga ta kuma vuxokoxoko lebyi mi nga byi nyika ehandleni ka mulavisisi.

Ku nghenelala ka n`wina ka nkhensiwa na kona swi ta pfuna fumo ku antswisa vukorhekeri etitliniki na swibendlhele.

Loko mi ri vutiso ma pfumeleriwa ku swi kongomisa eka mulavisisi hi nomboro ya riqingo ya **083 947 3970**.

Wa nwina.

_____ _____

Maluleke KD (Mulavisis: 9911323) **Siku**

Appendix 9(a): Adapted TREC consent form (English)

CONSENT FORM

Project title: **Prevalence and determinants of diabetic retinopathy in Maruleng healthcare facilities, Mopani district in Limpopo Province.**

Project leader: **Maluleke Khisimusi Debree (9911323)**

I, _____hereby voluntarily consent to participate in the following project: “Prevalence and determinants of diabetic retinopathy in Maruleng healthcare facilities, Mopani district in Limpopo Province.”

I understand that:

1. My responses will be treated with confidentiality and only be used for the purpose of the research.
2. No harm will be posed to me.
3. The research project aim has been explained to me.
4. I do not have to respond to any question that I do not wish to answer for any reason.
5. Access to the records that pertain to my participation in the study will be restricted to persons directly involved in the research.
6. Any questions that I may have regarding the research, or related matters, will be answered by the researcher.
7. Participation in this research is entirely voluntary and I can withdraw my participation at any stage.
8. I understood the information regarding my participation in the study and I agree to participate.

_____ _____

Signature of interviewee **Signature of witness**

_____

Signature of interviewer

Signed at_____ on this ____ day of _____20_____

Appendix 9(b): Adapted TREC consent form (Sepedi)

FOROMO YA DUMELELANO

Hlogo ya projeke: **Bolwetšing bjoo bo lego gona bja mahlo bja go hlola ke swikiri mo go tša maphelo ka Maruleng, seleteng sa Mopani ka Limpopo.**

Moetapelo wa projeke: **Maluleke Khisimusi Debree (9911323)**

Nna, _____ ke ya ithaopa go tšea karalo mo projekeng, ya 'Bolwetšing bjoo bo lego gona bja mahlo bja go hlola ke swikiri mo go tša maphelo ka Maruleng, seleteng sa Mopani ka Limpopo**.'**

Kea kwišiša gore:

1. Phetolo yaka etla tshwarwa bjalo ka sephiri le go šomišwa fela ka morero wa dinyakišišo.
2. A gona kotsi yeo e ka nhlagelago.
3. Ke hlaloseditšwe ka maikemišetšo a dinyakišišo tša projeke ye.
4. Nka se fetole potšišo yeo ke sa ikemišetšago go e araba ntle le lebaka.
5. A go motho yo a swanetšego go tseba ka dinyakišišo tše ge e se monyakišiši wa projeke ye.
6. Potšišo ye nngwe le ye nngwe ya go amana le dinyakišišo goba go tswalelana le dinyakišišo, e tla arabja ke monyakišiši.
7. Go tšea karolo mo dinyakišišong tše ke boithaopi, ebile nka tlogela nako ye nngwe le ye nngwe ge ke rata.
8. Ke kwišiša tshedimušo mabapi le go tšea karolo mo gare ga thuto ye, gomme ke ya dumela go tšea karolo

_____ **_____**

Tshaeno ya monyakišišiwa **Tshaeno ya hlatse**

_____

Tshaeno ya monyakiša

Tshaeno lefolong la_____

ka letšatši la di _____kweding ya _____ngwageng wa 20_____

Appendix 9(c): Adapted TREC consent form (Xitsonga)

FOMO YA MPFUMELELO

Hloko-mhaka ya porojeke**: <u>Vukona na swivangelo swa vuvabyi bya mahlo lebyi byi nga vangiwa hi vuvabyi bya chukela eMaruleng ka xifundza-ntsongo xa Mopani exifundzeni xa Limpopo.</u>**

Murhangeri wa porojeke: **Maluleke Khisimusi Debree (9911323)**

Mina, _____ ndzi nghenela hi ndzexe porojeke leyi landzelaka: 'Vukona na swivangelo swa vuvabyi bya mahlo lebyi byi nga vangiwa hi vuvabyi bya chukela eMaruleng ka xifundza-ntsongo xa Mopani exifundzeni xa Limpopo."

Ndza twisisa kuri:

1. Tinhlamulo ta mina ti ta va xihundla na ku va ta xikongomelo xa ndzavisiso lowu ntsena.
2. A ndzi nga ta vavisiwa.
3. Xikongomelo xa ndzavisiso ndzi hlamuseriwile.
4. A ndzi boheki ku hlamula xivutiso lexi ndzi nga laveku ku xihlamula hi xivangelo xo nkarhi.
5. Ku kuma vuxokoxoko bya mina bya ndzavisiso byi ta va byi sirheleriwile hi mulavisisi.
6. Swivutiso mayelano na ndzavisiso lowu na swin`wana na swin`wana swi ta hlamuriwa ntsena hi mulavisisi wa porojeke leyi.
7. Ku nghenela ndzavisiso lowu a ndzi boheleriwanga ndzi lo tihlawulela na kona ndzi nga ti humesa nkarhi wun`wana na wun`wana.
8. Ndza twisisa vuxokoxoko hinkwabyo mayeleno no nghenela ndzavisiso na kona ndzi pfumerile.

_____ _____

Sayino wa mulavisisiwa **Sayino wa mbhoni**

_____

Sayino wa mulavisisiwa

Ku sayiniwile e_____ hi siku____ n`wheti ya _____20_____

Appendix 10(a): Research instrument (English)

A. SOCIO-DEMOGRAPHIC PROFILE									
Age	**Gender**		**Educational level**			**Employment status**			
	Male	Female	No matric	Matric	Post Matric	Employed	Unemployed	Self-employed	Pensioner

Alcohol drinking and smoking habits											
Do you drink alcohol?	Yes	No	If yes: How often do you drink								
			Daily		Weekly		Less often				
Do you current smoke cigarette?	Yes	No	If yes: How often do you smoke								
			Daily		Weekly		Less often				

B. DIABETES MELLITUS BACKGROUND							
ITEMS	**Responses**						
1. At which age were you diagnosed with a diabetes?	<10	11-20	21-30	>31	Class	T1DM	T2DM
2. Do you taking diabetic treatment according to way you should take?				Yes	No		
3. Is there any member of your suffering from diabetes?				Yes	No		

C. VISION-RELATION INFORMATION			
ITEMS	**Responses**		
4. Have you ever went for vision or eye screening since you became diabetic?	Yes	No	
5. Have you ever experienced any blurred or cloudy vision?	Yes	No	
6. Do you experience any vision fluctuation sometimes?	Yes	No	
7. Do you see any spot or dark strings floating or dark or empty areas?	Yes	No	
8. Are you not experiencing any challenge when seeing colours?	Yes	No	
9. Are you using spectacle?	Yes	No	

D. CLINICAL ASSESSMENT												
ITEMS									**Measurements**			
10. Plasma glucose level in mill moles (mmol)	Pre-prandial		Postprandial									
11. SBP in millimeters of mercury (mmHg)												
12. BWT in kilograms (kg)												
13. HT in meters (m)												
14. Calculated BMI												
15. BMI Classification using **BMI=Weight in kg/ (Height in m)²**	Underweight **(≤18.5)kg/m²**		Normal **(18.5-24.5)kg/m²**		Overweight **(25.0-29.5) kg/m²**		Obese **(≥30)kg/m²**					
16. RE: Unaided DVA		Pinhole DVA		Habitual DVA		Impaired		Blind				
17. LE: Unaided DVA		Pinhole DVA		Habitual DVA		Impaired		Blind				
18. DR results	No DR		Mild NPDR		Moderate NPDR		Severe NPDR		PDR			
19. Causes of visual impairment/ blindness	DR		Refractive error		Other cause							

Interviewer/ Researcher **Date**

Appendix 10(b): Research instrument (Sepedi)

A. TSA SEDIDKODIKO									
Mengwaga	**Bong**		**Tša thuto**			**Tša mosomo**			
	Monna	Mosadi	Ga ona marematlou	Marematlou	Tša mphato wa godimo	Wa pereka	Ga o some	Wa ke pereka	Motšofe

Go ithabiša ka madila le motsoko								
O nwa madila?	Ee	Aowa	Ge ele gore wa nwa madila, ga kae?					
			Letšatši		Beke		Gannyane	
Kgoga motsoko ga bjale?	Ee	Aowa	Ge e le gore wa kgoga motsoko, Ga kae?					
			Ka letšatši		Ka beke		Gannyane	

B. NYAKISISO KA BOLWETSI BJA SWIKIRI							
Dinthla	**Dikarabo**						
1. O tsebile neng gore o phela ka bolwetši bja swikiri?	<10	11-20	21-30	>31	Mohuta	T1DM	T2DM
2. O nwa dihlare tša gago ka tsela ya maleba?				Ee	Aowa		
3. Go na le wa leloko la gago a phelang ka bolwetši bja swikiri?				Ee	Aowa		

C. SEEMO SA LEBONO			
Dinthla	**Dikarabo**		
4. O kile wa hlahlobiwa mahlo goba go bona go tlogela o phela ka bolwetši baj swikiri?	Ee	Aowa	
5. O kile o ba le bothata bja go se bone gabotse?	Ee	Aowa	
6. Go bona gag ago go a fetoga ka matšatši?	Ee	Aowa	
7. O ke o bone bontsho goba mmala o moso ge o lebelela?	Ee	Aowa	
8. Go bona dilo tsa mmala go gofa bothata?	Ee	Aowa	
9. O šomiša galase tša mahlo?	Ee	Aowa	

D. BONGA BJA BOHLAHLOBI												
Dinthla										**Boelo**		
10. Boemo bja swikiri mading	Pele o e ja		Ka morago ga goja									
11. SBP in millimeters of mercury (mmHg)												
12. BWT in kilograms (kg)												
13. HT in meters (m)												
14. Calculated BMI												
15. **BMI=Weight in kg/ (Height in m)²**	Go hloka boima bja maleba **(≤18.5)kg/m²**		Boima bja maleba **(18.5-24.5)kg/m²**		Boima bja bogolo **(25.0-29.5) kg/m²**		Boima bja go fetešiša **(≥30)kg/m²**					
16. RE: Ka thušo DVA		Ka moshuba DVA		Ka galase DVA						Bofofu		Bofofu
17. LE: Ka thušo DVA		Ka moshuba DVA		Ka galase DVA						Bofofu		Bofofu
18. Dipoelo	No DR		Mild NPDR		Moderate NPDR		Severe NPDR			PDR		
19. Dilotšeo di hlolago bofofu	DR		Magalase		A magwe							

Tshaeno ya munyakiša **letšatši**

Appendix 10(c): Research instrument (Xitsonga)

A. VUXOKOXOKO BYA XIYIMO XA MUNHU EMUGANGENI									
Male mbe	**Rimbewu**		**Xiyimo xa dyondzo**			**Ta ntirho**			
	Wanuna	Wansati	A wu na ntangha-khume	U na ntangha-khume	Ku hundza ntangha-khume	Wa ntirha	A wu ntirhi	Wa titirha	U mudende

Mintolovelo yo n`a byalwa no zaha fole								
Wa n`a byalwa na?	Ina	Ee	Loko ku ri ina: U n`a kangani xana?					
			Hi siku		Hi vhiki		Minkarhi yin`wana	
Wa zaha fole na?	Ina	Ee	Loko ku ri ina: U zaha kangani xana?					
			Hi siku		Hi vhiki		Minkarhi yin`wana	

B. VUXOKOXOKO BYA VUVABYI BYA CHUKELA							
Swivutiso	**Tinhlamulo**						
1. Byi ku khome u ri na malembe mangani xana?	<10	11-20	21-30	>31	Ntlawa	T1DM	T2DM
2. Xana wa teka mimirhi hi fanelo?				Ina	Ee		
3. A ku na wun`wana wa le kaya a vabyaka vuvabyi bya chukela xana?				Ina	Ee		

C. VUXOKOXOKO BYA MAVONELO YA MATIHLO			
Swivutiso	**Tinhlamulo**		
4. Xana u tshame u kamberiwa matihlo mpfuka u vabya vuvabyi bya chukela?	Ina	Ee	
5. Xana ku vona ka wena a ku tshamanga ku timeka?	Ina	Ee	
6. Ku vona ku wena a ku ncincanci xana?	Ina	Ee	
7. Xana a wu voni bakwa exibakabakeni?	Ina	Ee	
8. Xana a wu ntikeriwi ku vona minhlovo?	Ina	Ee	
9. Xana u ntirhisa manghilasi ya mahlo ke?	Ina	Ee	

D. KAMBELO-MAVABYI												
Vukamberi										**Mpimo**		
10. Mpimo wa chukelo engatini		U nga dyangi			U dyile							
11. Mpimo wa mafambelo ya ngati												
12. Ntiko wa munhu												
13. Ku leha ka munhu												
14. Hlayo ya ntiko												
15. Ntlawa wa ntiko **BMI=Weight in kg/ (Height in m)²**		Ntiko-hansi **(≤18.5)kg/m²**		Ntiko wa fanelo **(18.5-24.5)kg/m²**		Ntiko wa le hehla **(25.0-29.5) kg/m²**		Ntiko wu hundzisisa **(≥30)kg/m²**				
16. RE: mpfuno wo vona		Hi mbovo DVA		Hi manghilasi DVA		Riphume		Vubofu				
17. LE: mpfuno wo vona		Hi mbovo DVA		Hi manghilasi DVA		Riphume		Vubofu				
18. Mbuyelo	Ku hava	Byi ntsongo		Byi kona		Bya tika		Bya ntika swinene				
19. Xivangelo xa vubofu	Vuvabyi byo vangiwa hi chukelo			Riphume ro lava manghilasi		Kumbe byin`wana						

Sano wa mulavisisi **Siku**

Appendix 11: Evidence of Language editing

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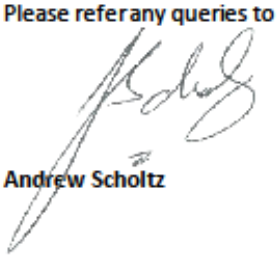
Date: 14 December 2020

To Whom it May Concern

I hereby confirm that I have proof-read the document entitled: "Prevalence and Determinants of Diabetic Retinopathy in Maruleng Healthcare Facilities, Mopani District in Limpopo Province" authored by Khisimusi Debree Maluleke and have suggested a number of changes that the author may or may not accept, at his discretion.

Each of us has our own unique voice as far as both spoken and written language is concerned. In my role as proof-reader I try not to let my own "written voice" overshadow the voice of the author, while at the same time attempting to ensure a readable document.

Please refer any queries to me.



Andrew Scholtz

Qualifications:

- MA (Digital Media in Education) – University of Kwazulu-Natal (2006)
- Accreditation of Assessors in Higher Education (Short Course) – Rhodes University (2007)
- Postgraduate Diploma in Dispute Settlement – University of Stellenbosch Business School (2013)
- SLP Family Law (Short Course) – North West University (2013)
- Strengthening Postgraduate Supervision (Short Course) – Rhodes University (2019)
- UCT Copy-editing Online Short Course – University of Cape Town (2020)

Evidence of qualifications are available on request.