CHARACTERISTICS OF POORLY CONTROLLED DIABETES MELLITUS PATIENTS AT MANKWENG HOSPITAL, LIMPOPO PROVINCE

By

DIBAKOANE, PALESA

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SUPERVISOR: Prof G. Marincowitz

CO-SUPERVISOR: Dr M. Shoyeb

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DEDICATION

First and foremost, to God I would like to express my gratitude for the divine wisdom, guidance, strength, courage, and enablement to embark on and complete this study, to you, Father, you deserve the glory and honour.

To my late father, thank you for your love and support, I know you are smiling down from heaven. My mother, thank you for taking care of us when my father went to be with the Lord, you love, support and always cheering me when the going got tough, I love you.

To my husband, thank you for believing in me, your support is appreciated. To the girls Tebogo, Moyahabo and Lerato, you guys are the best, mommy loves you. To the rest of the family, thank you.

DECLARATION

I, Palesa Dibakoane, declare that the contents of this thesis on the **Characteristics of Poorly Controlled Diabetes Mellitus Patients at Mankweng Hospital, Limpopo Province** represents my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references, and that this work has not been submitted before for academic examination towards any qualification.

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ABSTRACT

Introduction

Diabetes is a rising problem globally. The World Health Organization (WHO) has classified diabetes as an epidemic. The major impact of the disease is felt in low- and middle-income countries. The literature has emphasised the fact that most patients living with diabetes are undiagnosed, and those who are diagnosed are poorly controlled. The complications associated with diabetes usually occur over a long period of time and are mainly influenced by poor glycaemic control. In South Africa, diabetes is a major cause of morbidity and mortality and a burden to the already overstretched health system in the country. In this study, factors that impair a patient's ability to achieve good glycaemic control are investigated. '

Methods

In this cross-sectional, descriptive study was conducted at the general outpatients department (GOPD) of the Mankweng hospital in the Capricorn District of the Limpopo Province. A total number of 97 participants formed part of the study. An HbA1c test was used to classify patients into a well-controlled glycaemic group (HbA1c ≤ 7%) or a poorly controlled group (HbA1c > 7%). Factors for poor glycaemic control were investigated. The following factors were investigated to identify characteristics of poorly controlled diabetes patients: demographic data; adherence to treatment; and, clinical measurements characteristics. Frequency tables, univariate logistic regression models and chi-square tests were used to determine factors influencing glycaemic control.

Results

Of the 97 patients, only 63 (64.9%) had an HbA1C measurement done (measurable outcome). Of these patients, only 13 (15.7%) had well controlled diabetes, while diabetes in 50 patients was poorly controlled. Patients on oral treatment only comprised the bulk of the patients who were well controlled. Following multivariate analysis, being male was found to be a significant predictor of good glycaemic control.

Conclusions

Most patients who had an HbA1C done were poorly controlled. As a secondary observation, management of diabetes was suboptimal. Male patients treated with oral medication alone were more likely to have good glycaemic control.

Key concepts

Diabetes mellitus, HbA1C, glycaemic, hospital, general out-patient department, Limpopo

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DEFINITION OF KEY CONCEPTS

Diabetes mellitus

The term diabetes mellitus (DM) describes a metabolic disorder with heterogenous aetiologies which is characterised by chronic hyperglycaemia and disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both (World Health Organization [WHO], 2011). The term DM used in this study refers to type 2 DM.

HBA1c

Red blood cells are made from a molecule called haemoglobin. Glucose binds to the haemoglobin to make a 'glycosylated haemoglobin' molecule, called haemoglobin A1c or HbA1c. As a result, the more glucose in the blood, the more HbA1C will be present in the blood. The lifespan of red blood cells is 8 to 12 weeks before they are replaced. By measuring the HbA1c, one can determine how high the blood glucose has been, on average, over the last 8 to 12 weeks. A normal non-diabetic HbA1c is ≤ 5.5%. In diabetes, HbA1c is ≥ 6.5%. In diabetic patients who are on treatment, good glycaemic control is considered when HbA1c is ≤ 7% (WHO, 2011). HBA1c use in this study refers to poorly controlled DM, considered as HbA1c of > 7%.

Characteristics

Pertaining to, constituting, or indicating the character or peculiar quality of a person or thing, which is typical and distinctive. (Dictionary.com). Use in this study: It refers to the features that define the patients. Examples of characteristics are age, gender and adherence to treatment.

Patient

A patient is an individual who is suffering from disease, injury, an abnormal state, or a mental disorder and is engaged in related treatment ((Lois Oakes and Roper, 1981).

When used in this study, patient refers to an individual having type 2 DM.

Hospital

A hospital is an institution that provides medical and surgical treatment and nursing care to sick or injured people. When used in this study, hospital refers to the Mankweng hospital, a tertiary institution.

Assistant

An assistant is a person who helps or supports somebody, usually in their job. A research assistant in this study is a registrar in the Department of Family Medicine at the University of Limpopo, other than the main researcher, and the registered nurse who assisted with completion of questionnaires (Hornby, Cowie and J Windsor Lewis, 1977).

ACRONYMS AND ABBREVIATIONS

ANOVA	Analysis of variance
BMI	Body mass index
BP	Blood pressure
CV	Cardiovascular
DM	Diabetes mellitus
EDL	Essential drug list
GOPD	General outpatients department
HbA1C	Glycated haemoglobin (A1c)
HIV	Human immunodeficiency virus
HQI	Housing-quality index
ICU	Intensive care unit
IDF	International Diabetes Federation
LDL	Low density lipoprotein
LDL-C	Low density lipoprotein cholesterol
MmHg	Millimetres of mercury
NCD	Noncommunicable diseases
SD	Standard deviation
SSA	Sub-Saharan Africa
SSDC	School Senior Degrees Committee
SSPS	Statistical Package for the Social Sciences
TREC	Turfloop Research and Ethics Committee
WHO	World Health Organization

CHAPTER 1
BACKGROUND OF THE STUDY

1.1 Introduction

The purpose of this study was to describe the characteristics of poorly controlled diabetes mellitus (DM) patients in the general out-patients department (GOPD) of the Mankweng hospital. In this chapter, the researcher provides an introduction and background to the topic, as well as a review of the relevant literature.

DM is a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces, resulting in hyperglycaemia. (CDC, 2005; Bishop, Duben-Engelkirk & Fody, 2000:221).

DM is a major health problem worldwide. Literature sources, including the World Health Organization (WHO) and the International Diabetes Federation (IDF), reported that the number of people that are affected by DM is fast increasing at an alarming rate. DM is now being called a pandemic. Type 2 diabetes has been found to be the most prevalent type of diabetes that affects low- and middle-income-earning countries (World Health Organization [WHO], 2020).

In this chapter, the researcher provides an introduction of the study, providing a background into the characteristics of poorly controlled DM patients at the Mankweng hospital. The hospital is in a semi-urban area, with increasing urbanisation. During the study, the researcher tried to determine whether the characteristics of poorly controlled DM of patients at the Mankweng hospital were the same as those described in literature.

1.2 Background

Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. This indicates that the number of people living with DM is increasing globally. The global prevalence (age-standardised) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% of the adult population. This reflects an increase in associated risk factors, such as being overweight or obese. Over the past decade,

diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries. (WHO, 2020)

A study conducted by Timothy (2011) in three-community health centres in Johannesburg, South Africa, found that majority of patients (84.2% of a sample size of 394) attending the selected facilities for diabetes had poor glycaemic control. In the Timothy study, HbA1c > 7 was classified as poorly controlled and HbA1c ≤ 7 was classified as well controlled. The study concluded that patient-related factors were at the forefront of factors causing poor glycaemic control. Timothy also observed that management of diabetes in these centres was suboptimal. Some of the reasons provided for this by the staff were high patient to staff ratio, a lack of working equipment and need to improve diabetes management skills. Interestingly, in the Timothy study, only 62 (15.7%) patients had well controlled diabetes. Good glycaemia control was found to be associated with unemployment, short duration since diabetes diagnosis, treatment with oral medication alone and being male.

In a the study that was conducted in Mopani District (one of the districts in the Limpopo Province) looking at factors contributing to poor glycaemic control in diabetic patients, Shilubane (2010) found that a lack of money interferes with diabetes control. The majority of the patients (75%) in this study agreed that lack of money interfered with their ability to control their blood glucose as they could not afford to buy the necessary food and to visit the health institutions for check-ups and collection of treatment medication. This situation they found themselves in led to elevated blood glucose due to non-adherence to treatment and no access to advice.

Baumann, Chang and Hoebe (2002:191) said that morbidity from diabetes is more severe in low-income groups, while another factor observed in patients who are poorly controlled was defaulting on scheduled appointments at the hospital. Therefore, the findings from the Mopani District are similar to what is observed in other parts in the world.

DM is growing at an alarming rate and death due to diabetes complication is also increasing. It was also noted that diabetes is increasing in the low- to middle-income countries, of which South Africa is one. Therefore, it is of utmost importance that good

glycaemic control of diabetes and factors associated with poor control should be identified to curb premature deaths secondary to DM.

To achieve the above this study was conducted at the GOPD of the Mankweng hospital, in the Limpopo Province. Mankweng is a town in the Capricorn District Municipality in the Limpopo Province of South Africa.

1.3 Motivation for the study

While working in the Mankweng hospital GOPD, the researcher noted that most diabetic patients were poorly controlled. Most of the patients that were poorly controlled were on maximum doses of their oral treatment. In this study, the researcher sought to characterise these patients and to identify possible factors associated with the poorly controlled DM, as indicated by the HbA1c levels > 7%.

The United Kingdom Prospective Diabetes Study (UKPDS) showed that, in type 2 diabetes, each 1% reduction in mean HbA1c was associated with reductions in risk of 21% for deaths related to diabetes, 14% for myocardial infarction and 37% for microvascular complications. (McEwan, Bergenheim and Currie, 2006)

Frei et al. (2012) found that DM affects many working class people and, as a result, it has as a major and deleterious impact on both individual and national productivity. The socioeconomic consequences of diabetes and its complications could have a seriously negative impact on the economies of developed and developing nations, such as South Africa.

The researcher could not find similar studies conducted in the study setting of this study. Therefore, the findings of this study will add to the body of knowledge that is, in fact, understudied in our setting. The identification of factors that influence poorly controlled DM could assist in tailoring interventions aimed at improving glycaemic control in poorly controlled DM patients, thereby preventing or delaying diabetic complications, improving the quality of life of people living with diabetes mellitus and preventing premature deaths.

1.4 Significance of the study

DM is a chronic health problem with devastating, yet preventable consequences (Curtis, 2014). Diabetes and other non-communicable diseases (NCDs) that share the same risk factors represent a leading threat to health and human development (IDF, 2009). It has been well described in literature that people with poorly controlled DM develop microvascular and macrovascular complications at a rapid rate. These complications invariably lead to several debilitating morbidities and, eventually, mortality. These complications can be avoided if good glycaemic control is achieved in diabetic patients. The above is achieved when both the patient and the healthcare practitioners work together in managing the disease. Therefore, characterising diabetic patients who are poorly controlled and identifying factors that lead to poor control can be the starting point to improve glycaemic control and reduce or halt the development of microvascular and macrovascular complications, thereby improving the quality of life and prevent premature deaths in diabetic patients. (Amod, 2017). The study findings may also add to a growing body of knowledge and form basis for future research in the Mankweng hospital.

1.5 Research questions

The following research questions were posed in this study:

- What are the demographic characteristics of patients with uncontrolled type 2 diabetes mellitus?
- What are the factors associated with poorly controlled diabetes mellitus?

1.6 Aim of the study

The aim of the study was to determine the characteristics of uncontrolled type 2 DM patients at the Mankweng hospital.

1.7 Objectives of the study

The objectives of this study were:

- To determine the demographic characteristics of patients with uncontrolled type 2 diabetes mellitus at the Mankweng hospital.
- To identify factors associated with poorly controlled diabetes mellitus.

CHAPTER 2
LITERATURE REVIEW

2.1 Introduction

The literature review provides an overview of the current literature dealing with DM globally, in the IDF's African region (AFR) and then, finally, in South Africa. The literature review sought to understand the epidemiology, age and gender distribution, glycaemic control, factors associated with poor glycaemic control and complications of diabetes. Library database searches were undertaken in the medical and healthcare fields for relevant and recent journals, books, research theses from the national research institution repository and credible internet search engines. The following databases where used to search for literature: EMBASE; MEDLINE; Cochrane Database of Systematic Reviews; PubMed; and, Google Scholar. The following keywords were used to search: diabetes mellitus; HbA1C; glycaemic control' diabetes complications; and, treatment.

DM is a major health problem worldwide, with its prevalence increasing, thus becoming a pandemic. (Al-Khawaldeha, AlHassan & Froelicher, 2012:10-16). The chronicity of DM and the potential for serious complications often result in a significant financial burden and decreased quality of life, requiring major lifestyle changes for patients and their families. Poorly controlled diabetes too often results in complications such as heart disease, stroke, high blood pressure, blindness, kidney disease, nervous system disease, amputations of legs and premature death (Al-Khawaldeha, Al-Hassan & Froelicher 2012:10-16).

The mortality risk in people with diabetes is approximately 1.5 to 2.5 times higher than in the general population. In the case of people with type 2 DM, life expectancy adjusted by age is reduced by 5 to 8 years (Cardoso, 2014).

Evidence-based studies indicate that control of glucose (HbA1c < 7) decreases the incidence and progression of both microvascular and macrovascular complications of diabetes and is cost effective (Stuckey, 2009).

Present knowledge indicates that optimal treatment for diabetes is a mixture of measures and includes components such as appropriate diet, physical activity, oral medications, home blood glucose testing and insulin injections. As the disease progresses, the dosage and number of oral hypoglycaemic agents are increased, and many patients ultimately need to introduce insulin to maintain adequate glycaemic control (Tamir, 2012).

2.2 Epidemiology of diabetes

According to IDF, an estimated 463 million adults aged 20–79 years, worldwide, have diabetes. Furthermore, it is estimated that 79.4% live in low- and middle-income countries. Based on 2019 estimates, by 2030 a projected 578.4 million, and by 2045, 700.2 million adults aged 20–79 years, will be living with diabetes. (Huang et al., 2019)

An estimated 19.4 million adults in the AFR aged 20–79 years have diabetes, representing a regional prevalence of 3.9%. The AFR currently has the lowest prevalence of diabetes among all the IDF regions, which is likely due to lower levels of urbanisation, under-nutrition and under-reporting. In the AFR, 45.9% of people with diabetes live in low-income countries, while 54.1% live in middle-income countries. The highest prevalence (8.8%) of diabetes in the region is among adults aged between 65 and 69 years.

The prevalence of diabetes among South African adults aged 30 years and above has increased by 50% from 2009 to date. The highest age-adjusted comparative prevalence of diabetes in adults aged 20–79 years in the AFR is in South Africa (12.7%), followed by Seychelles (12.3%) and Comoros (12.3%). The most populous countries in the AFR have the highest number of people with diabetes, including South Africa (4.6 million), Nigeria (2.7 million), Democratic Republic of Congo (1.8 million) and Ethiopia (1.7 million).

The proportion of undiagnosed diabetes is highest in the AFR, where more than half (59.7%) of people living with diabetes are unaware of their condition. Diabetes prevalence is higher in urban (5.9%) than in rural (2.4%) areas. (Huang et al., 2018).

The prevalence of diabetes in South Africa varies from one province to another and within different population groups. The highest rates of diabetes have been reported among

Asian Indians and the mixed ancestry populations; however, data is limited. (Amod, 2017).

Goedecke, Jennings and Lambert (2005) also reported similar findings to Amod, finding that the prevalence of diabetes was the highest among the Asian Indian community, with 8.5% and 11.5% for men and women, respectively.

Statistics South Africa (StatsSA) classified DM as the third leading cause of death among South Africans. The ten leading natural causes of death classified by sex for a three-year period (2014–2016). Over this three-year period, tuberculosis remained the leading cause of deaths of males. However, in females, DM surpassed tuberculosis as the leading cause of death in 2016. In females, deaths due to DM have steadily increase, accounting for 6.5% of deaths in 2014, moving higher to 7.1% of deaths in 2015 and to 7.2 % of deaths in 2016. (Statistics South Africa [StatsSA], 2004).

2.3 Classification of diabetes

All the described forms of DM are characterised by hyperglycaemia, however, the mechanism by which these forms develop differs. The two main clinical types of diabetes have been identified as type 1 and type 2 DM.

Type 1 DM, sometimes known as juvenile DM or insulin dependent DM (IDDM), commonly occurs amongst children. Kunnamo, (2005:716) adds that, in 10–15% of type 1 diabetics patients, the illness appears at a later stage. Type 1 diabetics generally accounts for about 5% of all diabetics. The other form of diabetes is type 2 DM, also known as non-insulin DM (NIDDM), which normally occurs during adulthood. It accounts for more than 80% of all diabetics (ADA, 2004).

Other types of diabetes include gestational DM (GDM) and maturity onset diabetes of the young (MODY).

2.4 Risk factors (aetiology) of diabetes mellitus.

Diabetes is the result of a genetic predisposition and an interplay of environmental factors. The environmental factors thought to lead to the development of type 2 DM include

physical inactivity, obesity, drug toxicity, infections and location (Misra & Ganda, 2006; Sano, Terasaki, Tsutsumi, Imagawa & Hanafusa, 2008).

2.4.1 Diet and obesity

Diet is a crucial environmental factor for the development of obesity. Obesity is a condition in which there is accumulation of excess body fat to an extent that health may be adversely affected, (WHO). According to the WHO classification of body weight, an individual whose body mass index (BMI) exceeds 30kg/m^2 is considered obese (WHO, 2003).

According to WHO, it is estimated that there are currently about 300 million adults who are classified as obese, globally. In South Africa, more than 29% of men and 56% of women are classified as obese (Goedecke et al., 2005).

2.4.2 Physical activity

There is a strong link between the development of type 2 diabetes and the physical activity levels of an individual. Overweight, but especially central obesity, as well as physical inactivity, have been found to be powerful predictors for development of type 2 diabetes. Wandell, De Faire and Hellenius (2006) state that about 90% of type 2 diabetic cases can be prevented if one adopted a prudent diet, avoided being overweight and obese, engaged in moderate to vigorous physical activity, did not smoke and consumed moderate amounts of alcohol.

A systematic review of lifestyle weight loss interventions in overweight and obese adults with type 2 DM showed that a weight loss of > 5% is considered necessary for its beneficial effects on HbA1c, lipids and blood pressure. To achieve this level of weight loss, intense interventions, including energy restriction, regular physical activity and frequent contact with healthcare professionals, are required. (Leite et al., 2020).

2.4.3 Genetic factors

Many studies have provided evidence that glucose intolerance and diabetes can occur in members of the same family (Ramachandran, Snehalatha & Vijay, 2002).

Type 2 DM is a so-called multifactorial disease in which the genes not only interact with each other but also with environmental factors. It is probable that both insulin activity and secretion are subject to genetic variance at several loci. According to this multifactorial model, predisposition to the disease could be determined by many different combinations of genetic variants (genotypes) and environmental factors; the genetically predisposed subjects will not necessarily develop the overt syndrome unless they are also exposed to environmental factors. It is well known that exogenous factors such as age, physical activity, diet, and obesity play a major role in the disease aetiology of type 2 DM. (van Tilburg, 2001)

2.5 HbA1c

HbA1c is the ratio of glycosylated haemoglobin in relation to the total haemoglobin in circulation. (Bonora et al., 2001). Identification of the correlation between HbA1c and diabetic complications has yielded one of the most clinically useful biomarkers. HbA1c has revolutionised the diagnosis and monitoring of DM (Campbell, Pepper & Shipman, 2018).

For most patients, the recommended HbA1c target is < 7% to prevent microvascular complications and macrovascular complications when intensive treatment is instituted early in the course of the disease. (Amod, 2013)

2.6 Complications of diabetes mellitus

As a result of long standing, uncontrolled, high plasma glucose levels, diabetes leaves numerous structural changes in the body. This is worsened by the coexistence of other cardiovascular risk factors, such as hypertension, dyslipidaemia, obesity and smoking (Mundet et al., 2008). The complications of long-term DM include damage to the blood circulation (vascular) system; dysfunction and failure of various organs, such as the kidneys, eyes and nerves; and, recurrent skin infection (Mundet, Pou, Piquer, Isabel, Sanmartin, Tarruella, Gimbert & Farrus, 2008). A description of the complications of DM on various organs is provided below.

2.6.1 Cardiovascular system

Diabetes is an important risk factor for the development of cardiovascular disease. This is due to the gradual pathological changes that affect different blood vessels (Fowler, 2008).

2.6.2 Diabetic nephropathy

The kidney is an important organ whose function, among others, is to regulate body water volume and electrolytes or salts. Other than hypertension and autoimmune disorders, diabetes is the singlular most common cause of end stage renal disease (Bin, Song, Dong, Yang, Zhang, Wen, Yiming, Zhou, Zhao, Zhu & Renming, 2007; ADA, 2004).

2.6.3 Diabetic foot

Diabetic foot complications are one of the most common complications amongst diabetic patients. These complications also contribute to the bulk of hospital admissions, yet, if screened early enough, can be prevented.

2.6.4 Neuropathy

Neuropathy refers to damage caused to the nerves by diabetes (Boon, Colledge, Walker & Hunter, 2006:843). Prolonged hyperglycaemic states are thought to have a destructive effect on nerve tissue. This results in partial or complete nerve tissue necrosis. Patients with such complications experience a localised lack of sensation or pain. According to Parry, Godfrey, Mabey and Gill (2004:754), other effects of diabetic neuropathy are sexual dysfunction, gastrointestinal motility disturbance and abnormal sweating, among others.

2.6.5 Diabetic retinopathy

Over a period of time, diabetics develop retinopathy. Diabetic retinopathy is thought to be the most common diabetic eye disease and a leading cause of blindness amongst diabetics (Fong, Aiello, Gardner, King, Blankenship, Cavallerano, Ferris & Klein, 2003).

One of the major risk factors for the development and progression of diabetic retinopathy is the duration of the disease and how adequately the diabetes is controlled (Fong et al., 2003; Florkowski, Scott, Coope, Graham & Moir, 2000).

2.7 Treatment of diabetes

Once an individual has been diagnosed as a diabetic, appropriate management needs to be instituted. The Public Hospital Standard Treatment Guidelines (Adult) provides the guidelines which clinicians can refer to when treating diabetes. Furthermore, credible South African academic bodies add to the body of knowledge and recommendations for quality management of DM. An example of such a body is the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA). The treatment goal should be to maintain blood sugar levels at normal levels.

2.8 Conclusion

In this chapter, the researcher discussed diabetes in detail, focusing on the definition of diabetes and its epidemiology globally and in South Africa. The risk factors or aetiology of DM were discussed, as were the complications and monitoring of diabetic patients with the aim of delaying onset or preventing complications.

CHAPTER 3
METHODOLOGY

3.1 Introduction

In this chapter, the researcher describes the method used to conduct the study. The chapter will comprise the following sections: study design; study setting; study population; inclusion and exclusion criteria; sampling procedure and sample size; data collection and analysis; validity; reliability; bias; and ethical considerations.

3.2 Study design

A cross-sectional study involves looking at data from a population at a specific point in time. The participants in this type of study are selected based on variables of interest to the researcher. Cross-sectional studies are the best way to determine the prevalence of a phenomenon and are useful for identifying associations that can then be more rigorously studied using a cohort study or randomised controlled study method (Mann, 2003).

Using descriptive research, a researcher aims to accurately and systematically describe a population, situation or phenomenon, answering *what*, *where, when* and *how* questions, but not *why* questions. A descriptive research design can be used in a wide variety of research methods to investigate one or more variables. (McCombes & Van den Eertwegh, 2019).

In this study, a descriptive, cross-sectional, quantitative research approach was used to determine the characteristics of poorly controlled DM in the GOPD of the Mankweng hospital.

3.3 Study setting

The study was conducted in the GOPD of the Mankweng hospital, in Limpopo. Mankweng is a town in the Capricorn District Municipality, situated in the Limpopo Province of South Africa. The hospital is a government-funded tertiary or training hospital. It is located about 27 km east of Polokwane, the capital city of the province. Mankweng hospital was

established at the request of a Makgosi in the Thabamoopo region for the establishment of a hospital to cater for their people around the Mankweng area. The hospital is a 550-bed institution, offering the following services: specialist day clinics; 5 theatres; 24-hour emergency services; and. high care and ICU services. The Department of Family Medicine of the University of Limpopo at the runs several service points in the hospital. One of the core service delivery points is GOPD, which caters to an average of 2 200 patients a month.

3.4 Study period

Data collection took place between the 01 November and 30 November 2019. There were no public holidays during this period. Data was collected from Monday to Friday during each week of the study.

3.5 Study Population

The study population included all diabetic patients who were 18 years of age and older, and who attended the GOPD at the Mankweng hospital during the study period.

3.5.1 Inclusion criteria

The following criteria were set for inclusion in this study:

- All diabetic patients seen at the GOPD of the Mankweng hospital:
    - Who were 18 years of age or older,
    - Who were on an oral hypoglycaemic or on insulin or on both,
    - Who agreed to have HBA1c test done; and,
    - Who agreed to participate in the study.

The abovementioned patients are in the inclusion criteria because it will be easy to detect poorly controlled diabetes mellitus as they are already on treatment for diabetes.

3.5.2 Exclusion criteria

The following criteria were set for exclusion from this study:

- Patients who were not on treatment (oral hypoglycaemic or insulin),
- Patients with gestational DM; and,

- Patients who refused to participate.

These patients even if included would not provide relevant data, because they are not under treatment and because they also do not want to be part of the process.

3.6 Sampling and sample size

3.6.1 Sample size calculation

A sample size calculator is a statistical formula used to calculate the size of the sample to be used in a study. The calculator was chosen as a method for calculating the sample size because the formula works on an assumed precision of 5% and 95% confidence interval, which increases the probability that the sample size calculated will be a true indication of the population being studied. (Watson, 2001).

(Sample Size Calculator @calculator.net

Inputs:

Confidence Level: 95%

Confidence Interval: 5.00%

Population Proportion: 15.7%. The proportion of poorly controlled diabetes patient at Mankweng hospital was estimated to be the same as in study of Timothy (2011) done in Soweto.

Population Size: 180 (total number of patients with diabetes attending the Mankweng hospital)

Calculated sample size: **n= 96**

The following formula was used to calculate the sample size:

$$\text{Finite population: } n' = \frac{n}{1+\frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2 N}}$$

Where:

z is the z score

ε is the margin of error

N is population size

p̂ is the population proportion

3.6.2 Sampling procedure

Convenience sampling (also known as availability sampling) is a specific type of sampling method that relies on data collection from population members who are conveniently available to participate in study. In convenience sampling, all subjects are invited to participate (Saunders, Lewis & Thornhill, 2016).

In this study, convenience sampling was done because all patients who met the inclusion criteria, who attended GOPD on the day of data collection and who were willing to participate in the study were included. The estimated number of diabetic patients attending the Mankweng hospital GOPD monthly is 180 and the calculated sample size was 96. Based on the number of diabetic patients and sample size, it was convenient to include everyone in the study, because not all patients when given an appointment date honoured the appointment date and, therefore, the required number of participants may not have been reached when sampling was done.

3.7 Data collection

Data was collected by the researcher and one research assistant (interviewer), who was a registered professional nurse. The research assistant was trained by the principal researcher, to ensure that the questions were well understood and that minimal inter-observer variability occurred. The research assistant was fluent in local languages (Sepedi, Tsonga and Venda) and conducted interviews with patients in a language understood by the patients.

The design of the questionnaire was based on the standardised monitoring guidelines for DM patients in South Africa (Society for Endocrinology, Metabolism and Diabetes of South Africa [SEMDSA], 2012). SEMDSA is a society that contributes a great deal to the current body of knowledge regarding endocrine conditions, diabetes being one of them.

They have developed guidelines to assist clinicians who manage and monitor diabetic patients (see Appendix E).

The questionnaire used in this study is presented in Appendix A. The questionnaire comprises sections for collecting demographic information, evaluating the socioeconomic status of the participants, and determining adherence to treatment by the patient. For the study, the questionnaire was adapted from studies on the bio-psychosocial determinants of self-management in culturally diverse South African patients, by Professor K. F. H. Botha (Botha et al., 2002).

3.7.1 Clinical measurements

Clinical measurements, blood pressure, random blood glucose and urine dipsticks, weight all form part of the routine management for patients with diabetes and were conducted by nursing staff at the GOPD.

Doctors working at GOPD collected blood samples, and sometimes patients were sent to the phlebotomist, along with a request form completed by the doctor working in the outpatient department. Routine bloods done in diabetic patients included, but not limited to the following:

- HbA1C (to assess glycaemic control),
- Lipogram (assess co-morbid conditions); and,
- Urea and electrolytes (U+E: assess renal impairment, as one of the complications of diabetes).

The doctors working at GOPD may be from several the categories, from medical interns to medical officers (all grades 1 to 3), to registrars and consultants who are the overseers (family physician).

Blood test results were retrieved from the patient's file. If the results are not in the file, a lab sticker will be present, where the results can traced from the laboratory using the sticker number. No samples were collected for the purposes of the study.

3.7.2 Study variables

Table 3.1: A list of objectives and variables utilised in the study

OBJECTIVE VARIABLES
To determine the level of HbA1C <7 = well controlled diabetes mellitus glycaemic control of diabetes patient at Mankweng outpatient department. HbA1C ≥7 = Poorly controlled diabetes mellitus

Table 3.2: Categorisation of variables used to describe co-morbid factors

Variable	**Categories**
Blood pressure	Well controlled (≤ 140/90 mmHg) Uncontrolled (≥ 140/90 mmHg)
Lipid Profile	
Total cholesterol	Well controlled (≤ 4.5 mmol/L) Uncontrolled (> 4.5 mmol/L
HDL-cholesterol	Well controlled (female ≥ 1.2 mmol/L, male≥1.0mmol/L) Uncontrolled (female< 1.2 mmol/L, male <1.0mmol/L)
LDL-cholesterol	Well controlled (≤ 1.8 mmol/L) Uncontrolled (> 1.8 mmol/L)
Triglycerides	Well controlled (< 1.7 mmo/L) Uncontrolled (> 1.7 mmol/L)

3.8 Data analysis

Data obtained from the completed questionnaires was analysed using computer-based software. Continuous variables will be presented as means and standard deviations (SD), and categorical data as frequencies and percentages. Bivariate association measurements between the HbA1c and continuous variables were conducted using Pearson correlations, and between HbA1c and categorical variables using t-tests and one-way ANOVA (more than two groups). Multiple regression analysis was applied to examine the independent association between HbA1c and patient characteristics.

Frequency tables, means and standard deviations were used for summary purposes. Statistical significance was reported at a 95% confidence interval. The significance level (p-value < 0.05) was used as a guideline to determine significant relationships.

A chi-square test was used to test for statistical significance and a p-value of less than 0.05 was considered statistically significant. All analyses were calculated using the SPSS statistics software.

3.9 Reliability and validity of the study

3.9.1 Reliability

Joppe (2000:1) defines reliability as the extent to which results are consistent over time. An accurate representation of the total population under study is referred to as reliability and, if the results of a study can be reproduced under a similar methodology, then the research instrument is said to be reliable. In the study reliability was enhanced by using an adapted standardised questionnaire.

3.9.2 Validity

Validity is defined as the extent to which a concept is accurately measured in a quantitative study (Twycross, 2015; Joppe, 2000:1) provides the following explanation of what validity is in quantitative research. Validity determines whether the research truly measures that which it was intended to measure or how truthful the research results are. In other words, does the research instrument allow you to hit 'the bull's eye' of your

research object. Researchers generally determine validity by asking a series of questions and will often look for the answers in the research of others.

For the study, the questionnaire in Appendix A was adapted from studies on bio-psychosocial determinants of self-management in culturally diverse South African patients, by Professor K. F. H. Botha (Botha et al., 2002), SEMDSA and other South African researchers. The use of HbA1c is accepted universally for monitoring glycaemic control and as a predictor of complications associated with poorly controlled DM.

The definitions of reliability and validity in quantitative research reveal two strands. Firstly, with regards to reliability, whether the result is replicable. Secondly, with regards to validity, whether the means of measurement are accurate and whether they are measuring what they are intended to measure (Golafshani, 2003:598-599).

3.9.3 Bias

A term drawn from quantitative research, bias technically means a systematic error, where a particular research finding deviates from a 'true' finding. A discussion of areas of bias and the various ways to minimise them in this study follows.

Information bias refers to bias arising from a measurement error. Information bias is also referred to as observational bias and misclassification. The occurrence of information biases may not be independent of the occurrence of selection biases. Data was collected from files and the researcher did not employ interventions to the variables being studied. There is a likelihood for error due to incomplete data capturing in the files of the participants or misinformation.

To minimise information bias in this study, an adaptation of a standardised questionnaire was used to collect data, while SEMDSA guidelines were also used to collect the clinical data. The formal questionnaire used in the study was not translated into local languages, but data was collected by a trained research assistant who is fluent in the local languages. This could have introduced bias.

Selection bias is a distortion in a measurement of association (such as a risk ratio) due to a sample selection that does not accurately reflect the target population.

In this study, all patients who were available on the day of data collection and who were willing to participate in the study were included. This type of data collection is known as convenience sampling. The disadvantages of convenience sampling methods are that the method is highly vulnerable to selection bias and influences beyond the control of the researcher and a high level of sampling error.

Recall bias occurs when people remember past events and do not usually have a complete or accurate picture of what happened. Recall bias is also known as responder bias. Responder bias can be unintentional due to poor or incomplete memory recall, or it can be intentional; perhaps because the person is too embarrassed to admit the truth about past events (Andale, 2016).

In this study, recall bias was minimised by using a research assistant fluent in local languages to try and explain any misunderstandings to the participants and who had a good understanding of research methodology.

An adapted questionnaire developed and used in the South African context and SEMDSA guidelines were also used, together with information gleaned from other South African studies from literature to collect data.

3.10 Ethical considerations

Institutional approval to conduct this study was sought and obtained from the Turfloop Research and Ethics Committee (TREC) and from the School of Medicine, University of Limpopo. The TREC approval number is TREC/209/2019:PG (Appendix G). Permission from the management of Mankweng Hospital was sought prior to data collection (Appendix H).

Anonymity was maintained by not using patient names and by assigning a code to their hospital numbers during data capture and analysis.

Confidentiality was maintained by making sure that no one would have access to participant questionnaires. The information gathers has not been shared with anyone

else, other than the researcher. Respondents were assured that the information given would not be divulged to any third party, except for the purposes of this study.

Written consent was obtained from the respondents before proceeding with data collection. Participation in the study was completely voluntary. Participants had the right to withdraw at any point. Participants were allowed to choose whether they wanted to be part of the research or not. The researcher clearly explained to the participants what was required of them in the research and why it was required. Thereafter, they proceeded with the task. The participants were assured that they could withdrew from the study any time from the research should they so wish or if they were not willing to continue with the questionnaire.

CHAPTER 4
RESULTS

4.1 Introduction

In this chapter, the researcher will present the study findings as follows: First, a description of the study population and factors influencing glycaemic control at Mankweng Hospital will be presented. This will be followed by a frequency table analysis of these factors.

4.2 Demographic characteristics of participants

A total number of 97 patients fulfilled the study criteria and were included in the study. Females comprised most of the study population, accounting for 63% (n=61), while males made up 37% (n=36) of the study population.

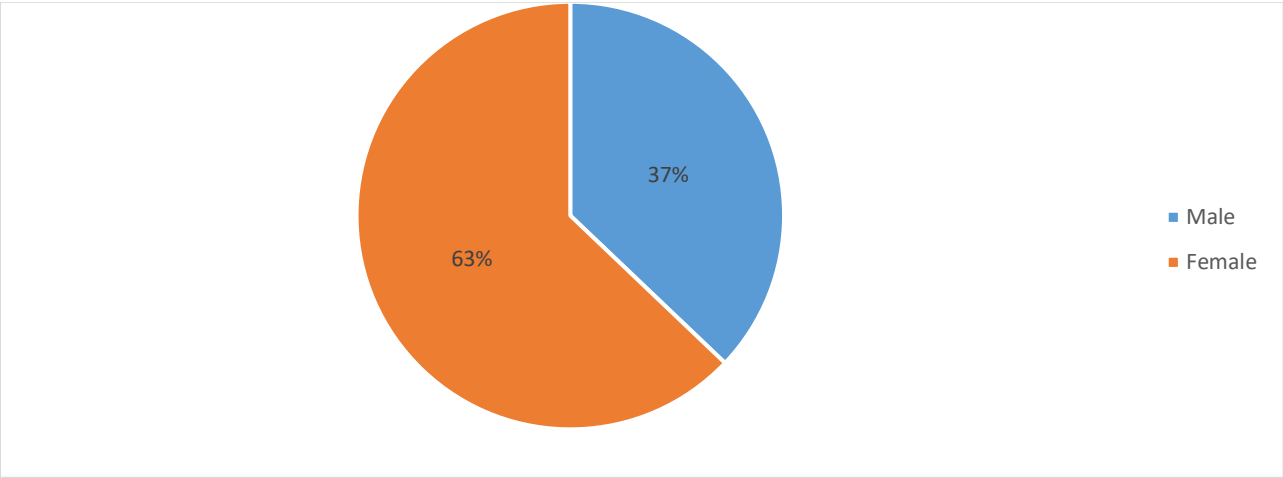


Figure 4.1: Sex distribution

In this study, most of patients were in the age group 50–59 years, comprising 40% of the total study population. The age group 30–39 years followed at 23%. The age group with the fewest participants were those falling between 29–29 years, comprising 4% of the study population.

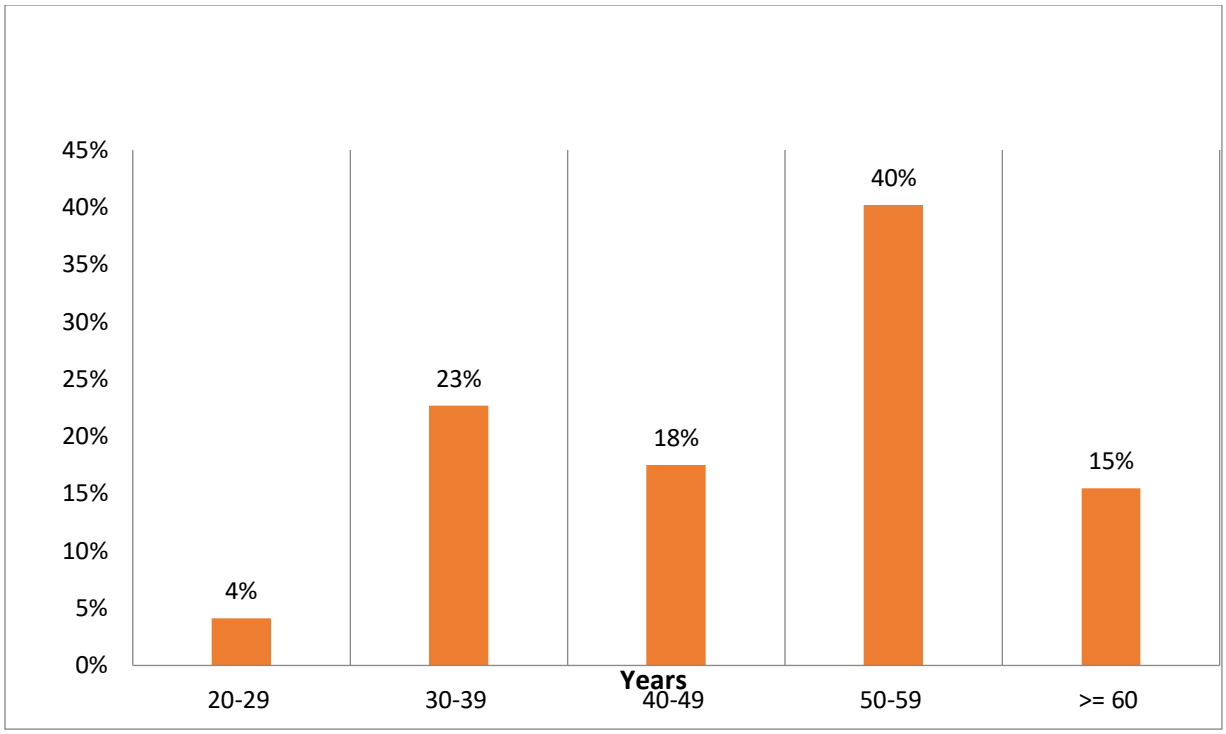


Figure 4.2: Age distribution

Most of the participant in this study had completed secondary schooling (35%). A total of 34% of participants had completed post-secondary schooling, while only 26% had a primary school level of education and 5% of the study participants had no formal schooling.

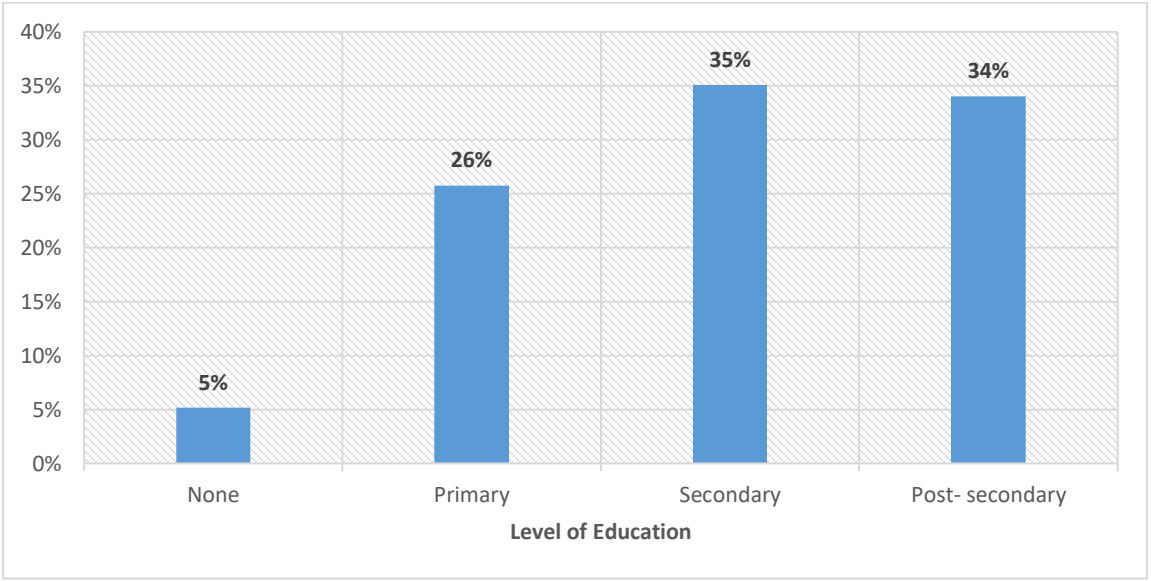


Figure 4.3: Levels of education

Most of the participants belonged to a household of between 7–9 members, making up 52% of the population, followed by those belonging to household of 4–6 family members, making up 39% of the study participants, While only 4% of the participants belonged to household of 1–3 members, which was the smallest group in the study.

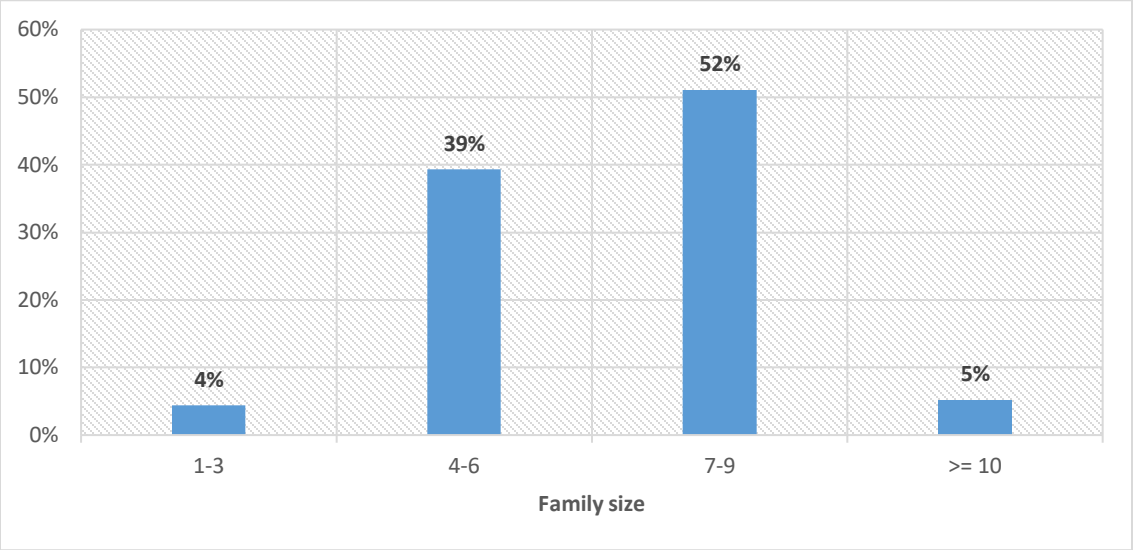


Figure 4.4: Size of family household

Most of the patients in the study population were married, accounting for 62%(n=64) of the participants, followed by single participants, at 31%(n=32). Those participants who were divorced from their partners accounted for 4%(n=3) of the study population. The lowest number participants were separated from their spouses and comprised 3% (n=1) of the study population.

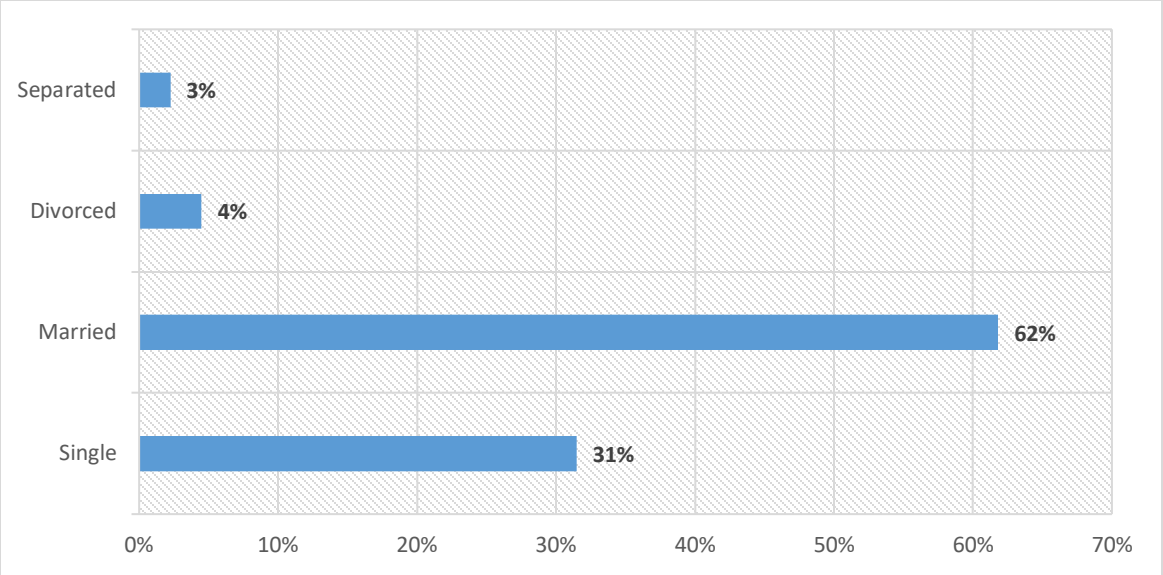


Figure 4.5: Marital status

Participants in this study population had different sources of income. The majority of the study participants, which compromised 54%(n=53) of the population, did not depend on a government social grant or family support. Only 22% (n=21) of the participants were dependent on a government grant for survival, e.g., a child support grant. Finally, 24% (n=23) of the participants were dependent on family support for income.

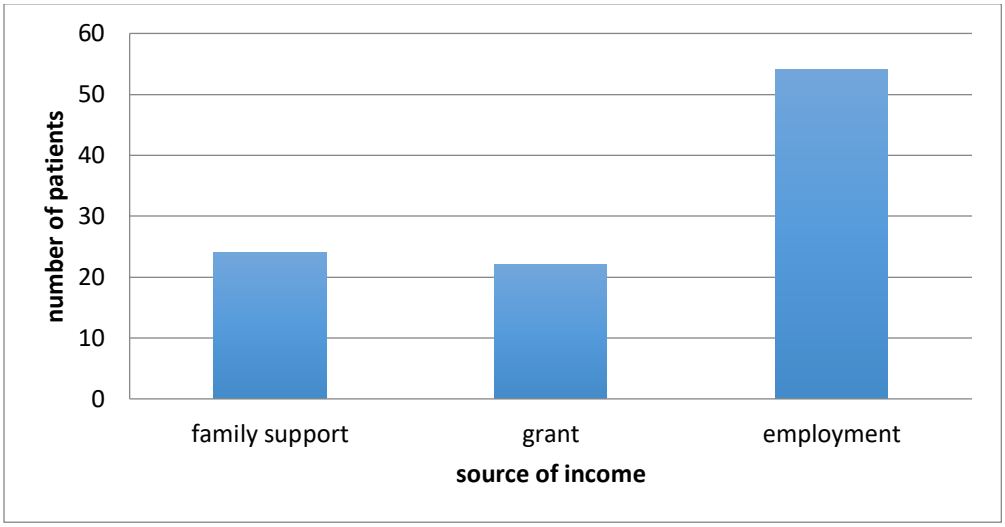


Figure 4.6: Source of income

Most participants were unemployed, including those receive an old age grant, comprising 51% (n=53) of the study population, followed by those employed in the informal sectors,

at 24%(n=22). Those employed in the formal sector comprised 14% (n=12) of the study population, while the lowest number of participants, at 11% (n=10), were self-employed.

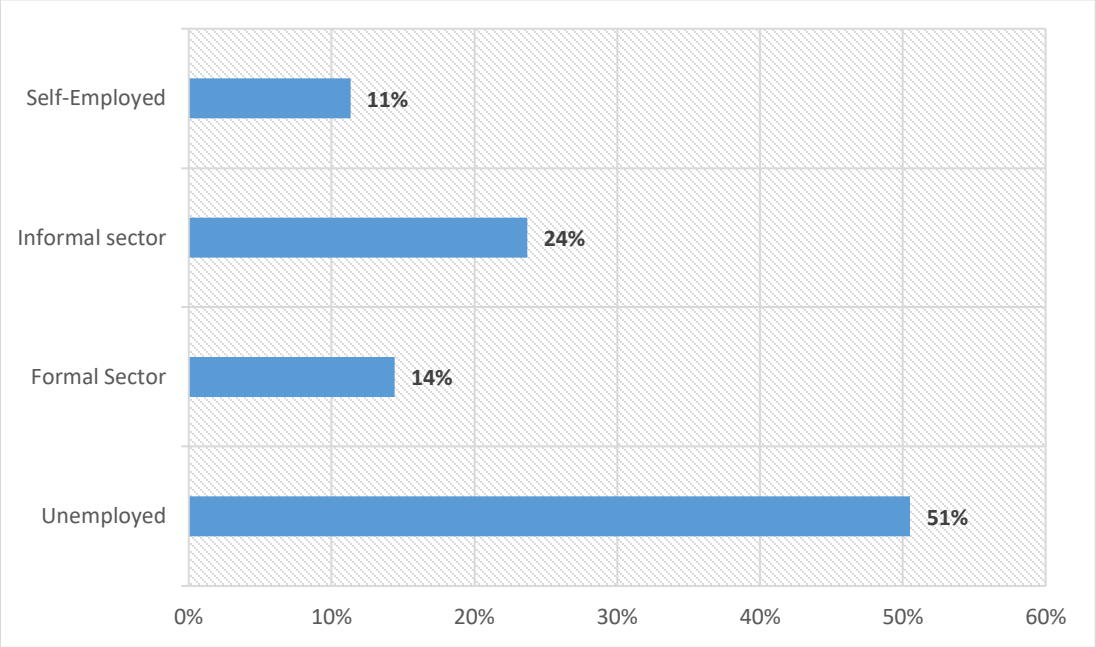


Figure 4.7: Employment

The figure below indicates monthly income per household. It was observed that most of the study participants were in the income bracket R2 000–R2 999 per month, while 23% of the participants received an income of R1 000–R1 999, equal in number to those receiving an income ≥ R5 000, also accounting for 23% of the study participants. The lowest number of participants were those in the income bracket R0–R999 per month, at 2% of the participants.

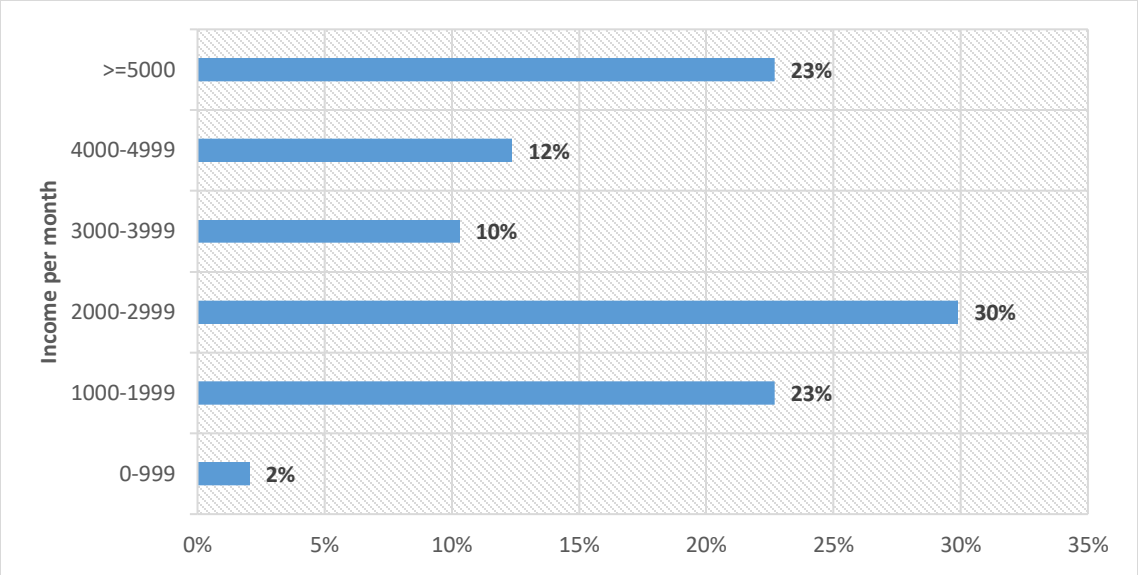


Figure 4.8: Range of income per household

Most of the patients lived between 16–20 km from the hospital, followed by those who lived between 6–10 km from the hospital. Those living 0–5 km from the hospital made up the smallest group of patients in the study population.

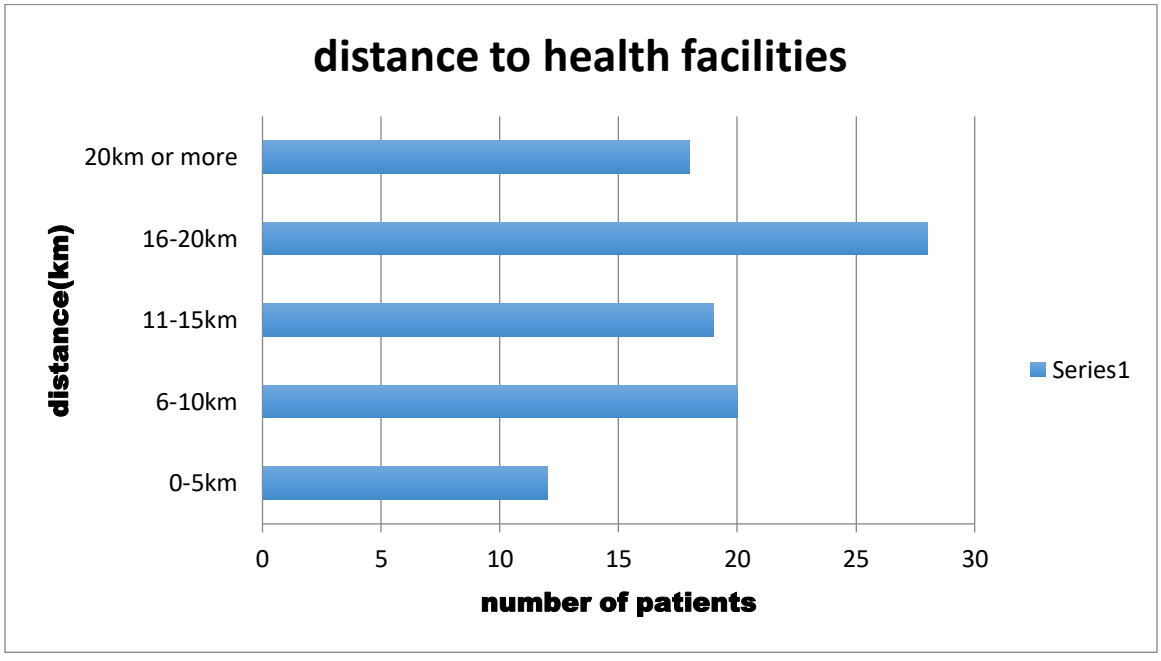


Figure 4.9: Distance to health facilities

4.3 Clinical characteristics of participants

Of the 97 participants in this study, only 63 (79%) had had HbA1c blood test done. In this study, an HbA1c of ≤ 7 was defined as well controlled and a HbA1c of > 7% was defined as poorly controlled. In those participants where the HbA1c was done, only 21% (n=13) had a well-controlled HbA1c.

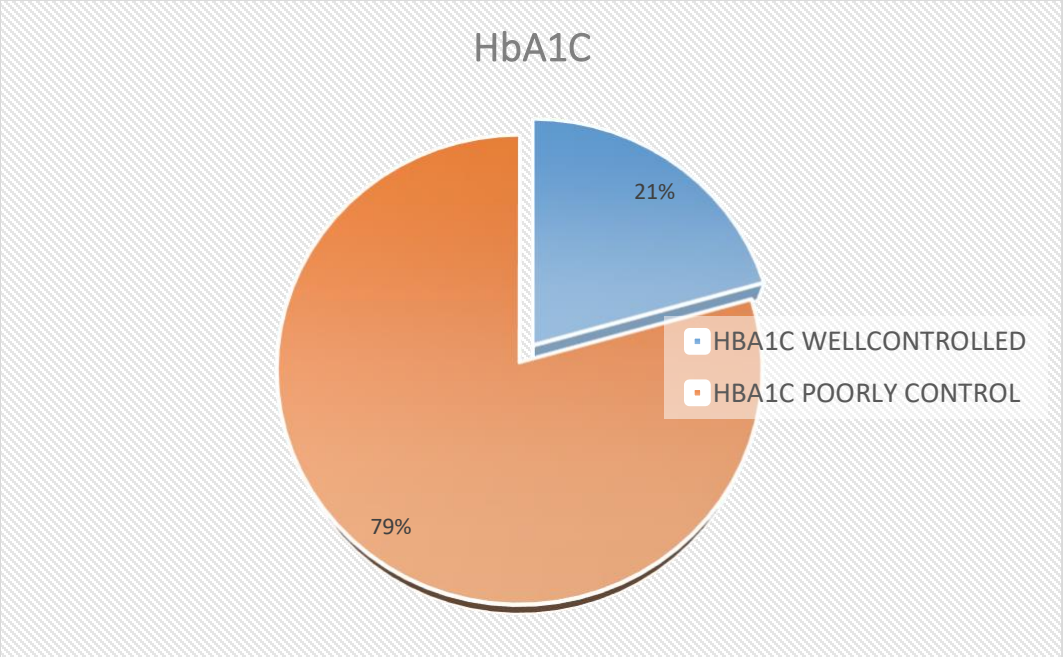


Figure 4.10: Patients with well controlled and poorly controlled HbA1c

Out of the 63 patients who had HbA1c done, 50 patients (79%) had an HbA1c of > 7% (poorly controlled) and 13 patients (21%) had an HbA1c of ≤ 7% (well controlled).

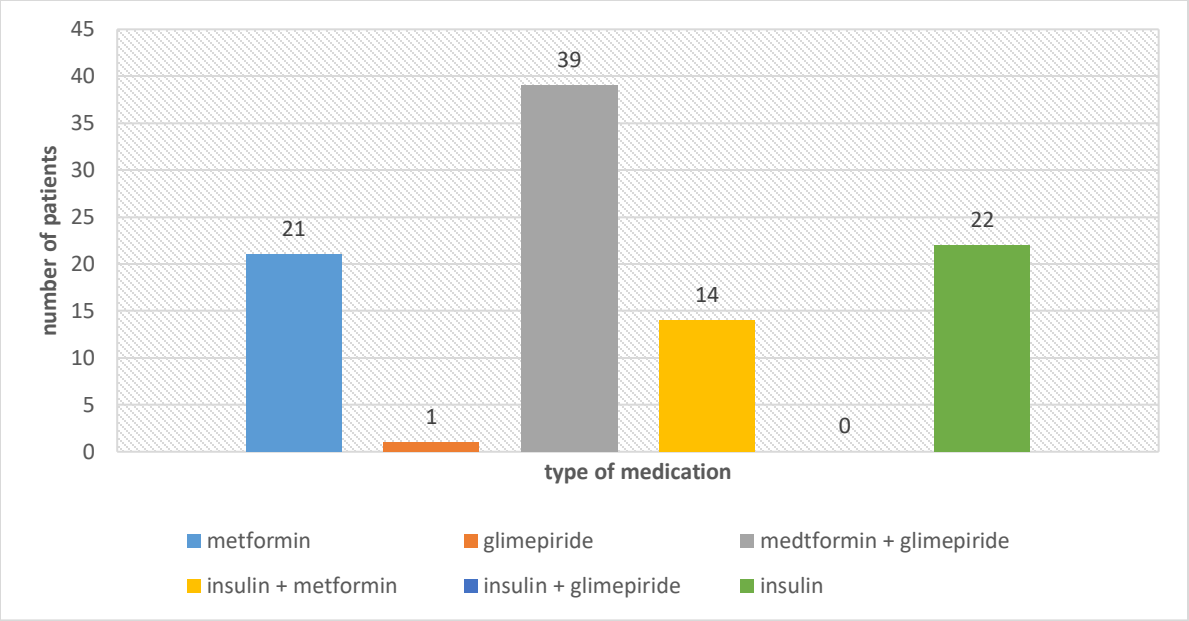


Figure 4.11: Medication used by patients

Figure 4.11 shows the number of patients and the medication they are taking for their diabetes. Metformin was prescribed to only 21 patients, 1 patient used glimepiride only, 39 patients used metformin and glimepiride, 14 patients used insulin and metformin, and, finally, 22 patients used insulin only. None of the patients were on glimepiride and insulin.

Table 4.1: Clinical characteristics of participants at the hospital

	MALE	**FEMALE**	**COMPLETE SAMPLE**
Known to have Blood Pressure Measurement			**hypertension n (%)**
	17(36%)	30(64%)	47(48.5%)
BP < 140/90 (controlled)	6(13%	13(28%)	19(40.4%)
Bp >140/90 (uncontrolled)	11(23%)	17(36%)	27(57.4%)
Total Cholesterol (mmol/L)			
Controlled (< 4.5)	12(28%)	16(37%)	28(65.1%)
Uncontrolled (> 4.5)	6(14%)	9(21%)	15(34.9%)

HDL-cholesterol (mmol/L)			
Controlled (female > 1.2, male >1.0)	6(14%)	12(27%)	18(41%)
Uncontrolled (female < 1.2, male<1.0)	11(25%)	15(34%)	26(59%)
LDL cholesterol (mmol/L)			
Controlled (< 1.8)	5(11%)	9(20%)	14(32%)
Uncontrolled (> 1.8)	12(27%)	18(41%)	30(68.2%)
Trig (mmol/L)			
Controlled (< 1.7)	9(20%)	15(34%)	24(55%)
Uncontrolled (>1.7)	7(16%)	13(30%)	20(45.4%)

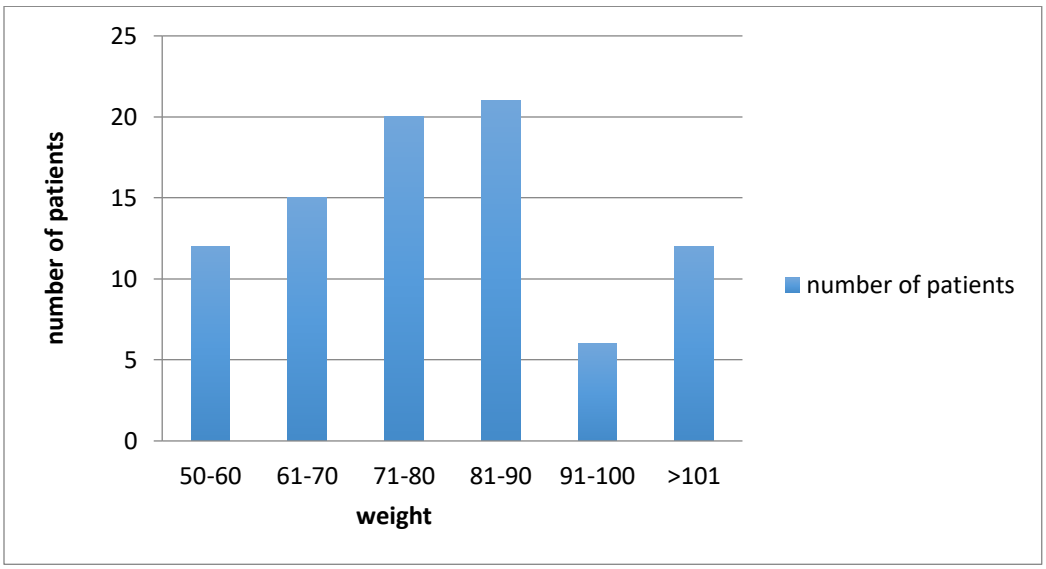


Figure 4.12: Weight ranges

This table shows that most patients had weight between 81–90 kg. None of the patients had height or waist circumference measurements done routinely.

Table 4.2: Comparison between the demographic data of controlled and uncontrolled DM patients

	Controlled n(%)= 13 (21%)		**Uncontrolled** n(%) = 50(79%)		p-value
	Frequency	Percentage	Frequency	Percentage	
Gender					
Male	8	27.5%	21	72.5%	0.020
Female	5	14.7%	29	85.3%	
Age					
20-29 years		0%	3	100%	
30-39 years	3	23%	10	77%	0.970
40-49 years	2	18%	9	82%	
50-59 years	5	20%	20	80%	
>=60 years	3	27%	8	73%	
Number of medications					
1	3	21%	11	79%	
3	7	30%	16	70%	0.642
4	1	10%	9	90%	
6	2	12.5%	14	87.5%	
Distance from health facility					
1	4	40%	6	60%	
2	1	8%	12	92%	0.522
3	2	17%	10	83%	
4	3	19%	13	81%	
5	3	25%	9	75%	
EGFR					0.442

<60	7	22.5%	24	77.5%	
>60	3	19%	13	81%	
Keep all appointments					
1	11	25%	33	75%	0.402
2	2	10.5%	17	89.5%	
3	0	0%	0	0%	
Adherence to lifestyle changes					
1	5	16%	16	84%	
2	26	44%	33	56%	0.234
3	2	66%	1	33%	
4	1	100%	0	0%	

In terms of uncontrolled patients, more patients surveyed with uncontrolled diabetes were female (58% female vs 42% male). Most of the patients in the study were in the age group 50–59 years.

The p-value for testing the significant differences between the number of controlled against the number of uncontrolled diabetic patients was more than 0.05 for all the variables. This suggests that there is no significant difference between age, medication used, distance from health facility, eGFR, keeping appointment dates and adherence to recommended lifestyle changes for controlled when analysed against the uncontrolled group of diabetic patients. However, there was a significant difference between the proportion of controlled against uncontrolled diabetic patients with a higher prevalence of uncontrolled females (58%) compared to controlled females (38%) with a P-value of 0.02.

The statistician used chi-square tests to calculate the confidence intervals.

4.4 Conclusion

The study findings were presented by the researcher in this chapter, along with the statistical analysis applied, the factors that were investigated and whether or not they were associated with poor glycaemic control. Only one was found to be of statistical significance, namely being male.

CHAPTER 5
DISCUSSION

5.1 Introduction

In this chapter, the researcher will discuss the results from the study, with reference to other published studies.

The aim of this study was to determine the characteristics of poorly controlled DM in patients at Mankweng hospital in Limpopo.

This study focused on HbA1c as a marker for indicating how well controlled DM was. Patients who had an HbA1C of ≤ 7% were considered to be well controlled, while those patients who had an HbA1C of > 7% were classified as poorly controlled.

In order to identify characteristics of poorly controlled DM, demographic features, clinical characteristics, access/distance to health facility and standard of care, e.g., treatment prescribed, investigations done and referral to other disciplines were all investigated. The researcher did not attempt to explore the psychological factors that can affect glycaemic control.

5.2 Glycaemic control

In the study population of 97 participants, only 63 had had an HbA1c done and of these 63 participants, only 13 participants had a well-controlled HbA1c (or exhibited good glycaemic control). Twenty-one per cent of the study population exhibited good glycaemic control. As the sample comprised only 63 participants, and not 96 as per sample size calculation, and the proportion of well controlled participants was 21%, and not 15.7% as anticipated, the margin of error is 8.13%. and not 5%,, as is the target or golden standard.

Good glycaemic control was only described in 21% of the study population who had an HbA1c done, which comprised 63 patients out of 97 participants. This proportion was slightly higher than the proportion in other studies that have investigated glycaemic control in South Africa. In a study carried out in Johannesburg, in three clinics in Chiawelo, Lenasia and Zola, good glycaemic control was described in only 15.7% of the population.

Of note is that the study had larger sample size compared to this study and the proportion of patients who had HbA1c done was higher. (Timothy, 2011).

In Kuwait, 66.7% of the studied population had an HbA1c ≥ 8%. (Al-Sultan & Al-Zanki,) In a study conducted in the United Kingdon, 69% of the study population had HbA1c > 7.5% (Prevalence of inadequate glycaemic control among patients with type 2 diabetes in the United Kingdom general practice research database: A series of retrospective analyses of data from 1998 through 2002, 2006).

5.3 Patient related factors influencing glycaemic control

The following factors influencing glycaemic control will be discussed: gender; weight/obesity; level of education; employment status; type of treatment; age, co-morbid conditions; and, compliance

5.3.1 Gender

A total number of 97 patients fulfilled the study inclusion criteria and were included in the study. Females comprised majority of the study population, accounting for 63% of the population, while males accounted for 37% of the population.

The high proportion of women in the study population is comparable to the number of women who participated in previous studies on glycaemic control in South Africa, indicating that the gender of patients attending primary care facilities for chronic disease care in South Africa is predominantly female (Van de Sande, Dippenaar & Rutten, 2007). Good glycaemic control was only described in 21% of the study population. Male participants were better controlled than female participants and this study finding was statistically significant.

5.3.2 Weight/obesity

In this study, body mass index could not be calculated because height, as shown in the frequency tables, was not measured in all patients. Nevertheless, a weight distribution graph was done, and it showed that most of the patients fell in a weight range of 80–90 kg. Since in the literature there is an assumption that normal weight for an adult is about

70 kg, it can be deduced from the weight distribution graph that majority of the patients wer either overweight or obese.

In a study conducted by Gilliland, Skipper, Carter, and Acton, obesity was considered a major risk factor for the development of type 2 diabetes. The basic metabolic abnormality of both diabetes and obesity is a resistance of the peripheral tissues to the action of insulin. Increasing levels of obesity and insulin resistance have been associated with poorer glycaemic control.. (Simmons et al., 2007)

It could be argued that the fact that women in South Africa are more obese than men may contribute to their poorer glycaemic control.

5.3.3 Level of education

Most of the participants in this study had completed secondary schooling (35%). A total of 34% of participants had completed post-secondary schooling, while only 26% had a primary school level of education and 5% had no formal schooling at all.

Nthangeni, Steyn, Alberts, Steyn, Levitt, Laubscher, et al. (2002:329-338) conducted a study that researched dietary compliance in South African type 2 diabetics and found that patients with low health literacy were unable to follow nutrition advice, especially when this advice was presented in ways that did not relate to the patient's cultural environment and was presented in ways that were not easy to comprehend.

5.3.4 Employment

Since most of the patients in the study were unemployed, it can be assumed that finances could play a role in making choices regarding the buying of foods that are healthy. In a similar study conducted in Johannesburg, factors associated with good glycaemic control was unemployment. (Timothy, 2011)

According to Larranaga, Arteagoitia, Rodriguez, et al., lower socioeconomic status was found to be related to poorly controlled diabetes but also to higher rates of obesity and hyperlipidaemia.

5.3.5 Type of treatment

Participants in this study on oral medication alone were found to have a statistically significant better glycaemic control than patients on combination therapy or on insulin alone. The association between treatment with a combination of oral and injectable medication and poor glycaemic control is consistent with the findings in other studies. (Goudswaard et al., 2003)

According to the literature, when patients have not achieved their HbA1c targets, HbA1c must be repeated every 3 months, and every 6 months for those who are well controlled. (Amod, 2017) It is recommended that monitoring be done as guided by the South African guidelines. Since most patients are on oral treatment only, it seems as if there is treatment inertia by clinicians to initiate insulin to achieve glycaemic control. (Puoane et al., 2002)

5.3.6 Age

It was observed in this study that a greater number of patients in the age group 50–59 years had an HbA1c ≤ 7%; however, when subjected to statistical analysis, this finding's p-value was not statistically significant.

Previous studies have reported that younger aged diabetics are more likely to be poorly controlled (Chuang et al., 2006). Early-onset type 2 diabetes is generally more associated with a poorer glycaemic control outcome, and the possibilities for this outcome include behavioural reasons, suggesting that glycaemic control may be much more difficult to achieve for some younger patients with a shorter duration of disease (Nichols et al., 2000).

5.3.7 Co-morbid conditions

In this study, 47 patients out of the 97 study participants were known to be hypertensive and on treatment. In the patients diagnosed with hypertension, there were more females (37 patients) than males (17 patients), and of note is that more patients were uncontrolled.

Previous studies in South Africa have shown that poorly controlled diabetics are often also found to be hypertensive and obese, with up to 76% of black diabetic women having coexisting hypertension and being obese in one study. (Nthangeni et al., 2002).

Levitt et.al. (1997) found a high prevalence of suboptimal glycaemic and blood pressure control with hypertension (blood pressure ≥ 160/95 mmHg and/or prescribed antihypertensive medication) present in 52% of diabetic patients.

Only a small proportion of patients with diabetes are on goal for recommended levels of HbA1c, blood pressure (BP) and lipids. Control of these factors, particularly blood pressure and LDL-C, is well-documented to reduce the risk of CVD events in persons with diabetes, and control of blood sugar results in substantial reductions in micro-vascular complications (Frei et al., 2012)

.

5.3.8 Compliance

Most of the patients in this study reported keeping all appointment dates and adhering to treatment and lifestyle changes, yet they were still poorly controlled. It is possible that patients were not truthful when answering the adherence questions or the way in which the questions were phrased did not capture their reality.

Compliance to medication is a key component of the self-management of diabetic patients and increased compliance is associated with substantial improvements in glycaemic control (Adams, Trinacty & Zhang, 2008).

5.4 Limitations of the study

The study findings must be interpreted considering the limitations of the study. The factors identified in the literature review were investigated in this study as independent variables only. Limitations of this study include the cross-sectional nature of data, which prevents the researcher from drawing causal inferences.

1) The study population comprised of 97 participants, but only 63 had had an HbA1C done (measurable outcome) and, of these 63 participants, only 13 participants had well-controlled HbA1c (or good glycaemic control). The percentage of those with good glycaemic control was 21%. As the sample comprised only 63 participants, and not 96 as per sample size calculation, and the proportion of well controlled participants was 21%,

and not 15.7%, as anticipated, the margin of error is 8.13%, and not 5% as is the target or golden standard.

The calculated margin error was 8.13%. The margin of error is the level of precision that the researcher achieved. This is the approximately number that is often reported with an estimated proportion and is also called the confidence interval. It represents the range in which the true population proportion is estimated to be and is often expressed in percentage points (e.g., = +/- 2%). A margin of error tells a researcher how many percentage points their results will differ from the real population value. It is the difference between true population and the estimated population from the study results (Kotinkaduwa & Choudhary, 2020).

2) BMI was not done because no height measurements were taken from all the patients.

3) Only 63 patients out of the 97 participants had had an HbA1C done. Based on the sample size calculated, a sample of n=96 was required. In this study, the sample size was reduced and not all the patients had HbA1c.

4) The sample size of 63 patients as guided by the HbA1c was not enough for generalisation of the study findings.

5) The sampling method used was convenient in nature because all patients who attended the GOPD on the day of data collection were included in the study.

It is possible that those who were not included in the study were female who were well controlled, because patients that are well controlled are usually given a 6 months review, while patients who are poorly controlled are reviewed more frequently, depending on the doctor’s assessment.

6) Questionnaire was not translated to local languages.

7) Self-reported variables, e.g., compliance to treatment, may have resulted in information bias. The usefulness of these measures is also limited due to the closed nature of the questions asked.

8) The questionnaire was not tested for reliability and/or validity.

CHAPTER 6
CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Most patients in this study exhibited poor glycaemic control. Numerous studies have indicated that the determinants of glycaemic control in the care of diabetic patients are multiple, including the patient, accessible and affordable health facilities and healthcare provider (McEwan, Bergenheim and Currie, 2006).

The only patient characteristics found to be statistically significantly associated with good glycaemic control were male diabetic patients, who were more likely to have good glycaemic control than female patients.

Although in the study assessing quality of health care was not part of the objectives, it is of note to highlight that the organisation of diabetes care adapted from SEMDSA (Appendix E), guides the management of diabetic patients, including how to undertake treatment, screening for complications and referrals to other disciplines. It was noted that the screening of complications and referrals to other disciplines was not done for all patients, as indicated in the frequency table. There appears to be poor adherence to diabetes guidelines by healthcare professionals, as evidenced by many patients (34/97 or 35%) having never had an HbA_{1c} test done.

It was also not part of the study to assess the diabetes management skills of healthcare professionals, yet it is also important to note that, although patients we poorly controlled, most were only on oral treatment alone.

The family practitioner plays a crucial role in the management of type 2 diabetes patients, not only in the prevention and early diagnosis of diabetes, but also in the long-term follow-up and repeated adjustments necessary. The family practitioner is in an ideal position to maintain close patient contact since they are the entry point for most patients into the healthcare system and have the most frequent patient contact. This makes the family physician the ideal person to undertake patient education and the monitoring of progress

of glycaemic control, as well as the management of the other cardiovascular risk factors that contribute to a significantly higher risk in diabetic patients (Van Zyl, 2006).

Addressing these findings with a comprehensive plan of action is needed to help reduce the prevalence of poorly controlled DM and its complications among diabetic patients attending the GOPD of the Mankweng hospital.

6.2 Recommendations

There is a definite need to improve glycaemic control in the GOPD of the Mankweng hospital.

The findings of this study should be used to contribute to the strategic plans of the Mankweng hospital towards addressing the growing diabetes epidemic in the province. This can be achieved by ensuring that the current clinical management guidelines are adapted such that people who are diabetic are managed comprehensively, based on current evidence-based guidelines.

The care of diabetes involves the institution of a comprehensive a multidisciplinary approach, meaning that patients must be timeously referred to other disciplines, e.g., the ophthalmologist, dietician or podiatrist, to prevent or delay diabetic-related complications.

Currently, the hospital level (adult) standard treatment guidelines and essential medicines have two classes of oral hypoglycaemics, namely biguanides and sulphonyl ureas, and then insulin; however, the SEMDSA guidelines also include the other classes as part of managing DM, especially in special circumstances. It is possible that the study findings could help by adding to the available options of oral hypoglycaemic in order to achieve glycaemic control in patients who are poorly controlled.

Further studies should focus on healthcare professionals, assessing their confidence and knowledge in managing DM and on the healthcare establishment for availability of resources, including drugs, as outlined in the SEMDSA guidelines.

Healthcare workers play an important role in the patient achieving good glycaemic control. Continuous professional development to help all categories, including nurses, doctors

and allied health members, to deal better with DM in the form of education and training will enable them to provide quality health care, ensuring good glycaemic control, and the early detection and prevention of diabetic complications.

REFERENCES

1. Adams AS, Trinacty CM, Zhang F. (2008)., etc al. Medication adherence and racial differences in A1C control. Diabetes Care; 31:916-21.

2. Adeniyi OV,Yogeswaran P,Longo-Mbenza B, Goon DT and Ajayi AI. (2016). Cross- sectional study of patients with type 2 diabetes in OR-Tambo-district, South Africa. BMJ Open (2016).,6: e010875.doi:10.1136/bmjopen-(2015).,-010875.

3. Ajlouni K., Khader, YS Batieha, A., et al. (2008). An increase in prevalence of diabetes mellitus in Jordan during ten years Journal of Diabetes and its Complications, 22 (5)., pp. 317–324.

4. Al-Khawaldeha, O.A., Al-Hassanb, M.A., & Froelicher, E.S., (2012). Self-efficacy, selfmanagement, and glycemic control in adults with type 2 diabetes mellitus. Journal of Diabetes and Its Complications 26, pp10–16.

5. Al-Sultan, F. A., & Al-Zanki, N. Clinical epidemiology of Type 2diabetes mellitus in Kuwait. Kuwait Medical Journal 2005; 37(2):98−104.

6. Amod, A. (2011). 46th Congress of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) and 10th Congress of the Lipid and Atherosclerosis Society of Southern Africa (LASSA) 9–11 April 2011, Bloemfontein. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*, 16(1), pp.29–41.

7. Amod, A. (2012). SEMDSA Guideline for the Management of Type 2 Diabetes (Revised). JEMDSA 2012 Volume 17 Number 2 (Supplement 1) S1-S95

8. Amod (2013). JEMDSA 2013 Volume 18 Number 2. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*, 18(2), pp.128–129.

9. Andale (2016). Recall bias definition, examples, strategies to avoid it. www.statisticshowto.com>recall-bias. Accessed 29/06/2017.

10. Baumann, LC; Chang M & Hoebeke, R. (2002). Clinical outcomes for low-income adults with hypertension and diabetes. Nursing research.51(3).

11. Blaum, C.S., Velez, L., Hiss, R.G. and Halter, J.B. (1997). Characteristics Related to Poor Glycemic Control in NIDDM Patients in Community Practice. *Diabetes Care*, 20(1), pp.7–111. (2009).

12. Borgharkar, S.S. and Das, S.S. (2019). Real-world evidence of glycemic control among patients with type 2 diabetes mellitus in India: the TIGHT study. *BMJ Open Diabetes Research & Care*, [online] 7(1), p.e000654. Available at: https://drc.bmj.com/content/7/1/e000654.

13. Bradley H, Puoane, T. (2006). Ability to manage diabetes – Community health worker's knowledge, attitudes and beliefs. J Endocrinol Metabol Diabetes S Afr.; 11(1):10–14. http://dx.doi.org/10.1080/22201009.2006.10872134

14. BradshawD,NormanR,PieterseD,LevittNSandtheSouthAfrican Comparative Risk Assessment Collaborating Group. Estimating the burden of disease attributable to diabetes in South Africa in 2000. S Afr Med J 2007 Aug; 97(8 Pt 2):700-706.

15. Bulbulia, S., Variava, F. and Bayat, Z. (2019). Are type 2 diabetic patients meeting targets? A Helen Joseph Hospital Diabetic Clinic Audit. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*, 25(1), pp.12–17.

16. Campbell, L., Pepper, T. and Shipman, K. (2018). HbA1c: a review of non-glycaemic variables. *Journal of Clinical Pathology*, 72(1), pp.12–19.

17. Characteristics in the Chronic Care Model for Type 2 Diabetes. United States ContempClinTrials. (4):366–374. Doi: 10.1016/j.cct.03.002 (November–December 2008).

18. Characteristics of Diabetics with Poor Glycemic Control Who22 Achieve Good Control. JABFM Vol. 21 No. 6 from http://www.jabfm.org

19. Chuang, L.-M., Soegondo, S., Soewondo, P., Young-Seol, K., Mohamed, M., Dalisay, E., Go, R., Lee, W., Tong-Yuan, T., Tandhanand, S., Nitiyanant, W., The-Trach, M., Cockram, C. and Jing-Ping, Y. (2006). Comparisons of the outcomes on control, type of management and complications status in early onset and late onset type 2 diabetes in Asia. *Diabetes Research and Clinical Practice*, 71(2), pp.146–155.

20. Curtis, B.L., (2014). Journal of Empirical Research on Human Research Ethics; 9(1):58-70. doi: 10.1525/jer.2014.9.1.58

21. Davies, B., & Logan, J., (2012). Reading Research: A User-Friendly Guide for Health Professionals, Elsevier, Canada. Diabetic studies 47 Vol. 9 · No. 1 ·

22. Eugene, S. (2012). Diabetes research and clinical practice 95, 30-36.

23. Florkowski, C.M., Scott, R.S., Coope, P.A., Graham, P.J. and Moir, C.L. (2000). Age at diagnosis, glycaemic control and the development of retinopathy; a population-based cohort study in type 1 diabetic subjects in Canterbury, New Zealand. *Diabetes Research and Clinical Practice*, 50, p.250.

24. Fong, D.S., Aiello, L., Gardner, T.W., King, G.L., Blankenship, G., Cavallerano, J.D., Ferris, F.L. and Klein, R. (2003). Diabetic Retinopathy. *Diabetes Care*, 26(1), pp.226–229.

25. Frei, A., Herzog, S., Woitzek, K., Held, U., Senn, O., Rosemann, T. and Chmiel, C. (2012). Characteristics of poorly controlled Type 2 diabetes patients in Swiss primary care. *Cardiovascular Diabetology*, [online] 11(1), p.70. Available at: https://cardiab.biomedcentral.com/articles/10.1186/1475-2840-11-70 [Accessed 13 Oct. 2019].

26. Gilliland S, Skipper B, Carter J, Acton K. (2002). HbA1c levels among American Indian/Alaska native adults. Diabetes Care; 25: 2178-2183.

27. Golafshani, N. (2003). Understanding Reliability and Validity in Qualitative Research. The Qualitative Report, 8(4), 597-606.

28. Goudswaard, A.N., Stolk, R.P., de Valk, H.W. and Rutten, G.E.H.M. (2003). Improving glycaemic control in patients with Type 2 diabetes mellitus without insulin therapy. *Diabetic Medicine*, 20(7), pp.540–544.

29. Greco, D., Gambina, F. & Maggio, F. Acta Diabetol (2009). 46: 23. doi:10.1007/s00592-008-0053- 8. http://dx.doi.org/10.4135/9781412961288.n183. http://dx.doi.org/10.1016/j.pcd.2014.06.0040021_22_research_methodology/CMRM610 3_Research_methodology_08.pdf (accessed 26 June 2017)

30. GroblerF.DiabetesontheincreaseinAfrica.Mail&GuardianOnline21 August 2002; <http://www.mg.co.za/Content/13.jsp> [Accessed Dec 2008].

31. Hornby, A.S., Cowie, A.P. and J Windsor Lewis (1977). *Oxford advance learner's dictionary of current English*. Oxford: Oxford University Press.

32. Huang, Y., Karuranga, S., Malanda, B. and Williams, D.R.R. (2018). Call for data contribution to the IDF Diabetes Atlas 9th Edition 2019. *Diabetes Research and Clinical Practice*, 140(ISBN: 978-2-930229-87-4), pp.351–352.

33. International Diabetes Federation (IDF) Diabetes Atlas 4th Edition, Brussels. (2010). Oxford Advanced Learner's Dictionary. 8th edition. Oxford New York.

34. InternationalDiabetesFederation.TheDiabetesAtlas.ThirdEdition. Brussels: International Diabetes Federation; 2006. <www.eatlas.idf.org> [Accessed 16 Sept 2008].

35. JEMDSA 2013 Volume 18 Number 2. (2013). Journal of Endocrinology, Metabolism and Diabetes of South Africa, 18(2), pp.128–129.

36. Joppe, M. (2000). The Research Process. From http://www.ryerson.ca/~mjoppe/rp.htm. Accessed 26/june/2017

37. Kotinkaduwa, L.N. and Choudhary, P.K. (2020). A segmented measurement error model for modeling and analysis of method comparison data. *Statistics in Medicine*, 39(25), pp.3491–3502.

38. Larranaga I, Arteagoitia JM, Rodriguez J.L. (2005). et al. Socio-economic inequalities in the prevalence of Type 2 diabetes, cardiovascular risk factors and chronic diabetic complications in the Basque Country, Spain. Diabet Med; 22: 1047-53.

39. Levitt, N.S. (2008). Diabetes in Africa: epidemiology, management and healthcare challenges. *Heart*, [online] 94(11), pp.1376–1382. Available at: https://heart.bmj.com/content/94/11/1376.long [Accessed 24 Aug. 2019].

40. Levitt, N.S., Bradshaw, D., Zwarenstein, M.F., Bawa, A.A. and Maphumolo, S. (1997). Audit of public sector primary diabetes care in Cape Town, South Africa: high prevalence of complications, uncontrolled hyperglycaemia, and hypertension. *Diabetic Medicine*, 14(12), pp.1073–1077.

41. Lois Oakes and Roper, N. (1981). *Medical dictionary*. Stuttgart ; New York: G. Fischer.

42. Mann, C.J. (2003). Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emergency Medicine Journal*, 20(1), pp.54–60.

43. Mash, B., & Ogunbanjo, G.A., African Primary Care Research: Quantitative analysis and presentation of results http://www.phcfm.org doi:10.4102/phcfm. v6i1.646

44. MashRJ,DeVriesE,AbdulI.DiabetesinAfrica,thenewpandemic:Report on the 19th World Diabetes Congress, Cape Town, December 2006. SA Fam Pract 2007:49(6) <http://www.safpj.co.za/index.php/safpj/article/viewFile/869/782> [Accessed 12 Sept 2009].

45. McCombes, S. and Van den Eertwegh, L. (2019). Editorial: Courses of Nature. *Junctions: Graduate Journal of the Humanities*, 4(1), p.1.

46. Metabolic control and therapeutic profile of patients with diabetes in Portuguese primary care

47. Mohammad, Q.D. (2012). Non-communicable disease (NCD) - high time to address. *Journal of Dhaka Medical College*, 20(2), p.95.

48. MotalaAA,PirieFJ,RauffS,BacusHB.Cost-effectivemanagementof diabetes mellitus. Ethn Dis 2006; 16(2 Suppl 2):S2-79-84.

49. Mutyambizi, C., Booysen, F., Stokes, A., Pavlova, M. and Groot, W. (2019). Lifestyle and socio-economic inequalities in diabetes prevalence in South Africa: A decomposition analysis. *PLOS ONE*, 14(1), p.e0211208.

50. NH Shilubane, Cur M. (September 2010)., Lecturer, Department of Advanced Nursing Science: University of Venda. Factors contributing to poor glycaemic control in diabetic patients at Mopani District. pp44-45.

51. Nichols, G.A., Hillier, T.A., Javor, K. and Brown, J.B. (2000). Predictors of glycemic control in insulin-using adults with type 2 diabetes. *Diabetes Care*, 23(3), pp.273–277.

52. NormanR,BradshawD,SchneiderM,PieterseD,GroenewaldP.Revised Burden of Disease Estimates for the Comparative Risk Factor Assessment, South Africa 2000. Methodological Note. Cape Town: South African Medical

53. Nthangeni NG, Steyn NP, Alberts M, Steyn K, Levitt NS, Laubscher R, (2002)., et al. Dietary intake and barriers to dietary compliance in black type 2 diabetic patients attending primary health-care services. Public Health Nutrition; 5(2): 329-338.

54. Nthangeni, G., Steyn, N.P., Alberts, M., Steyn, K., Levitt, N.S., Laubscher, R., Bourne, L., Dick, J. and Temple, N. (2002). Dietary intake and barriers to dietary

compliance in black type 2 diabetic patients attending primary health-care services. *Public Health Nutrition*, 5(2), pp.329–338.

55. Piette JD, Richardson C, Valenstein M. (2004). Addressing the needs of patients with multiple chronic illnesses: The case of diabetes and depression. Am J Manag Care, 10(2):152–162.

56. practitioner. SA Fam Pract ;48(10), PP22-29.25

57. Prevalence of inadequate glycemic control among patients with type 2 diabetes in the United Kingdom general practice research database: A series of retrospective analyses of data from 1998 through 2002. (2006). *Clinical Therapeutics*, [online] 28(3), pp.388–395. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0149291806000701 [Accessed 14 Apr. 2021].

58. Puoane, T., Steyn, K., Bradshaw, D., Laubscher, R., Fourie, J., Lambert, V. and Mbananga, N. (2002). Obesity in South Africa: the South African demographic and health survey. *Obesity research*, [online] 10(10), pp.1038–48. Available at: https://www.ncbi.nlm.nih.gov/pubmed/12376585 [Accessed 25 Aug. 2019].

59. Roglic G, Unwin N, Benneth P (2005). et al. The burden of mortality attributable to diabetes realistic e stimates for the year 2000. Diabetes C a r e, 28(1):2130–2135. http://dx.doi.org/10.2337/diacare.28.9.2130

60. Salkind N.J. (2010). Encyclopedia of research design. doi: (2008). Sample Size Calculator. Calculator.net. (Accessed 22 June 2017). From: http://www.calculator.net/sample-size.

61. Sampling Methods for Quantitative Research - Center for Innovation in research and teaching... Accessed (30/06/2017).https://cirt.gcu.edu/research/developmentresources/research.../quantresearch/sample_met(July 30 2009).

62. Saunders, M., Lewis, P. and Thornhill, A. (2016). *Research Methods for Business Students.* 7th ed. Pearson.

63. Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C. (2002 July). et al. Association of health literacy with diabetes outcomes. JAMA 288(4):475-82.

64. Shani, M,Tylor R, Vinkers, Lustman A, Erez R, Elhayang A and Labad A.(2015). Standard Treatment Guidelines and Essential Medicines List for South Africa Hospital Level, Adults.

65. Simmons, D., Lillis, S., Swan, J. and Haar, J. (2007). Discordance in Perceptions of Barriers to Diabetes Care Between Patients and Primary Care and Secondary Care. *Diabetes Care*, 30(3), pp.490–495.

66. STATSSA.StatisticalreleaseP0309.3-MortalityandcausesofdeathinSouth Africa 2003-2004

67. stories/docs/BehavioralHealth/2016/FundamentalsQualitativeResearch_LaFrance.pdf

68. Stratton, I.M. (2000). Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ*, [online] 321(7258), pp.405–412. Available at: https://www.bmj.com/content/321/7258/405 [Accessed 7 Jun. 2019].

69. Stuckey .H.L.Dellasega .C.Graber .N.J. Manger .D.T. Lendet .I. andconductedR.A. (2009).

70. Sukamolson, S. (2016). Fundamentals of quantitative research. From accessed. (26 June 2017). . http://www.aihec.org/our

71. Tamir.O. Wainstein.J. Raz.I. Shener.J. and Heymann.A. (2012). Quality of Life and PatientPerceived Difficulties in the Treatment of Type 2 Diabetes and the Review

72. Timothy.G.A.(26-06-2017). Factors influencing glycaemic control in diabetics at three community health centres in Johannesburg. (2011-03-10). http://hdl.handle net/10539/9132.

73. Twycross, R. (2015). Desire to hasten death. *Evidence Based Nursing*, 18(4), pp.97–97.

74. McEwan, P., Bergenheim, K. and Currie, C. (2006). pdb23 external validation of the ukpds outcomes model equations (ukpds 68), and the ukpds risk engine equations (ukpds 56 and 60) in forecasting cardiovascular outcomes in people with type 2 diabetes. *Value in Health*, 9(3), pp.A37–A38.

75. Van de Sande, M., Dippenaar, H. and Rutten, G.E.H.M. (2007). The relationship between patient education and glycaemic control in a South African township. *Primary Care Diabetes*, 1(2), pp.87–91.

76. Van Zyl, D. (2006). Optimal glucose control in type 2 diabetes mellitus—a guide for the family practitioner. *South African Family Practice*, 48(10), pp.22–29.

77. Watson (2001). *Penn State Extension*. [online] Penn State Extension. Available at: http://www.extension.psu.edu/evaluation/pdf/TS60.pdf [Accessed 5 Jul. 2021].

78. World Health Organization (2016). Global report on diabetes. *Who.int*, [online] p.ISBN 978 92 4 156525 7. Available at: https://apps.who.int/iris/handle/10665/204871 [Accessed 30 Mar. 2019].

79. World Health Organization. Department Of Noncommunicable Disease Surveillance (1999). *Definition, diagnosis, and classification of diabetes mellitus and its complications: report of a WHO consultation.* Geneva: World Health Organization, Dept. Of Noncommunicable Disease Surveillance.

80. World Health Organization. Preventing chronic disease: a vital investment. WHO global report. WHO: Geneva; 2005?

81. World Health Organization. Regional Office for The Western Pacific and Western Pacific Region Of Idf (2000). Report: WHO/WPRO and IDF/WPR Joint Meeting on the Western Pacific Declaration on Diabetes, Kuala Lumpur, Malaysia, 2-4 June 2000. Manila, Philippines: The Office

APPENDIX A: BIOGRAPHIC AND ADHERENCE QUESTIONNAIRE

PERSONAL DATA (Mark with X, next to the appropriate answer)

1. SEX				
(a) Male		(b) Female		
2. AGE				
(a) 20 – 29 years	(b) 30 – 39 years	(c) 40 – 49 years	(d) 50 – 59 years	(e) 60 and above
3. MARITAL STATUS				
(a) Single	(b) Married	(c) Divorced	(d) Separated	(e) Widowed
4. FAMILY SIZE				
(a) 1 – 3	(b) 4 – 6	(c) 7 – 9	(d) 10 and more.	
5. LEVEL OF EDUCATION				
(a) None	(b) Primary	(c) Secondary	(d) Post-secondary	
6. SOURCE OF INCOME				
(a) Unemployed	(b) Employed in formal Sector	(c) Employed in informal Sector	(d) Self employed	
7. IF UNEMPLOYED WHAT IS THE SOURCE OF INCOME				
(a) Family support	(b) Grant	(c) Others		
8. INCOME PER MONTH				

(a) R0 – 999	(b) R1000 – 1999	(c) R2000 – 2999	(d) R3000 – 3999	(e) R4000 – 4999	(f) R5000 and More
9. HOW LONG HAS THE PATIENT BEEN DIABETIC					
(a) Less than a month			(b) More than a month		
10. DOES PATIENT KEEP ALL APPOINTMENT					
(a) Always	(b) Most of the time		(c) Sometimes	(d) Seldom	
11. HOW FAR DO YOU LIVE FROM HEALTH FACILITY WHERE YOU TAKE TREATMENT					
(a) 0 – 5km	(b) 6 – 10km	(c) 11 – 15km	(d) 16 – 20km	(e) 20km and More	
12. WHAT MEDICATION(S) DO YOU TAKE					
(a) Metformin Alone	(b) Glimepiride Alone	(c) Metformin + Glimepiride	(d) Insulin + Metformin	(e) Insulin + Glimepiride	(f) Insulin alone
13. HAVE YOU BEEN COUNSELLED ABOUT RECOMMENDED LIFESTYLE CHANGES					
(a) Yes			(b) No		
14. INFORMATION ABOUT ADHERENCE ON PATIENT FILE					
(a) How many times has the patient been admitted since diagnosis				(b) Others	
15. DO YOU TAKE YOUR MEDICATION REGULARLY/AS PRESCRIBED?					

(a) Always	(b) Frequently	(c) Only when I experience diabetic symptoms	(d) Never
16. WHAT STRATEGIES DO YOU USE TO HELP YOU TO TAKE YOUR MEDICATION REGULARLY?			
(a) Set reminder	(b) Take at meal time	(c) Assisted by treatment Supporter	(d) Others

17. IF YOU DO NOT TAKE YOUR MEDICATION REGULARLY AS PRESCRIBED, WHY?	
a) I forgot	
b) I am not responsible for taking my medication	
c) I do not believe that it will help me	
d) I miss my clinic appointment because I must go to work	
e) I also use traditional medicine	
f) I need only spiritual or Godly power to get better	
g) When I drink alcohol, I forget to use my medication	
h) Treatment supporter was not available to give medications	
i) I am too old to go to the clinic by myself	
j) My diabetic pills got lost	
k) Do not have transport money to go to clinic	

l) I am taking care of a sick family member	
m) I do not have food to eat before I take my pills	
n) I do not have to drink my pills if I feel better	
o) There is no specific reason for me to stop drinking my pills	
p) The clinic did not have my pills	
q) The health worker at the clinic said I could stop my pills	
r) The medicine makes me feel worse	
s) I travelled to visit family/friends/job and did not have enough pills for my stay	
t) Did not take medication because I was not informed about how to take it	
u) Work did not allow time to go the clinic	

18. DOES THE PATIENT BECOME ADHERENT TO MEDICATION AFTER A PERIOD OF ILLNESS

DUE TO TEMPORARY PROBLEM WHICH CAUSE POOR ADHERENCE TO MEDICATION

(a) Yes		(b) No	

19. DO YOU ADHERE TO THE RECOMMENDED LIFESTYLE CHANGES

(a) Always	(b) Frequently	(c) Only when I experience symptoms of	(d) Never

20. WHAT STRATEGIES DO YOU USE TO HELP YOU TO ADHERE TO THE LIFESTYLE CHANGES THAT ARE RECOMMENDED?		
(a) Set a reminder	(b) Assisted by a family member	(c) Others

21. IF THE LIFESTYLE CHANGES WAS RECOMMENDED TO YOU BUT YOU DO NOT MANAGE TO KEEP TO IT, WHY?	
a) I forget	
b) I am not responsible for carrying out the changes	
c) I do not believe that it will help me	
d) I struggle to motivate myself	
e) I do not have enough time for that	
f) I need only spiritual or Godly power to get better	
g) when I drink alcohol, I forget	
h) I am too old	
i) I am taking care of a sick family member	
j) I do not have to adhere to lifestyle changes if I feel better	
k) there is no specific reason for me not to	
l) the health worker at the clinic ask me to stop	

m) the lifestyle changes makes me feel worse	
n) work did not allow me to carry out the changes	

22. DOES THE PATIENT BECOME ADHERENT TO LIFESTYLE RECOMMENDATIONS AFTER A

PERIOD OF ILLNESS DUE TO TEMPORARY PROBLEM WHICH CAUSES POOR ADHERENCE TO LIFESTYLE MODIFICATION?

(a) Yes		(b) No	

23 HOUSING QUALITY INDEX QUESTIONNAIRE

Housing	Live house built with bricks with zinc or tile roof.
Water	Running water in the yard.
Sanitation	In a yard with either a flush toilet or septic tank.

Housing quality index questionnaire (HQI) validated for south Africa Measures socio-economic status

APPENDIX B: INFORMATION LEAFLET FOR RESEARCH PARTICIPANTS

I Dr Palesa Dibakoane, am conducting a study titled "**Characteristics of Poorly Controlled Diabetes Mellitus Patients at Mankweng Hospital, Limpopo Province.**".

- The aim of this research study is to determine the characteristics of uncontrolled type 2 diabetes mellitus, and to identify the factors associated with poorly controlled diabetes mellitus.
- Participation in the study is voluntary.
- There is no potential risk or harm related to study participants.
- The research study has been approved by relevant research ethics committees.
- The information received will be highly confidential and questionnaires will be completed anonymously.
- Once you agree to take part in the study, you will be requested to sign a consent form before completing the questionnaire.
- I look forward to working with you.
- Your cooperation will be highly appreciated.

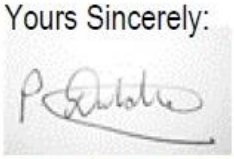
If you have any questions about the research project or require further information you may contact the following:

Student Researcher:	Dr P Dibakoane	Email: ppdibucks@gmail.com
Supervisor:	Prof G Marincowitz	Email: rhinorth@webmail.co.za

If you have any concerns or complaints and wish to contact an independent person about this research project, you may contact:

Dean of the School of Medicine: Prof SM Risenga.	Email: sam.risenga@gmail.com

Yours Sincerely:



Dr P Dibakoane

APPENDIX C: CONSENT FORM

Research Title: Characteristics of Poorly Controlled Diabetes Mellitus Patients at Mankweng Hospital, Limpopo Province.

Statement Concerning Participation in the Research Project

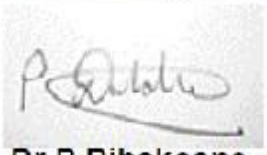
- I have read the information on the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue.
- The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.
- I understand that participation in this study is completely voluntary and that I may withdraw from it at any time and without supplying reasons.
- I know that this study has been approved by the Research and Ethics Committee of University of Limpopo.
- I am fully aware that the results of this of this study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.
- I hereby give consent to participate in this study.

Name of participant	Signature of participant

Place	Date	Witness

APPENDIX D: STATEMENT BY THE RESEARCHER

- I provided verbal and/or written information regarding this study.
- I agree to answer any future questions concerning the study as best as I am able.
- I will adhere to the approved protocol when conducting the research.

Name & Signature	Date	Place
 **Dr P Dibakoane**	**01 April 2017**	**Polokwane**

Address for correspondence (Postal)
18 Devine Heights Hilary Street Bendor Polokwane 0699

Telephonic Contact Details
Cell number: 072 820 3484 Landline (work): 015 2861000

E-mail address
ppdibucks@gmail.com

APPENDIX E: ORGANISATION OF DIABETES CARE, ADAPTED FROM SEMDSA GUIDELINES.

INVESTIGATIONS	YES	NO
1) BLOOD		
Glucose		
HbA1c		
Lipids(TC,HDLc, TG, LDL)		
Creatinine &eGFR		
Potassium		
HIV		
2) URINE		
Dipstix		
Glucose		
Ketones		
Proteins		
3) ECG		
4) CONTINUOUS GLUCOSE MONITORING		
EXAMINATION	YES	NO

Weight		
Height		
BMI(kg/m2)		
Waist circumference		
Bp		
FEET DETAILED EXAMINATION		
Monofilament assessment		
Vibration sensation assessment		
ORAL CAVITY		

Dental caries		
Gum disease		
EYE EXAMINATION		
Visual acuity		
Retinal examination		

APPENDIX F: LIMPOPO DEPARTMENT OF HEALTH APPROVAL

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

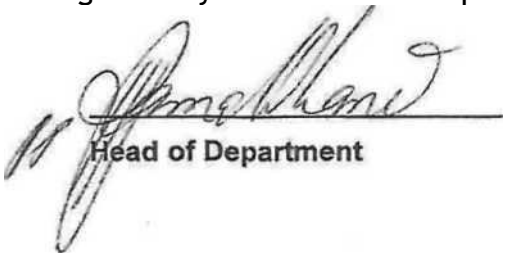
DEPARTMENT OF HEALTH

PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES

Your Study Topic as indicated below.

Characteristics of Poorly Controlled Diabetes meliitus Patients at Mankweng Hospital, 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.



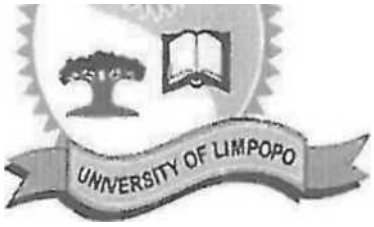
Head of Department

Your cooperation will be highly appreciated

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

APPENDIX G: UNIVERSITY ETHICS APPROVAL 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: 6 August 2019

PROJECT NUMBER: TREC/209/2019: PG

PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

PROJECT:

Title:	Characteristics of poorly controlled diabetes mellitus patients at Mankweng Hospital, Limpopo Province
Researcher:	Dr P Dibakwane
Supervisor:	Prof G Marincowitz N/A
School:	Health Care Sciences

Degree: Master of Medicine in Family Medicine

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

iii)