THE PREVALENCE AND MANAGEMENT OF DIABETES MELLITUS COMPLICATIONS AT MANKWENG HOSPITAL, LIMPOPO PROVINCE

by

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DECLARATION

I, **Tawanda Nyamazana**, hereby declare that the work on which this study is based is original, except where acknowledgements indicate otherwise.

This dissertation is submitted for the degree **Masters in Pharmacy** at the University of Limpopo. Neither the whole work nor any part of it was submitted before for any degree or examination at this or any other university.

Signed……on the……day of……

DEDICATION

I would like to dedicate this piece of work to everyone who contributed much in the success of this research paper.

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ABBREVIATIONS AND ACRONYMS

DKA	Diabetic ketoacidosis
DM	Diabetes mellitus
DSME	Diabetes self-management education
DSME/S	Diabetes self-management education and support
HbA1c	Glycated Haemoglobin
HCPs	Healthcare professionals
IDF	International Diabetes Federation
MI	Myocardial Infarction
NDoH	National Department of Health
NKHS	Non-ketotic Hyperosmolar State
PAD	Peripheral Arterial Disease
RAAS	Renin Angiotensin Aldosterone System
SA	South Africa
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus

ABSTRACT

Introduction:

Diabetes mellitus (DM) is a major public health problem, challenging patients, healthcare professionals, health planners and policy makers worldwide. Its prevalence has been on the rise for the past four decades, with this trend expected to continue. With this challenge, the management of DM should be done following evidence-based guidelines to prevent or slow down the development of DM-related complications. According to the Society of Endocrinology Metabolism and Diabetes South Africa (SEMDSA) guidelines, it has been shown that strict glycaemic control and proper clinical monitoring can help with prevention and slowing down development of complications. If left untreated or poorly controlled, DM progresses into an array of complications which may increase morbidity and mortality. The prevalence and management of DM complications was investigated.

Objectives:

- To determine the prevalence of DM complications at Mankweng Hospital.
- To evaluate the management of patients with DM complications at Mankweng Hospital.
- To determine the factors contributing to the development of complications.
- To determine preventive measures taken on non-complicated patients to prevent them from complicating.

Method:

A retrospective longitudinal review of 134 randomly selected patient records was conducted for a five-year period spanning from June 2012 to May 2017. A pretested DM complications checklist was used to collect data from the patient records.

A cross-sectional study was conducted amongst healthcare professionals caring for patients with DM. A total of 41 healthcare professionals were included in the study where a self-administered questionnaire was used to obtain the data. Both sets of data obtained were analysed using IBM SPSS version 25.

Results:

Retrospective study

The study sample population was entirely consisted of African patients with 70.1% (n=94) females and 29.9% (n=44) males. In the sample, 17.2% were suffering from T1DM while 82.8% were suffering from T2DM. The complications with the highest prevalence were diabetic nephropathy, peripheral neuropathy and diabetic retinopathy with prevalence of 35.8%, 32.1% and 22.4% respectively. Vascular diseases, autonomic neuropathy and diabetic foot ulcer had prevalence of 9.7%, 9% and 6% respectively. The overall prevalence of complications in general was 67.2% which was very high.

Cross-sectional study

A self-administered questionnaire was distributed amongst 41 healthcare professionals (14 males and 27 females). This sample consisted of 9.8% doctors, 41.5% pharmacists, 17.1% professional nurses, 17.1% physiotherapists, 2.4% podiatrists and 12.2% optometrists. It was discovered that only 92.6% and 84.6% of the participants were compliant with the guidelines in terms of random blood glucose tests and blood pressure (BP) per every visit. Only 50% of the HCPs revealed that HbA1c tests should be done according to the guidelines. Merely 5.6%, 8.3%, 5.3% and 22.7% of the HCPs correctly indicated the frequency of foot examinations, eye examinations, renal function tests and lipogram tests respectively, as per the guidelines. Patient related factors were rated as the most contributory factors (56.4%) to the development of complications. Socio-economic and medication related factors had most of the HCPs (36.1% and 29% respectively) rating them as moderate in terms of how much they contribute to the development of complications. The factors rated the least were healthcare team (32.4%) and health system (33.3%) related factors.

Conclusion:

There was a high prevalence of overall complications in general, with diabetic nephropathy, peripheral neuropathy and diabetic retinopathy being the three highest individual complications. There was poor monitoring of patients with complications as the compliance with the SEMDSA guidelines was very low. Patient related factors

were rated the most contributory factors to the development of complications in patients with DM.

Recommendations:

There is need to implement patient-centred DM care which makes sure that the patient is involved in decision making so that they take responsibility of their own health. There is need for the development and implementation of institutional quality improvement programs where regular audits of the processes of DM care and outcomes are monitored.

Limitations:

- The limitations of the study are that the researcher completely relied on patient records.
- The sample size for HCPs was very small and therefore the study results cannot be generalised.

CHAPTER 1
INTRODUCTION

1.1 INTRODUCTION

This chapter addresses the following topics: background and rationale for the study, problem statement, research questions, aim and objectives of the study, significance of the study and summary. This overview is essential to present a solid platform in which to start the study.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

Diabetes mellitus (DM) is a metabolic disorder resulting from disturbances in insulin production, its action or both. Its hallmark characteristic is chronic hyperglycaemia with disturbances in the metabolism of carbohydrates, fats and proteins. If left untreated, its effects include long-term damage, malfunction and multiple organ failure. DM is usually characterised by the following symptoms, polyuria, polydipsia, blurred vision and weight loss (American Diabetes Association, 2018).

DM exists in two major types known as type 1 diabetes mellitus (T1DM) and T2DM. T1DM is characterised by insulin insufficiency mostly due to an autoimmune-mediated destruction of the pancreatic beta cells of the islets of Langerhans (Aathira & Jain, 2014). This destruction results in either complete or near complete insulin deficiency (Kahn, Cooper & Del Prato, 2014). This type of diabetes requires insulin replacement therapy, which is essential for the prevention of ketoacidosis, coma and death. Type 1 DM is more prevalent in children and adolescents but it can also affect adults especially around their early 40s. On the other hand, T2DM is most commonly associated with an interference in insulin action combined with reduced insulin secretion. It is more prevalent in people over the age of 40 years (Kahn *et al*., 2014). The condition in both its forms leads to diminished glucose utilisation by the muscles, which manifests as hyperglycaemia (American Diabetes Association, 2018).

DM is the highest prevailing chronic non-infectious disease in the world with its prevalence on the increase (Shaw, Sicree & Zimmet, 2010). Urbanisation is the major factor contributing to lifestyle changes in African nations. The living conditions

in towns and cities mimic those of developed countries. These changes result in physical inactivity and increased unhealthy eating habits leading to obesity (Shaw, Sicree & Zimmet, 2010).

The International Diabetes Federation (IDF) estimated that 7% of South Africans between 21 and 79 years of age are suffering from DM (International Diabetes Federation, 2015). Based on the latest population estimates for South Africa (SA) (Statistics South Africa, 2015), an estimated population of 3.85 million South Africans in the above-mentioned age range may have diabetes. In 2010, the prevalence of type 2 diabetes mellitus (T2DM) in South Africa was estimated to be 4.5% (International Diabetes Federation, 2015). This shows a very significant rise of about 56% in the prevalence of diabetes within 6 years.

Diabetes-related complications are classified into acute and chronic complications. Acute complications are mostly because of metabolic derangements and healthcare providers must treat them as emergency cases, and they include diabetic ketoacidosis (DKA) and non-ketotic hyperosmolar state (NKHS). These life-threatening complications need patients to be hospitalised for insulin administration, intravenous rehydration and strict monitoring of electrolytes and metabolic parameters (Powers & D'Alessio, 2011). DKA is predominantly found in T1DM while NKHS is found in T2DM. Both DKA and NKHS are related to complete or relative insulin deficiency, dehydration and altered mental state (American Diabetes Association, 2018).

The occurrence of chronic complications is strongly predicted by prolonged hyperglycaemia in DM population. An increase in morbidity and mortality comes directly as a result of the chronic complications affecting multi-organ systems. Chronic DM complications are classified as vascular and non-vascular complications. Vascular complications have two subdivisions which are microvascular and macrovascular complications. Microvascular complications include retinopathy and nephropathy. Macrovascular complications include cerebrovascular, peripheral arterial and coronary artery diseases (Nathan, 2014). Non-vascular complications include neuropathy, gastroparesis due to vagus nerve damage, impotence caused by a combination of neuropathy and angiopathy and diabetic dermopathy (Triplitt, Repas & Alvarez, 2014; Vinik & Mehrabyan, 2004).

Diabetic complications have economic and health consequences to both the nation and the patient and therefore must be prevented at all cost. Treating diabetic complications is by far more expensive than controlling the disease (Nathan, 2014). Therefore, a lot of effort must be exerted on controlling the condition so as to improve the patients' quality of life as well as saving a lot of money for the government in trying to treat the debilitating complications.

Constant proper medical care and health education are essential components for the prevention of acute and chronic complications in DM. The provision of quality health care by a multi-disciplinary team and patient and community engagement are the backbone to achieve the set goals in the treatment and care of patients diagnosed with DM (American Diabetes Association, 2018). Evidence based standard treatment guidelines for sustained glycaemic control have been developed and conformed for the South African status (Amod, 2012; Rotchford & Rotchford, 2002). Tight glycaemic control help reduce the occurrence of DM complications.

The management of diabetic complications differ from complication to complication, with all of them requiring a combination of their specific management and tight blood glucose control. Diabetic retinopathy has been successfully managed with laser photocoagulation (Triplitt *et al*., 2014). It can also be treated with fenofibrate which prevents the progression of vision loss (Wong, Simo & Mitchell, 2012). Neuropathy, the most common diabetic complication, is managed symptomatically by vitamin supplements, antidepressants, anticonvulsants and analgesics. Tight blood pressure and glucose control are the most important factors in nephropathy prevention. The control of blood pressure done by ACE inhibitors and ARB prevents the progression of renal diseases. Peripheral vascular disease and diabetic foot ulcers can be managed by some lifestyle modifications which may include smoking cessation. Pharmacological management involves correction of dyslipidaemia and antiplatelet therapy. Appropriate foot care and local debridement are important for early management of foot injuries. Coronary artery disease can be managed by multiple strategies which include antiplatelet therapy, antihypertensives, antihyperlipidaemics and lifestyle modifications (Triplitt *et al*., 2014).

In this study, the researcher investigated the prevalence of DM complications as well as how they were managed at Mankweng hospital. The management of DM

complications was evaluated against the standard treatment guidelines and essential medicines list for SA.

1.3 PROBLEM STATEMENT

As the focus in Africa remains on infectious diseases such as Acquired Immunodeficiency Syndrome (AIDS) and Tuberculosis (TB) there is little awareness around chronic non-infectious conditions such as DM and its complications (Shaw, Sicree & Zimmet, 2010). A larger share of the health budget is therefore taken by HIV and TB, leaving the non-infectious chronic conditions with just a meagre share which cannot suffice the challenges they present to the community. Many diabetic patients go undiagnosed or do not receive appropriate treatment in time (International Diabetes Federation, 2015). This therefore increases the prevalence of complications and in turn morbidity and mortality amongst patients diagnosed with DM. There was a 56% increase from 4.5% in the prevalence of diabetes mellitus in SA between 2010 and 2015 (International Diabetes Federation, 2015). However, there is no literature about the prevalence of complications in Limpopo province amongst DM patients. Henceforth, the need to investigate on the prevalence of DM complications and the factors contributing to their development.

1.4 RESEARCH QUESTIONS

- What is the prevalence of DM complications at Mankweng hospital?
- What is the management of diabetic patients with DM complications at Mankweng hospital?
- Which factors contribute to the development of DM complications at Mankweng hospital?
- Which preventive measures are in place to prevent non-complicated DM patients from developing complications at Mankweng hospital?

1.5 AIM OF THE STUDY

The main aim of this study was to investigate the prevalence and the management of diabetes mellitus complications at Mankweng Hospital, Limpopo Province.

1.6 OBJECTIVES OF THE STUDY

The objectives of the study were as follows:

- To determine the prevalence of DM complications at Mankweng Hospital.
- To evaluate the management of diabetic patients with DM complications at Mankweng Hospital.
- To determine the factors contributing to the development of the DM complications.
- To determine preventive measures taken on non-complicated patients to prevent them from complicating.

1.7 IMPORTANCE OR SIGNIFICANCE OF THE STUDY

This study will provide information about the prevalence of DM complications at Mankweng hospital. It will also help identify if there are any gaps between the current practices in the management of DM complications and the standard treatment guidelines at Mankweng Hospital. This helps provide information for policy and decision makers tasked with the management of DM to act accordingly.

1.8 SUMMARY

This chapter focused on the background of the study, providing the gaps identified and the significance of the study. The following chapter will look at the existing literature in-depth related to the study.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

This chapter discusses the relevant literature that was explored concerning the study. It provides an in-depth analysis and assessment of what other researchers have found about the prevalence and management of DM complications. This was done to make comparisons with the current study and to identify any gaps in previous similar studies. In compilation of the literature review, journal articles, relevant academic books as well as websites were used. The chapter provides an overview on DM, types, treatment, complications and their management and prevention.

2.2 DIABETES MELLITUS OVERVIEW

In 2015, the IDF estimated that one in eleven adults has DM and of those, 50% is undiagnosed. It also estimated that the management of DM spends 12% of the total global health expenditure (International Diabetes Federation, 2015). During diagnosis, a full medical assessment of the patient must be done in order to classify the DM. The existence of complications must be investigated while current and previous treatment and glycaemic control reviewed in confirmed DM patients. This helps in preparation of a sound and appropriate individualised therapeutic plan and provision of a backbone for continuous patient care. Individualised laboratory evaluations such as glycated haemoglobin (HbA1c), albuminuria and plasma lipid profile corresponding with a patient's medical condition must be performed and monitored. This is to ensure an optimal management of the patient by the healthcare team (American Diabetes Association, 2018).

Successful management of DM entails maintained glycaemic control over a long period to lower the risk of chronic complications. The UK Prospective Diabetes Study (UKPDS) revealed that for every 1% reduction in HbA1c there was a 14% decrease in myocardial infarction (MI) as well as a 37% reduction in microvascular complications (Bos & Agyemang 2013; Coccheri, 2007). Results of a 10-year follow-up study revealed that T2DM patients with sustained good glycaemic control

experienced benefits of reduced rates of complication-related morbidity and mortality (Nathan, 2014).

Medications for diseases like HIV increase the prevalence and progression of DM. This occurs due to insulin resistance and metabolic syndrome that are associated with the use of protease inhibitors (Samad, Harris, Puskas, Ye, Chia *et al*., 2017). The prevalence of DM in treatment-naïve HIV was reported to be 2.6%, however, a study conducted over a four-year period showed a fourfold increase in the risk of developing DM (Murphy & McKay, 2013). This therefore, requires healthcare professionals to pay special attention to the patients at risk of developing DM and slow down the progression of complications.

Failure to achieve and maintain normoglycaemia in patients with DM results in increased risks of developing diabetes-related complications and consequently increased morbidity and mortality (American Diabetes Association, 2018). Cardiovascular diseases (CVD) are the major cause of mortality in DM patients. Hypertension, alcohol consumption, smoking, hyperlipidaemia and reduced physical activity are the risk factors associated with an increase in cardiovascular complications (Bos & Agyemang, 2013). Adult blindness in DM patients is mostly because of diabetic retinopathy. Occurrence of cataracts and open-angle glaucoma is six and 1.4 times respectively more in patients diagnosed with DM than in the general population (Wong *et al.,* 2012). Diabetic neuropathy may be asymptomatic or may present with autonomic dysfunction, sensory loss, pain and weakness. It may result in high morbidity rates and may contribute to other major complications, such as foot ulceration and lower limb amputation, which is the most debilitating complication (Garoushi, Johnson & Tashani, 2018).

2.3 TYPES OF DIABETES MELLITUS

There are two major types of diabetes mellitus, namely T1DM and T2DM.

2.3.1 Type 1 diabetes mellitus (T1DM)

T1DM is a multisystem chronic condition with both metabolic and structural consequences. It is characterised by insulin insufficiency caused by a destruction of the pancreatic beta cells (Aathira & Jain, 2014). Insulin insufficiency cause a

disturbance in the metabolism of carbohydrate, fat and protein resulting in chronic hyperglycaemia (Triplitt *et al.,* 2015; Aathira & Jain, 2014). T1DM may manifest at any age, however, it is most common in juveniles with some cases developing in adults around their early 40s (Aathira & Jain, 2014). T1DM requires lifelong insulin replacement therapy. This type of DM affects approximately 5 to 10% of all DM patients (Georgoulis, Kontogianni & Yiannakouris, 2014).

There are three types of T1DM, which are, autoimmune, idiopathic and fulminant (Aathira and Jain, 2014; Wang, Zheng, Tu, Dai, Lin & Zhou, 2016). Autoimmune T1DM is characterised by an abnormal activation of the immune system, resulting in inflammatory response and the production of autoantibodies to beta-cell antigen, insulin and glutamic acid decarboxylase (GAD) (Wang *et al.*, 2016). This results in the destruction of the beta cells and subsequently insulin insufficiency. In idiopathic T1DM, the patient does not have any autoantibodies in their system making its cause to be unknown. Fulminant T1DM is an aggressive condition with an abrupt onset of insulin insufficiency hyperglycaemia with rapid ketosis (Wang *et al.*, 2016). The pathogenesis is still under research; however, some researchers have found traces of autoimmune antibodies in some patients (Aathira, 2014; Wang *et al.*, 2016).

2.3.2 Type 2 diabetes mellitus (T2DM)

T2DM is a complex metabolic condition characterised by hyperglycaemia, resulting from a combination of peripheral insulin resistance and insulin insufficiency (American Diabetes Association, 2018). It affects about 90 to 95% of all the diabetic population (Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). T2DM patients do not completely rely on lifelong insulin therapy. The existence of either of insulin insufficiency or insulin resistance alone does not result in T2DM. Both insulin resistance and insulin insufficiency should be present for T2DM to manifest (Aathira & Jain, 2014). In contrast with T1DM patients, those with T2DM mostly present with obesity.

2.4 MANAGEMENT OF DIABETES MELLITUS

Elimination of symptoms and, prevention and slowing down complication progression are the main goals of DM management (Huang, Liu, Moffet, John & Karter, 2011).

Limiting the occurrence and the management of pre-existing complications as well as sustained blood glucose control require a multidisciplinary team which consists of a medical doctor, pharmacist, nurse, and dietitian, sometimes with regular consultations of specialists (American Diabetes Association, 2018). Comprehensive DM management involves glycaemic control, management of comorbidities and screening for and management of complications (Huang *et al*. 2011). Glycaemic control includes a combination of non-pharmacological and pharmacological therapy.

2.4.1 Pharmacological management

The pharmacological management depends on the type of DM being treated. For T1DM, insulin replacement therapy where insulin insufficiency is supplemented by exogenous insulin while in T2DM, oral antihyperglycaemics are used alone or in combination with insulin (Aathira, 2014). Insulin works by increasing peripheral glucose uptake and reducing hepatic gluconeogenesis (Huang *et al*., 2011). The oral antihyperglycaemics may be agents that decrease insulin resistance, decrease postprandial insulin needs or those that improve and increase endogenous insulin secretion. The use of exogenous insulin is for the replacement of endogenous insulin (Aathira & Jain, 2014).

Improved glycaemic control and reduced chronic complications are achieved by early initiation of pharmacologic therapy in T2DM patients. Well-established oral monotherapy of either metformin, sulfonylureas or acarbose are initially used while recently a new class of thiazolidinediones has become available (Alvin & D'Alessio, 2011). Inadequate control of T2DM with monotherapy calls for the use of a combination of two different classes of drugs. The most widely used combination is metformin and a sulfonylurea. Triple therapy, which includes insulin therapy, is used in case of failure of dual therapy to control the blood glucose levels of the patient (Kahn *et al.,* 2014).

Insulin therapy requires that the blood glucose levels be monitored to prevent hypoglycaemia. Blood glucose self-monitoring forms the basis of daily dosage adjustments for individual patients to suit their requirements (American Diabetes Association, 2018).

2.4.2 Non-pharmacological management

In T2DM, non-pharmacological management includes dietary adjustments, physical exercise and smoking cessation. The main aim for dietary adjustments and exercise in T2DM is to expedite loss of weight in obese patients (Norris, Zhang, Avenell, Gregg, Brown, Schmid & Lau, 2016). Dietary adjustments are a very important aspect of DM prevention and management. Limitations in the intake of calories and saturated fats are the dietary adjustments that improve glycaemic control. A low-carbohydrate, Mediterranean-style diet has a greater advantage than low-fat diet in T2DM patients (Georgoulis *et al.,* 2014).

Average weight losses of about 5-10% have shown meaningful improvements in cardiovascular complications risk factors. Furthermore, an increased weight loss of 10-15% body weight registered an even better risk factor reduction. Reduced glycated haemoglobin levels, blood pressure and plasma triglycerides and increased high-density lipoproteins are some of the benefits associated with weight loss (Wing, Lang, Wadden, Safford, Knowler, Bertoni, Hill, Brancati, Peters, Wagenknecht & The Look AHEAD Research Group, 2011).

Physical exercise assists to achieve a number of goals in the management of DM. The goals include improved glycaemic control, increased insulin sensitivity, cardiorespiratory fitness, improved lipid profile, decreased blood pressure and weight loss (Colberg, Sigal, Yardley, Riddell, Dunstan, Dempsey, Horton, Castorino & Tate, 2016). All these goals are beneficial for DM management. Randomised trials have proven that supervised physical activity achieves better HbA1c and lipid levels, reduced cardiovascular and mortality and slowing down the development of peripheral neuropathy (Sigal, Armstrong, Bacon, Boulé, Dasgupta, Kenny & Riddell, 2018).

Smoking has been linked to a 1.37 times increase in the development of T2DM as compared to non-smokers. The risk of cardiovascular diseases is increased by smoking in the general population and evidence has been gathered that the risk is even higher in diabetic patients (Zhu, Pan, Sheng, Chen & Pan, 2017). Cigarette smoking is known to negatively affect glycaemic control by inducing insulin resistance. This results from increasing inflammation and oxidative stress, impairing endothelial function (Bajaj, 2012; Zhu *et al.*, 2017). However, the benefits of smoking

cessation are not immediately recognised as studies have shown that there was an increase in HbA1c in the first year of quitting smoking. The studies also showed that although the HbA1c increased in those who quitted, it was lower than those who continued smoking. Glycaemic control was however, improved after one year. The long term benefits outweigh the short term harmful effects of smoking (Tonstad, 2009; Zhu *et al.*, 2017).

2.5 PROGNOSIS

Despite the different pathophysiology of DM, the unifying characteristic is hyperglycaemia resulting from dysfunction of the pancreatic beta cells. There is a continuous impaired glucose control as insulin insufficiency increases with time. The key to staging DM and identifying when and how interventions can be best implemented to prevent or delay its progression and complications (Skyler, Bakris, Bonifacio, Darsow, Eckel, Groop, Groop, Handelsman, Insel, Mathieu, McElvaine, Palmer, Pugliese, Schatz, Sosenko, Wilding & Ratner, 2017). The most important prognostic factors for DM are; blood pressure, lipids, weight, HbA1c and glycaemic control.

2.5.1 Type 1 diabetes mellitus prognosis

T1DM causes high morbidity and premature death. About 40% of patients with T1DM present a greater risk of severe visual impairment, end-stage renal impairment, neuropathy and CVS complications. The remaining fraction do not develop serious complications with time. Patients who normally live for about 10-20 years after diagnosis without developing any complications usually have a possibility of maintaining a good health (American Diabetes Association, 2018).

2.5.2 Type 2 diabetes mellitus prognosis

Poor glycaemic control in T2DM is associated with an increase in mortality. According to American Diabetic Association (2018), an increase in HbA1c by 1% triggers a 66% increase in mortality. Low HbA1c levels of 6% and below correlates with best prognostic results.

2.6 DIABETES MELLITUS COMPLICATIONS

T1DM and T2DM are both the main risk factors for cardiovascular diseases. Cardiovascular complications account for 67% of deaths in diabetic patients, and approximately 3 in 10 of the patients treated in intensive care units for cardiovascular diseases are patients diagnosed with DM. Microvascular and macrovascular complications prevalence have been found in both T1DM and T2DM (Bos & Agyemang, 2013).

2.6.1 Coronary heart disease (CHD)

Approximately 4 in 5 of all deaths in diabetic patients are because of cardiovascular events. Of such deaths, coronary heart disease accounts for 75% while cerebrovascular and peripheral arterial disease combined account for the remaining fraction. Cardiovascular risks significantly increase with age and duration of DM (Nathan, 2014). Investigations of CHD must be done if there is existence of atypical cardiac and related vascular diseases symptoms (American Diabetes Association, 2018).

Intensive lifestyle modifications targeting weight loss achieved through dietary modifications and physical exercise are known for improving quality of life, glycaemic control, fitness and CHD risk reduction (Look AHEAD Research Group, 2013). Smoking cessation is also essential as smoking is one of the major risk factors of CHD and it offers better prognosis. Patients presenting with an increased CHD risk must be given low dose aspirin, and statin therapy. In the presence of hypertension, an ACE inhibitor or an ARB should be added.

2.6.2 Cerebrovascular disease

Diabetic cerebrovascular diseases accounts for a significant number of deaths in DM patients (Zhou, Zhang & Lu, 2014). DM patients with hyperlipidaemia and/or hypertension comorbidities are at an increased risk of cerebrovascular disease and its accompanying disabilities and mortality. Hyperlipidaemia leads to the development of atherosclerosis in DM patients resulting in increased blood viscosity and changes haemodynamics leading to development of an atheroma. Simultaneously, hypertension also promotes arteriolosclerosis and fibrinoid necrosis

of the vascular walls. It also causes micro-aneurysms that easily rupture. All these processes happen on the vascular in brain for a long time, leading to the development of stroke. Approximately 20% to 40% of type 2 patients diagnosed with DM suffer from cerebrovascular diseases. The main pathological process of the cerebrovascular diseases in T2DM patients is atherosclerosis. It is an inflammatory response in essence after damage of the vascular endothelium due to prolonged exposure to high blood glucose (Zhou *et al.,* 2014).

Prevention of cerebrovascular diseases in patients with DM begins with identifying followed by interventions of modifiable risk factors. The modifiable risk factors include alcohol consumption, obesity, physical inactivity, DM, hypertension, smoking and hyperlipidaemia (Antonios & Silliman, 2005; Goldstein, Adams, Alberts, Appel, Brass, Bushnell,Culebras, DeGraba, Gorelick, Guyton, Hart, Howard, Kelly-Hayes, Nixon & Sacco, 2006).

2.6.3 Peripheral arterial disease

DM is one of the major risk factors for peripheral arterial disease (PAD) with about 3-fold risk increase (American Diabetes Association, 2018). Smoking, hypertension and dyslipidaemia are some of the risk factors associated with PAD in patients with DM (Bos & Agyemang, 2013). Smoking causes damage to the vascular endothelium due to nicotine circulating in the blood. Hypertension induces arteriosclerosis while hyperlipidaemia causes atherosclerosis leading to PAD. PAD increases the chances of lower limb amputations (Zhou *et al.,* 2014).

Glycaemic control is the basic management strategy for DM patients with PAD. Dual therapy of Aspirin and Clopidogrel has been found to be effective in terms of restoration of functional status and lowering CVS risks (Hirsh & Bhatt, 2004). Smoking cessation, lipid lowering, and hypertension control and weight loss for patients with body mass index (BMI) greater than 25 are known risk factor modifications beneficial in the delay of onset of PAD (Hirsch, Criqui, Treat-Jacobson, Regensteiner, Creager, Olin. Krook, Hunninghake, Comerota, Walsh, McDermott & Hiatt, 2001; Peach, Griffin, Jones, Thompson & Hinchliffe, 2012).

2.6.4 Venous thromboembolism

Patients diagnosed with DM are more prone to venous thromboembolism than the general population (14.9% vs 10.7%) and long-term major bleeding complications (16.4% vs 11.7%) as proven by most epidemiological studies (Piazza, Goldhaber, Kroll, Goldberg, Emery & Spencer, 2012). Sustained elevation of glucose levels causes the endothelial cells lining the blood vessels to absorb unhealthy high levels of glucose. Haemodynamic changes in patients diagnosed with DM due to hyperglycaemia leads to platelet dysfunction therefore resulting in embolism (Bai, Ding, Du, Zhao, Wang & Ma, 2015).

2.6.5 Diabetic nephropathy

Diabetic nephropathy is prevalent in both T1DM and T2DM. It affects about 30% of all patients diagnosed with DM (Wada & Makino, 2013). The extent of renal damage determines the progression of end stage renal failure. Renal failure is the second major cause of death in patients diagnosed with DM. The prognosis of patients with microalbuminuria if left untreated is that 20-40% will advance to overt nephropathy. Both micro- and macro-albuminuria are consistent with the risks of renal failure, cardiovascular events and death. Either haemodialysis or kidney transplant is required for the management of renal failure in diabetic patients (Wada & Makino, 2013).

New knowledge has connected hypertension and diabetic nephropathy founded on the understanding of the renin-angiotensin-aldosterone system (RAAS). Stimulation of angiotensin II in patients diagnosed with DM is accompanied with vasoconstriction and vascular damage, which in turn is responsible for hypertension and glomerular injury inducing albuminuria and kidney damage. The other cause of a reduction in the interaction of insulin and glucose by a decrease in peripheral blood flow resulting from the activation of angiotensin II. This activation of angiotensin may also result in insulin insufficiency due to the harmful effects of the pancreatic RAAS on the beta cell thereby affecting their structure and function (Wada & Makino, 2013).

Intensive glucose control as well as aggressive control of hypertension and other cardiovascular risk factors must be done to achieve prevention of onset and delayed

progression to chronic kidney disease (CKD) (American Diabetes Association, 2018).

The management of diabetic nephropathy involves prevention of end stage renal failure through blood pressure control. Blood pressure control through the use of ACE inhibitors and ARBs have shown effective renoprotective properties in diabetes mellitus patients with hypertension (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017). However, these medications should never be taken together as they increase the risk of hyperkalaemia and renal dysfunction (Fried, Emanuele, Zhang, Brophy, Conner, Duckworth, Leehey, McCullough, O'connor, Palevsky & Reilly, 2013). ACE inhibitors are considered as the first line treatment of diabetic nephropathy in patients with DM who have established albuminuria (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017).

2.6.6 Diabetic retinopathy

Progressive vision loss and blindness in DM patients are as a result of diabetic retinopathy. Duration of DM and poor glycaemic control are the major determinants of retinopathy. In addition to DM duration and poor glycaemic control, the other contributing factors to diabetic retinopathy include hypertension, diabetic nephropathy and dyslipidaemia. A review of diabetic complications in Africa reported that more than 50% of patients with T2DM had retinopathy, which accounted for 32% of all eye complications (Tesfaye & Gill, 2011;American Diabetes Association, 2018). There is a 90% lifetime risk of developing DR in the DM population as compared to the non-DM population. The risk rises with cumulative duration of DM. As the global DM prevalence is constantly on an increase, the incidence of DR is estimated to approximately triple in the subsequent four decades. DM causes microvascular damage in the retina, which then manifests as DR (American Diabetes Association, 2018). The pathophysiology of diabetic retinopathy involves neuronal, inflammatory and vascular pathways (Semeraro, Cancarini, dell’Omo, Rezzola, Romano & Costaglio, 2015).

Diabetic retinopathy is divided into two depending on the clinical severity of the condition; non-proliferative diabetic retinopathy and proliferative retinopathy. Non-proliferative diabetic retinopathy is characterised by microvascular abnormalities

which include micro-aneurysms and intraretinal bleeding. Proliferative diabetic retinopathy is associated with vitreal bleeding and angiogenesis. Another indication for diabetic retinopathy is diabetic macular oedema, a result of fluid accumulation leading to thickening of the macular (Marozas & Fort, 2014). The delay of onset and progression of diabetic retinopathy can be done by tight glycaemic control, blood pressure control, lipid control and antiplatelet therapy.

Treatment of diabetic retinopathy consists of laser therapy, intraocular pharmacologic and vitreoretinal intervention. The Early Treatment Diabetic Retinopathy Study (ETDRS) and the Diabetic Retinopathy Study (DRS), established reduction of legal blindness in proliferative or non-proliferative retinopathy by the use of photocoagulation laser therapy of the retinal periphery. The long-term benefits of photocoagulation were confirmed through long-term follow-up studies to the original photocoagulation study (Chew, Ferris, Csaky, Murphy, Agron, Thompson, Reed & Schachat, 2003).

Two anti-VEGF drugs are used for the treatment of diabetic retinopathy based on the knowledge of the primary role of VEGF in the development of macular oedema. Two phase III randomised trials, RIDE and RISE where ranibizumab was used monthly with or without laser improved visual acuity as compared to the control group. In the RISE trial, there was an improvement in 15 letters or more of acuity in 44% and 39% of the patients receiving 0.3 and 0.5mg ranibizumab respectively as compared to only 18% of the control group. In the RIDE, improvement of 15 letters or more was recorded in 33% and 45% of patients receiving 0.3 and 0.5mg ranibizumab respectively (Nguyen, Brown, Marcus, Boyer, Patel, Feiner, Gibson, Sy, Rundle, Hopkins, Rubio, & Ehrlich, 2012).

Intraocular injections of steroids combined with laser showed similar benefits to those of ranibizumab. However, steroids were associated with a greater incidence of glaucoma (Elman, Bressler, Qin, Beck, Ferris, Friedman, Glassman, Scott, Stockdale, Sun & The Diabetic Retinopathy Clinical Research Network, 2011).

2.6.7 Diabetic neuropathy

DM is the most common cause of neuropathy globally (Albers & Pop-Busui, 2014). The two major pathogenic factors of diabetic neuropathy are persistent

hyperglycaemia and ischaemia. Diabetic neuropathy can be divided into three namely; motor, sensory and autonomic forms. It is present in 60% of all DM patients in differing levels (American Diabetes Association, 2018).

Muscle atrophy of the lower limbs as well as structural alterations of the feet are mainly induced by motor neuropathy. Nociceptive, heat and touch functions are affected by sensory neuropathy while autonomic neuropathy predominantly alters the microvascular circulation and the heart. Diabetic foot is a result of loss of sensory functions, which plays an important role in the development of diabetic foot. Approximately 60% of all diabetic foot result from diabetic neuropathy, while the remaining share is because of the coexistence of neuropathy and microvascular and macrovascular damage (Albers & Pop-Busui, 2014).

The primary prevention of diabetic neuropathy involves intensive glycaemic control. In T1DM, the benefits of intensive insulin therapy extend over a decade for the prevention of diabetic neuropathy. Intensive glycaemic control in T2DM is associated with reduced incidence of neuropathy. Currently there are no other disease-modifying treatments (Bril, Perkins & Toth, 2013).

There are many treatment options available for neuropathic pain. However, an observation has been made that only a few patients are completely relieved of their symptoms with any treatment and that a 30 to 50% reduction is clinically significant (Bril *et al.*, 2013). Glycaemic control does not reverse nerve damage. Therapeutic agents can be used to relieve symptoms and improve the quality of life (American Diabetes Association, 2018). The pharmacological agents used for the management of peripheral neuropathy include: anticonvulsants, antidepressants and opioids. However, opioids, though effective, should be reserved for use only after the other treatments have failed due to their potential for dependency, tolerance and abuse (Bril *et al*., 2013).

Tricyclic antidepressants (TCAs) for example, amitriptyline inhibits the presynaptic reuptake of serotonin and norepinephrine and the activity of sodium channels and N-methyl-D-aspartate (NMDA) receptors which are involved in the transmission of pain (Zeng, Alongkronrusmee & van Rijn, 2017). Researches have also shown that serotonin and norepinephrine reuptake inhibitors (SRNIs), duloxetine and

venlafaxine possess antinociceptive properties due to their increased noradrenergic and serotonergic effects (Zeng *et al*., 2017).

Gabapentin and pregabalin are GABAergic anticonvulsants that are also used in the management of diabetic neuropathy. The GABAergic agents inhibit neuronal excitability and synaptic plasticity, resulting in inhibition of pain processing (Zeng *et al*., 2017).

2.7 DELAY OF ONSET AND PROGRESSION OF DM COMPLICATIONS

The most effective way of delaying onset and progression of DM complications is individualised strict glycaemic control (American Diabetes Association, 2018). However, the use of a combination of blood pressure, plasma lipid and tight glycaemic control can prevent risks of developing chronic complications. In patients diagnosed with DM, the management of hypertension is initially done with the use of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB). These agents have renoprotective properties, thereby preventing diabetes-related kidney diseases (American Diabetes Association, 2003).

Strict blood pressure management, lipid profiles and glycaemic control can inhibit the development of cerebrovascular and cardiovascular complications. In highly susceptible patients among the patients diagnosed with DM, antihyperlipidaemics and aspirin therapy have shown a reduction in the development of these complications (American Diabetes Association, 2018).

2.7.1 Glycaemic control

Early optimal glycaemic control soon after diagnosis have shown to delay the onset and progression of DM complications (McFarlane, Gilbert, McCallum & Senior, 2013). Glycaemic control with targets of HbA1c ≤ 7%, demonstrated a significant reduction in diabetic retinopathy, CKD, diabetic neuropathy and PAD (McFarlane *et al.*, 2013; Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017).

As DM is considered to significantly increase the risk of cerebrovascular events, directly responsible for 12 to 22% of total stroke cases (Luitse, Biessels, Rutten & Kappelle, 2012). Hyperglycaemia increases the risks of atherosclerosis and

atherogenic risk factors, which include hyperlipidaemia and hypertension. Glycaemic control has been shown to reduce the cardiovascular risk factor in people with PAD, however, tight glycaemic control lacks evidence in ameliorating PAD (American Diabetes Association, 2003). Nevertheless, good glycaemic control should be one of the goals of therapy in DM patients with PAD.

Early optimal glycaemic control soon after diagnosis have shown reduced risk of diabetic nephropathy (McFarlane *et al*., 2013). Tight glycaemic control have been associated with reduction in albuminuria, however, there is lack of evidence in terms of clinically important renal endpoints (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017). Major researches such as the DCCT and the UKPDS have supported renal protection in intensively managed patients with an HbA1c of about 7% (McFarlane, Cherney, Gilbert & Senior, 2018).

Glycaemic control with targets of HbA1c ≤ 7%, demonstrated a significant reduction in diabetic retinopathy development and progression (Boyd, Advani, Altomare & Stockl, 2013). The UKPDS and the Diabetes Control and Complications Trial (DCCT), also showed that lowering HbA1c to 7% remarkably reduced the development and progression of diabetic retinopathy. There is a 30-40% diabetic retinopathy risk reduction for every 1% HbA1c reduction (Symes, Liew & Tufail, 2014). In an eye study done by the Action to Control Cardiovascular Diseases (ACCORD), it was found out that a combination of intensive glycaemic control and intensive combined therapy of dyslipidaemia is closely associated with delayed onset and progression of diabetic retinopathy (ACCORD Study Group and ACCORD Eye Study Group, 2010). Another study conducted in 2009 showed a positive trend towards the benefits of intensive glycaemic control and blood pressure control, although the two insignificantly reduced diabetic retinopathy incidence and progression (Beulens, Patel, Vingerling, Cruickshank, Hughes, Stanton, Lu, Thom, Grobbee & Stolk, 2009).

Point of care testing is also a concept used in the improvement of DM management and slowing down of its complications. It has been established that the use of point of care in DM is associated with improved adherence with testing frequency and treatment modifications, improved clinical outcomes and the patient's quality of life (Schnell, Crocker & Weng, 2017). Even though, the cost of point of care testing is

higher than a central laboratory testing, the healthcare cost for the patients is reduced as their number of visits is reduced (Lee-Lewandrowski & Lewandrowski, 2009).

2.7.2 Blood pressure control

Hypertension is identified as an independent risk factor for the development of stroke and target organ damage. Optimal control of BP has indicated some benefits in the delay of onset and progression of DM complications. BP control is achieved through the use of medications that block the renin angiotensin aldosterone system (RAAS) in people with DM and hypertension (McFarlane *et al*., 2018).

Blood pressure control is the most effective prevention of stroke in DM and non-DM patients (Antonios & Silliman, 2005). Hypertension is identified as an independent risk factor for both cerebral infarction and intracerebral haemorrhage (Fields, Burt, Cutler, Hughes, Roccella & Sorlie, 2004). Optimum blood pressure control contributes to the prevention of stroke and target organ damage (Goldstein *et al.*, 2006). The incidence of stroke is reduced by 35 to 44% with antihypertensive therapy (Blood Pressure Lowering Treatment Trialists' Collaboration, 2005).

The classes that are mostly used for blood pressure control include ACE inhibitors, ARBs, diuretics and calcium channel blockers (Weber, Bakris, Dahlöf, Pitt, Velazquez, Gupte, Lefkowitz, Hester, Shi, Weir & Kjeldsen, 2007). The choice of pharmacological therapy however, has to be individualised (Goldstein *et al.*, 2006).

Optimal control of BP has indicated some benefits in the delay of onset and progression of diabetic nephropathy (McFarlane *et al.*, 2013). Medications that block the renin angiotensin aldosterone system (RAAS) are mostly used in people with diabetes and hypertension. These include the angiotensin converting enzyme (ACE) inhibitors and the angiotensin receptor blockers (ARB). These drugs have shown to have renoprotective properties in hypertensive patients rather than in normotensive individuals with diabetes (McFarlane *et al.*, 2013). ACE inhibitors have been proven to reduce albuminuria and progression of nephropathy (Andersen, Tarnow, Rossing, Hansen & Parving, 2000).

Diabetic retinopathy progression can be modified through blood pressure control, which is an independent risk factor for diabetic retinopathy in diabetic patients (Boyd *et al*., 2013). A study by UKPDS revealed that blood pressure control in patients with T2DM results in a reduction in the incidence and progression of diabetic retinopathy. There are suggestions that diabetic retinopathy comes as a result of mechanical stretching of the retinal blood vessels contributing to damage of the endothelial cells and vascular endothelial growth factor (VEGF). It has been found that for every 10mmHg increase in blood pressure, there is a 10% risk increment of early retinopathy progression and 15% risk progression to proliferative retinopathy (Symes *et al*, 2014).

2.7.3 Foot care

Proper foot care and footwear can prevent many foot problems. Daily washing and proper drying of feet accompanied with foot examination may reduce foot pathogenesis by up to 80% (American Diabetes Association, 2018). Foot ulcers can worsen and lead to amputation of the feet. Amputation of feet can result in major patient, family and societal economic implications. Prevention of foot ulcers and consequently amputations is through prevention of foot injuries by wearing appropriate footwear and tight glycaemic control.

2.7.4 Diabetes self-management education and support

Diabetes self-management education and support (DSME/S) is one of the most critical components of DM management. It prepares the patients to be able to cope with their condition as well as to proactively participate in the decision making and proper management of their conditions. This therefore, helps reduce the chances of progression of DM to complications (American Diabetes Association, 2018).

DSME/S has to be done in four critical times which are; during diagnosis, yearly for health preservation and prevention of complications, when there are new complicating factors that may affect self-management and during transition in care. During these critical times, the DSME/S should be provided, assessed and adjusted as per patient's needs (Powers, Bardsley, Cypress, Duker, Funnell, Fischl, Maryniuk, Siminerio & Vivian, 2017). The education and support plan must be developed in

consultation with the patient ensuring that the patient's abilities, limitations and expectations are taken into account. Therefore, this requires the DSME/S to be individualised (Haas, Maryniuk, Beck, Cox, Duker, Edwards, Fisher, Hanson, Kent, Kolb & McLaughlin, 2012).

2.7.5 Lifestyle modification

Lifestyle modifications are an integral part of DM care and it encompasses behavioural interventions, dietary modifications, physical activity and smoking cessation. Healthcare professionals must focus on lifestyle management from the time of diagnosis with DM to avoid or slow down the progression of complications (American Diabetes Association, 2018).

2.7.6 Dietary modification

Dietary modification forms an integral part of self-management and treatment of DM. The goals of dietary modification include improvement and maintenance of quality of life and prevention and treatment of DM complications. Dietary education provided by a dietician either in a group or individual setting proved to be beneficial in the slowing down the development of DM complications (Dworatzek, Arcudi, Gougeon, Husein, Sievenpiper & Williams, 2013).

The most difficult part of implementing dietary modification is to determine what to eat and being prepared to follow an eating plan. This therefore calls for all the members of the multidisciplinary team to be knowledgeable of the dietary management of DM patients and be proactive in its implementation. In coming up with an individualised dietary plan, the following must be considered; cultural and personal preferences, access to healthy food, the patient's will and capability to make behavioural changes and obstacles to change (American Diabetes Association, 2018).

Dietary modifications have shown an improvement in glycaemic control by 1 to 2% reduction in HbA1c levels. If combined with other DM standards of care can result in reduced morbidity due to improved clinical and metabolic outcomes (Pastors, Warshaw, Daly, Franz & Kulkarni, 2002; Gaetke, Stuart & Truszczynska, 2006). Patients with DM should not follow a generic feeding pattern and therefore, an

individualised eating plan must be designed with the active participation of the patient (American Diabetes Association, 2018).

2.7.7 Physical activity

Physical activity involves any type of action that increases energy utilisation. Apart from improved glycaemic control and reduced insulin resistance, other benefits of physical activity include cardiopulmonary fitness, improved lipid profile, reduced blood pressure and weight loss (Sigal, Armstrong, Colby, Kenny, Plotnikoff, Reichert & Riddel, 2013). The response to physical activity varies depending on the type of DM, degree of glycaemic control, insulin bioavailability and diet (Bhaskarabhatla & Birrer, 2005). Physical activity helps prevent chronic DM complications and thereby improving the quality of life among people living with DM (World Health Organisation, 2016).

Pre-exercise must be done to assess if there is presence of contraindicated conditions that might adversely affect the patient. This therefore ensures that each patient's exercise is customised to best suit their status (American Diabetes Association, 2018). If physical activity is done at the right intensity for an optimal time it can lead to positive results which include reduced morbidity, prevention or slow progression of complications and premature mortality.

2.7.8 Smoking cessation

Smoking is a known independent factor that causes an increased risk in CVD and when combined with DM further increases the risk factors causing increased morbidity and premature mortality. Smoking causes the following effects in the DM population; reduced insulin sensitivity, impaired glycaemic control and lipid metabolism, increased blood pressure, increased total cholesterol and obesity. All these factors increase the chances of onset and progression of diabetic complications (Beziaud, Halimi, Lecomte & Tichet, 2004). DM patients who smoke need higher insulin doses to achieve glycaemic control.

2.8 IMPLICATIONS OF DM COMPLICATIONS

The nature and extent of DM complications plays key role in affecting the quality-adjusted life years of a patient. Individuals with complications have a lower quality of life as compared to those without (Hayes, Clarke, Voysey & Keech, 2011).

2.8.1 Health implications

If DM is not well controlled, it leads to an array of systemic complications and subsequent increased morbidity (World Health Organization, 2016). The longer the duration of DM, the greater the chances of developing complications. These complications negatively affect the patient's health status as some of them tend to have debilitating effects such as lower limb amputations, diabetic nephropathy, and diabetic retinopathy (World Health Organization, 2016).

Clinical implications of diabetic nephropathy on DM treatment

Patients with advanced stage kidney disease are at risk of adverse drug reactions due to reduced renal clearance of the drugs leading to accumulation of the drugs and adverse effects. This therefore, requires dose adjustments of the drugs the patient is taking to prevent adverse effects (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017). Table 2.1 below shows antihyperglycaemics and how they are supposed to be adjusted in the presence of diabetic nephropathy.

Table 2.1: Antidiabetic treatment adjustments

Class	Drug	Dosing recommendations in stage 3 and 4 CKD or kidney transplant	Dosing recommendations in dialysis
Insulin	Insulin	Downward dosage adjustment as there is decreased renal clearance of insulin with advanced CKD.	
Biguanides	Metformin	Use should be reviewed when the patient reaches stage 3 CKD. Avoid in stage 4 CKD.	Avoid use.
Sulfonylureas	Gliclazide and Glipizide	Preferred sulfonylureas No dose adjustments	Preferred sulfonylureas No dose adjustments
	Glibenclamide	Avoid use	Avoid use
	Glimepiride	Initiate at 1mg/day and titrate as required	Avoid use
Meglitinides	Repaglinide	No dose adjustment required	Avoid use
	Nateglinide	Initiate at 60mg before each meal	Avoid use
Thiazolidinediones	Pioglitazone	No dose adjustment required	No dose adjustment required.

Source: (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017)

Sick day medication list

When a patient feels sick and is unable to rehydrate or if they are dehydrated (due to diarrhoea and vomiting), they must withhold or dose-adjust some medications that may worsen their kidney disease (McFarlane, et al., 2018; Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017). These medications can be grouped

into two categories as shown below in table 2.2, which shows some examples in each category.

Table 2.2: Sick-Day Medication List

Medications that increase risk for a decline in kidney function	**Medications with reduced clearance and increased adverse effects**
ACE inhibitors	Sulfonylureas
ARBs	ACE inhibitors
Direct renin inhibitors	Diuretics, Direct renin inhibitors
NSAIDS	Metformin
Diuretics	ARBs
SGLT2 inhibitors	NSAIDS, SGLT2 inhibitors

Source: (McFarlane *et al*., 2018)

2.8.2 Economic implications

DM complications imposes a great economic burden on the global health care system. The burden is due to direct medical expenses, indirect expenses linked to reduced productivity, absenteeism from work, early retirement and premature mortality (World Health Organization, 2016). Direct medical expenses include paying hospital bills and buying medications (Hayes, Arima, Woodward, Chalmers, Poulter, Hamet & Clarke, 2016). The burden is on both the patient and the nation at large. In 2011, the United Kingdom, estimated that the treatment of DM complications accounted for 80% of the cost of DM to the National Health Service (Institute of Diabetes for Older People (IDOP) & Novo Nordisk, 2013).

2.9 SUMMARY

This chapter provided an extensive analysis of the existing literature on DM management, DM complications management and prevention. The chapter provided the available researches related to the current study and was used to identify if there

were any gaps in the existing literature. The next chapter will focus on the methodology used in data collection and ethical considerations followed to protect the participants.

CHAPTER 3
METHODOLOGY

3.1 INTRODUCTION

This chapter discusses the methods used in data collection and analysis in trying to address the research questions of the study. It describes the research design, sampling techniques and data collection methods used; and describes how data collected from the research was analysed.

3.2 BACKGROUND TO THE METHOD

Quantitative research method entails the emphasis of quantification in the data collection and analysis. It represents a deductive approach whereby a theory is tested in relation to the research. The research method incorporates the norms and practices of the natural scientific model, particularly positivism. It also incorporates objectivism in social reality (Bryman, 2016).

3.3 STUDY DESIGN

The research was done as a retrospective and cross-sectional quantitative study, divided into two phases namely retrospective and cross-sectional phases.

3.3.1 Retrospective study

The study involves the collection of data from past events where an outcome has already occurred at the time of data collection. This phase of the study involved reviewing patient records to gather relevant information for the study. The retrospective data was collected from the patients' past medical records for a period of five years spanning from June 2012 to May 2017. A retrospective study groups participants in terms of their shared exposure factor and ascertain its role in the progression of a disease. In this type of a study, the researcher looked back and identified DM patients who were initially complication free but possessed a risk of developing DM complications. The researcher then uses the available data sources or past records to determine what happens to the subjects from the beginning to the end of the study period.

3.3.2 Cross-sectional study

The second phase involved healthcare professionals (HCPs), where a self-administered questionnaire was used to obtain cross-sectional data about the current management practices of DM complications at Mankweng Hospital. The main objective of a cross-sectional study is the provision of data on the entire population under study. It involves the analysis of data collected from a population, or a representative subset, at one specific point in time.

3.4 STUDY SITE

This research was carried out at Mankweng tertiary hospital, situated approximately 30 km east of Polokwane in Limpopo Province. Mankweng tertiary hospital is one of the two major referral hospitals in Limpopo Province. It has a DM clinic that is dedicated for the provision of essential DM management. It services about 19 local clinics as a referral centre and is found in the rural areas within Capricorn district.

3.5 STUDY POPULATION

Retrospective study

In the retrospective stage of the study, DM patient records were used as the study population.

3.6 STUDY PERIOD

The study was done over a period of six months, stretching from January to June 2018. However, for the retrospective study, data accumulated over a 5-year period spanning from June 2012 to May 2017 was collected.

3.7 PILOT STUDY

Pre-testing of a data collection tool is essential in order to determine its accuracy before the main study. Pre-testing of a questionnaire involves trying it on a limited number of subjects who have characteristics similar to those of the target population the research intended to involve. (Welman, Kruger & Mitchell, 2005). Pilot studies

were conducted at Mankweng Hospital and University of Limpopo for DM complications checklist and HCPs' questionnaire respectively. The medical records used for pilot study were marked and excluded from the main study.

The pilot study was carried out to:

- Test the feasibility of patient files review process of the study.
- Check if the patient files were readily accessible when requested.
- Check if the checklist and the questionnaire addressed the objectives of the study and if necessary modify them.

3.8 SAMPLE SELECTION

Retrospective study

The researcher went to Mankweng Hospital OPD department to get the register for DM clinic. A list of the patients who attend the DM clinic was compiled and submitted to Records Department for retrieval of the patient files. After getting the files, the researcher started to select the files randomly using simple random sampling. Data was collected from the ones that met the inclusion criteria and the ones that did not meet the criteria were put aside.

Cross-sectional study

Due to small population of the HCPs, all HCPs working in the departments which formed part of the study's population were approached to participate in the study. However, not everyone approached was willing to take part in the study, further reducing the actual number of participants. The HCPs chosen for this study included medical doctors, pharmacists, professional nurses, physiotherapists, optometrists and a podiatrist. These HCPs were chosen because of the active roles they play in DM management and prevention and management of its complications. Medical doctors are there to monitor the progress and complication of DM, pharmacists play a role of providing pharmaceutical care, they interact with the patient on a regular basis allowing them to follow-up on patients and advise them to seek further help if there are complications arising when the patients are on the DM medication. Nurses

do the anthropometric tests and examination of blood glucose and blood pressure; this gives them a crucial role as these tests are used to reflect progress or degrading health condition. Another complication of DM is retinopathy, which is why I had to include optometrists as they are the first line of response if a diabetic patient is developing diabetic retinopathy. The podiatrist is involved in early detection of peripheral neuropathy.

3.9 INCLUSION AND EXCLUSION CRITERIA

3.9.1 Inclusion criteria

Retrospective study

- All Mankweng Hospital DM patient files with information from June 2012 to June 2017 were included as part of the study.

Cross-sectional study

- The HCPs included in this study were medical doctors and professional nurses from out-patients department and medical wards as well as pharmacists, physiotherapists, optometrists, and a podiatrist.

3.9.2 Exclusion criteria

Retrospective study

The following patients' medical records were excluded from the study:

- Those that did not contain adequate information for the period of study mentioned in the study.
- Patient files with the information haphazardly arranged making it difficult to sequentially follow the events.

Cross-sectional study

- Newly employed HCPs, specifically those employed from January 2016 onwards.

3.10 DATA COLLECTION INSTRUMENTS

Two data collection tools were used in this study. For phase I, a diabetes complications checklist was used as an audit tool to collect the relevant information required for this study. A self-administered questionnaire was used in phase II, where HCPs had to fill in the questionnaire. These tools are briefly described below.

3.10.1 Diabetes Complications Checklist

The researcher used a self-originated diabetes complications checklist to collect data from medical records at Mankweng Hospital. The checklist was divided into two sections: Section 1 comprised of the demographic data while section 2 focused on the clinical data (DM complications and monitoring tests done per every visit). Below are the parameters that were investigated:

- Demographic data: gender, age, and race;
- Clinical data: type of DM, treatment, comorbidities, presence of complications, year of diagnosis of complication, clinical tests and examinations done and how frequent they were done.

3.10.2 Questionnaire

In phase II of the study, the researcher used a self-administered questionnaire, which was distributed amongst different HCPs. The questionnaire consisted of two sections; section A (biographical data) and section B (DM complications management).

3.11 DATA CAPTURE AND ANALYSIS

After data collection, the data was captured and analysed using IBM SPSS version 25. The data was coded, captured, audited and cleaned before analysis to maintain integrity of the collected data. Descriptive statistics was determined using frequencies of DM complications at Mankweng Hospital.

3.12 BIAS

Bias can occur during data collection, analysis, interpretation and publication. It leads to drawing of false conclusions and recommendations in research. To avoid biasness in this research, the researcher used random sampling of patient files during data collection.

3.13 RELIABILITY AND VALIDITY

Ensuring reliability and validity of a study is a major concern, failure to do so can lead to rejection of the study findings. Reliability means that the study is reproducible. In this study, it refers to consistency of the data collecting tools to have reproducible results. Reliability and validity of the data collection tools was ensured by conducting pilot studies at Mankweng Hospital and University of Limpopo. A tenth each of the total population sizes was used and the files used in the pilot studies were marked and excluded from the main study. This was done to check if the data collection tools are answering the objectives of the study.

To ensure validity and reliability of the collected data, only the researcher was involved in data collection. The researcher submitted the data collection tools to the supervisors to verify if they covered the objectives of the study. The university statistician was also consulted to evaluate and carryout statistical tests on the validity of the data collection tools. The supervisors and the statistician checked if all the variables were recorded and categorised accordingly during data capturing.

3.14 ETHICAL CONSIDERATIONS

It is essential for a researcher to follow set ethical guidelines in order to protect the participants of the research from actual or potential harm. The moral standards set are of concern to the researcher as the success of their research depends on public cooperation and henceforth, the ethics should be always adhered to. It was the researcher’s obligation to protect and, not coerce or deceive participants.

Respect and dignity

It is of great importance that ethical guidelines are followed when conducting a research. The researcher has an obligation to ensure respect and dignity of the participants who will provide data in this study by not harming, forcing or deceiving them. Permission to use the patients' records was sought from the hospital management. The researcher used a coding system and omitted any information that could identify the patients. The researcher acknowledged and protected the autonomy of the participants. Respect and human dignity forms the basis of the following ethical requirements.

Approval

Ethics were strictly observed and approval to carry on with the research was sought. The following things were done:

- Ethical clearance was obtained from University of Limpopo Turfloop Research and Ethics Committee (TREC) (Appendix 1).
- Approval to conduct the study at Mankweng Hospital was sought from and granted by the Department of Health, Limpopo Province (Appendix 2)
- Permission to use patient records and distribute questionnaires to healthcare professionals was given by Mankweng Hospital Chief Executive Officer (Appendix 3)

Informed consent and voluntary participation

Participation was voluntary, and participants had the right to withdraw at any time without any penalty imposition. HCPs were given informed consent forms to sign as an agreement that they understood what the study was all about and were voluntarily participating in the research study.

Anonymity and confidentiality

Participants were assured of the confidentiality of the study by limiting access to the collected data to the researcher and the supervisors only. The information obtained was not used for any other purposes other than for research purposes. No names were required from the patient files or HCPs participating in the study. No other

information obtained from the files questionnaires that could potentially identify any participant were published in the research.

3.15 SUMMARY

This chapter discussed about the methodology that was used in conducting this study. Also addressed in this section was the ethical considerations followed as the study involved human beings. The results obtained will be presented and discussed in chapter 4.

CHAPTER 4
RETROSPECTIVE STUDY RESULTS AND DISCUSSION

4.1 INTRODUCTION

This section focuses on the results of the study that investigated the prevalence of DM complications at Mankweng Hospital, Limpopo Province. The results were discussed and compared with other results from previous studies.

4.2 PATIENT DEMOGRAPHICS

Patient demographics are presented in table 4.1. The data were extrapolated from patient records through retrospective study. A total of 134 patient records were reviewed. Of those 134, 29.9% were males and 70.1% were females. The highest proportion (61.2%) of patients by age were above 60 years, followed by those between 51 and 60 years at roughly 20%. The age group with the least number of patients was 21-30 years, with only one (0.7%) patient. The data shows that most the diabetic patients in this study were elderly people. There was no significant relationship between age and gender (p=0.44).

As expected, most (82.8%) of the diabetic patients in this study had T2DM. Within the male patients, 72.5% had T2DM while 27.5% had T1DM. Amongst the female patients, 87.2% had T2DM and 12.8% had T1DM. The comparison between gender and type of DM showed that males are more likely to have T1DM (27.5% vs. 12.8%). Chi-square showed that there was a statistically significant difference between type of DM and gender (p=0.038). The results also showed that all patients below 40 years had T1DM and its prevalence decreased with increase in age. This trend was statistically significant (p=0.000).

Table 4.1: Patient Demographics

	Male N=40 (29.9%)	Female N=94 (70.1%)	Total N=134
Age			
21-30	0	1	1
	0.0%	1.1%	0.7%
31-40	5	4	9
	12.5%	4.3%	6.7%
41-50	5	10	15
	12.5%	10.6%	11.2%
51-60	8	19	27
	20.0%	20.2%	20.1%
Above 60	22	60	82
	55.0%	63.8%	61.2%
Type of DM			
T1DM	11	12	23
	27.5%	12.8%	17.2%
T2DM	29	82	111
	72.5%	87.2%	82.8%

4.3 TREATMENT

Figure 4.1 shows the treatment options that were prescribed for the patients at the point of data collection. The highest number (42.5%) of patients were prescribed oral hypoglycaemics only, followed by those that were prescribed insulin only with 35.1%. The remaining 22.4% were prescribed a combination of an oral hypoglycaemic and insulin. A majority (51.4%) of T2DM patients were on oral hypoglycaemics only.

Metformin in combination with glimepiride was the most prescribed oral hypoglycaemic regimen followed by metformin alone. A majority (73.9%) of T1DM patients were treated with insulin only. As per South African treatment guidelines, none of T1DM patients were on oral hypoglycaemic only. The results indicate that patients with T2DM are more likely to be on oral hypoglycaemics therapy whereas patients on T1DM are more likely to be on insulin. There was a statistically significant relationship between the type of DM and treatment received by the patient (p=0.000).

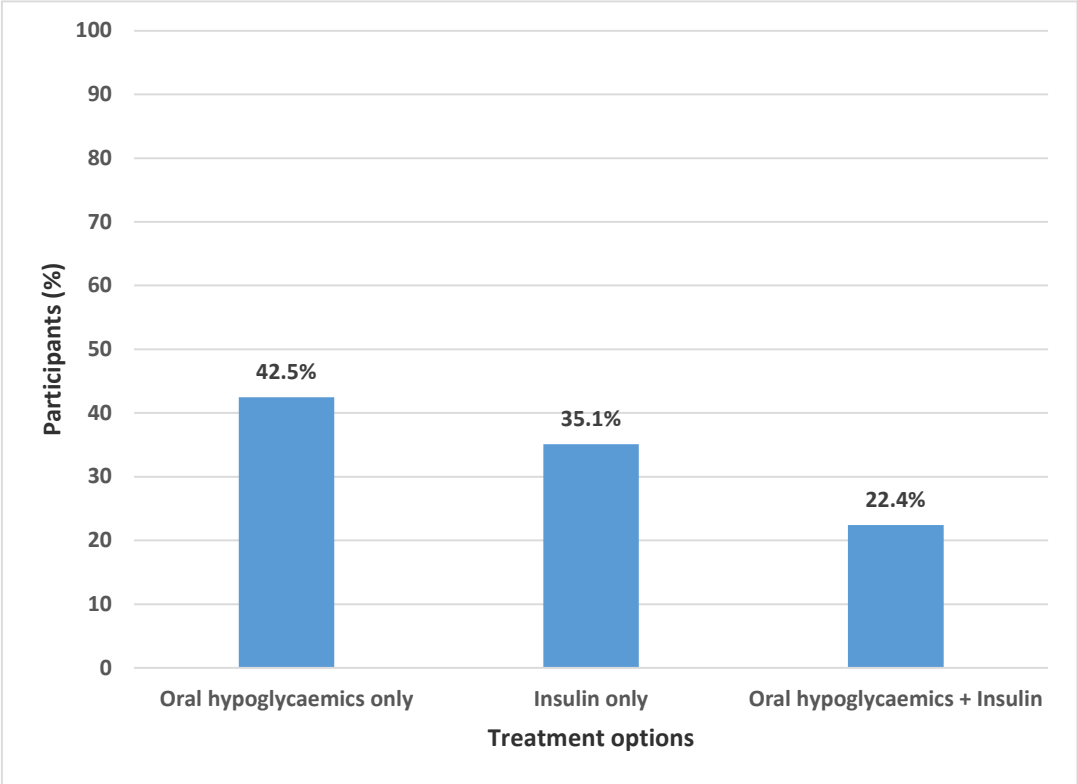

Figure 4.1: Treatment regimens versus percentage population

4.4 COMORBIDITIES

For the purpose of differentiating comorbidities and DM complications, the comorbidities represented in this section were those diagnosed before or during the diagnosis of DM. As shown in figure 4.2, hypertension was the most (94.8%) prevalent comorbidity amongst the patients. Tables 4.2 and 4.3 show the prevalence of comorbidities within gender and type of DM respectively. Hypertension was more prevalent in female patients as compared to their male counterparts (97.9% vs. 87.5%). Chi-square test showed that this relationship was statistically significant

(p=0.014). It was also noted that amongst the patients with T2DM, the prevalence of hypertension was overwhelmingly high (99.1%).

The second most prevalent comorbidity was dyslipidaemia with 42.5% and it had a higher prevalence within female patients as compared to their male counterparts, (46.8% vs. 32.5%). The results obtained did not show a statistically significant relationship between dyslipidaemia and gender (p=0.125). The results also showed a higher prevalence of dyslipidaemia among T2DM as compared to T1DM patients (45% vs. 30.4%), with no statistically significant relationship (p=0.197).

Obesity was the least prevalent (10.4%) comorbidity in this study, showing a higher prevalence among female patients than males (13.8% vs. 2.5%). As expected, obesity was higher amongst T2DM patients as compared to those with T1DM (11.7% vs. 4.3%). There was no statistically significant relationship between obesity and the demographic factors (gender and type of DM). As observed earlier that all patients below 40 years had T1DM, it was noted that none of these patients were obese.

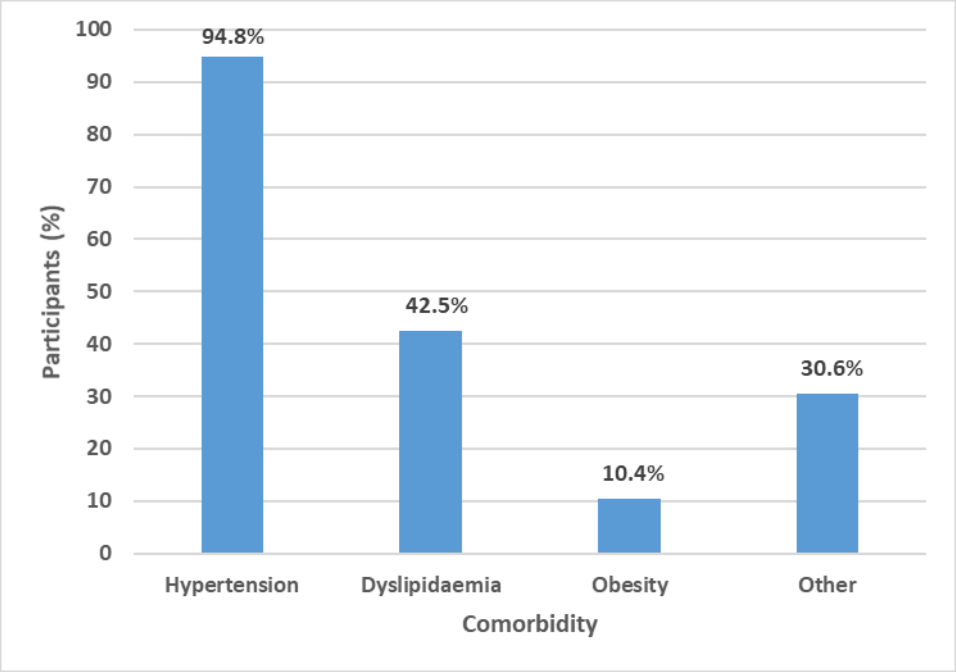

Figure 4.2: Prevalence of comorbidities

Table 4.2: Prevalence of comorbidities according to gender

Comorbidity	Male	Female	Total	*p* value
Hypertension	35(87.5%)	92(97.9%)	127(94.8%)	0.014
Dyslipidaemia	13(32.5%)	44(46.8%)	57(42.5%)	0.125
Obesity	1(2.5%)	13(13.8%)	14(10.4%)	0.050

Table 4.3: Prevalence of comorbidities according to type of DM

Comorbidity	T1DM	T2DM	Total	*p* value
Hypertension	17(73.9%)	110(99.1%)	127	0.000
Dyslipidaemia	7(30.4%)	50(45%)	57	0.197
Obesity	1(4.3%)	13(11.7%)	14	0.293

4.5 GLYCAEMIC CONTROL

Under glycaemic control, the researcher looked at random blood glucose and HbA1c results. As hyperglycaemia plays a pivotal role in the development of DM complications, it is of paramount importance to ensure that it is well controlled to delay the onset and progression of complications.

4.5.1 Random blood glucose results

Continuous glucose monitoring may be used to assess glycaemic control which is essential in making therapeutic decisions. In the current study patients with controlled RBG was defined as those with highly controlled, controlled and sub-optimally controlled RBG. Table 4.4 shows the results obtained from this study. The cumulative percentages of the patients who were controlled were 56.5%, 62.6%, 54.0%, 59.1% and 62.3% from year 1 to year 5 respectively. Generally, these results show a poor glycaemic control as significant percentages are uncontrolled. The sustained hyperglycaemic conditions result in the development of complications and

subsequent poor prognosis. Year 2 and 3 represents the highest and second highest percentages of controlled participants at 62.6% and 62.3%. However, there has been improvements from year 3 to year 5, with more people's blood glucose becoming more controlled.

Table 4.4: Random Blood Glucose Results

	Year 1	***Year 2***	***Year 3***	***Year 4***	***Year 5***
Highly controlled (%)	8.7%	6.3%	7.0%	7.1%	6.9%
Controlled (%)	27.5%	42.5%	31.0%	34.7%	35.6%
Sub-optimally Controlled (%)	20.3%	13.8%	16.0%	17.3%	19.8%
Not Controlled (%)	29.0%	12.5%	21.0%	17.3%	23.8%
Highly Not Controlled (%)	14.5%	25.0%	25.0%	23.5%	13.9%
Total (%)	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

(Highly controlled BG ≤ 5; Controlled BG = 6 - 8; Sub-optimally Controlled BG = 9 - 10; Not Controlled BG = 11 - 14; Highly Not Controlled BG ≥ 15)

4.5.2 HbA1c results

Optimal glycaemic control forms one of the most fundamental aspects of DM management. HbA1c >7% is associated with a significant increased risk of DM complications (Imran, Agarwal, Bajaj & Ross, 2018). Table 4.5 summarises the HbA1c results obtained in this study. The table shows that there has been a reduction in the fractions of patients with poorly controlled HbA1c levels with time. This pattern continues in a downward trend (48.0%, 46.7%, 39.1%, 35.9% & 29.9%) from year 1 to year 5. This represents improvement in the management of DM.

The patients with HbA1c which was sub-optimally controlled, had the lowest value in year 2 with 17.8% whereas the highest was recorded in year 4 with 37.0%. This category falls within the range of 7.1 to 8.5%. This target is acceptable for the elderly, weak, those with short life expectancy, multiple co-morbidities, recurrent hypoglycaemia and advanced chronic kidney disease (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017).

The percentages of patients falling within the target recommended for many patients with DM recorded the lowest in year 1 and the highest in year 2, with 24.0% and 35.6% respectively. These figures show that most patients in this study fell outside the optimal HbA1c target. This reveals that the management of DM used is failing to control most of the patients which subsequently affects the expected clinical outcomes. The main aim is to have many patients reach this target of HbA1c ≤ 7%. Evidence obtained from several researches shows that early optimal glycaemic control significantly reduces the occurrence of DM complications. In summation, these results may lead to an increased morbidity and mortality due to a high prevalence of DM complications.

Table 4.5: HbA1c Results

	Year 1	***Year 2***	***Year 3***	***Year 4***	***Year 5***
Well-controlled (%)	24.0%	35.6%	30.4%	27.2%	33.3%
Sub-optimally Controlled (%)	28.0%	17.8%	30.4%	37.0%	36.8%
Poorly Controlled (%)	48.0%	46.7%	39.1%	35.9%	29.9%
Total (%)	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

(Well-controlled HbA1c ≤ 7%; Sub-optimally Controlled HbA1c = 7.1% – 8.5%; Poorly Controlled HbA1c ≥ 8.6%)

Findings from the current study revealed that the risk to develop complications increases with the duration of DM despite the glycaemic control of the patient. In year one, none of the well-controlled patients had complications. However, from year two to year five, there was a steady increase (21.7% to 33.9%) in the occurrence of complications within the well-controlled patients.

4.6 PREVALENCE OF DM COMPLICATIONS

4.6.1 Prevalence of complications overview

The results revealed that at the point of data collection, two-thirds of the patients had one form of complication. In year one, the number of patients with complications was 28 (20.9%). Further looking into year one, most of the patients had peripheral

neuropathy and/or diabetic retinopathy. Diabetic neuropathy stood at 57.1% and retinopathy at 50%. The least prevalent complication within the patients with complications in year one was diabetic foot ulcer at 17.9%.

Diabetic neuropathy remained the most prevalent complication within the patients with complications in year two at 55.6%. Diabetic nephropathy increased to be the second most prevalent complication from 32.1% in year one to 46.7% in year two. Diabetic retinopathy reduced from 50% in year one to 37.8% in year two. Diabetic foot ulcer remained the least prevalent complication at 11.1%.

In year three, diabetic nephropathy prevalence continued on an upward trend to become the most prevalent complication at 53.7%. Peripheral neuropathy was recorded at 49.3% in year three. Diabetic retinopathy continued to decrease from 37.8% in year two to 34.3% in year three. Diabetic foot ulcer prevalence reduced from 17.9% in year one to 9% in year three, remaining the least prevalent complication.

In year four, more than half of the patients had one form of complication. Within this population, the most prevalent complication remained diabetic nephropathy at 57%, followed by peripheral neuropathy at 49.4%. Diabetic foot ulcer was the least prevalent complication, with a prevalence of 7.6%. Diabetic retinopathy showed a slight increase in year four from 34.3% in year three to 36.7%.

In year five, the overall prevalence of complications was 67.2% and of these, 53.3% had diabetic nephropathy. The second highest prevalent complication was peripheral neuropathy at 47.8% following diabetic nephropathy. Diabetic foot ulcer was the least prevalent complication in year five at 8.9%. However, diabetic foot ulcer and vascular diseases showed slight increases (1.5% and 0.5%, respectively) in their prevalence in year five. This was contrary to all the other complications which showed reductions in their prevalence.

The prevalence of complications in general increased with time from year one to year five (20.9% to 67.2%). Amongst the complications, the prevalence of diabetic nephropathy continuously increased with time. Peripheral neuropathy and diabetic retinopathy prevalence showed continuous decreases from year one to year five. The prevalence of vascular diseases and autonomic neuropathy were constantly

less than 25% with an average prevalence of 16% and 17% respectively for the five-year period. The prevalence of diabetic foot ulcer steadily remained the least throughout the five-year period with an average of 10.9%. The total number of complications exceeded the actual number of patients with complications, indicating that some patients had more than one complication at a given time. In year one, the results indicated that among patients with complications, there were at least two complications per patient. While the number of complications over the years increased, the ratio per patient decreased from 1:2 to at least 1:1.5.

4.6.2 Relationship between different types of complications

Majority (75%) of the patients with diabetic foot ulcer had peripheral neuropathy. The results indicate that patients with diabetic foot ulcer are more likely to have peripheral neuropathy. This relationship was statistically significant (p=0.007). Furthermore, the results indicated that 62.5% of the patients with diabetic foot ulcer also had diabetic retinopathy. This shows that patients with diabetic foot ulcer are more likely to have diabetic retinopathy. This trend showed a statistically significant relationship (p=0.005). These results showed that at least a third of the patients with diabetic foot ulcer also had autonomic neuropathy. The Chi-tests showed that this relationship was statistically significant (p=0.004). Notably, 44.2% of the patients with diabetic nephropathy also presented with peripheral neuropathy, showing a statistically significant relationship (p=0.038).

4.6.3 Relationship between complications and demographic variables

Complications and gender

The results further revealed that more than half of the patients who had one form of complication were females. Nonetheless, Chi-tests did not show any statistically significant relationship with gender. The results obtained indicated that the prevalence of diabetic foot ulcer was higher in males (62.5%) than in females. Chi-tests revealed that there was statistically significant relationship between diabetic foot ulcer and gender (p=0.037).

Complications and age

The majority (75%) of patients with diabetic nephropathy were those above 60 years of age. Less than 10% of these patients were 40 years and below. The results revealed a statistically significant relationship between diabetic nephropathy and age (p=0.010). The results further revealed that 67.4% of the patients with peripheral neuropathy were above the age of 60 years. However, this did not show a statistically significant relationship (p=0.089). Furthermore, the results indicated that diabetic retinopathy prevalence was higher (46.7%) in patients above 60 years.

Complications and type of DM

Findings from this study revealed that 69.4% of the patients with T2DM had complications as compared to 56.5% with T1DM. This showed that both types of DM have more than 50% chance of developing complications. Chi-square analysis revealed that there is no statistically significant relationship between the development of complications and type of DM (p=0.232).

4.6.4 Prevalence of individual complications

Figure 4.4 shows the prevalence of individual complications within the sample population. The complications with the highest prevalence in this study in a descending order were diabetic nephropathy, diabetic neuropathy and diabetic retinopathy with 35.8%, 32.1% and 22.4% prevalence respectively.

Diabetic nephropathy presents one of the most complex diabetic complications with need to take extra caution in providing pharmacotherapy for the patient. Locally, the prevalence of diabetic nephropathy is between 14-16% and of these, 30.4% requires renal replacement therapy (Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). This therefore, shows that in the current study, there was an over-representation in prevalence by more than double at 35.8%. Of all the patients with diabetic nephropathy, 84% were suffering from T2DM while T1DM accounted for the remaining 16%. However, when the prevalence of diabetic nephropathy was checked against the type of DM, it was found to have 34.8% and 36% prevalence in T1DM and T2DM respectively (p=0.909). Hypertension was found to contribute to the aetiology of diabetic nephropathy (Society of Endocrinology Metabolism and

Diabetes of South Africa, 2017). In this current study, the prevalence of hypertension within the patients with diabetic nephropathy was 93.8% (p=0.690%).

The prevalence of peripheral neuropathy was 32.1% in the current study, showing the second highest prevalent DM complication. The prevalence of peripheral neuropathy in patients with T1DM was 21.7% as compared to 34.2% in those with T2DM (p=0.243). In the current study, is no association between the prevalence of peripheral neuropathy and type of DM. Peripheral neuropathy is usually present in varying degrees in 50% of people with DM and are older than 60 years (Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). Of the 32.1% who had peripheral neuropathy, 11.6% had T1DM while 88.4% had T2DM. Clinical peripheral neuropathy may be present in people with T2DM at the diagnosis time or even in the pre-diabetes stage while it is uncommon in people with T1DM during the first 5 years of diagnosis (Bril *et al*., 2013). The least prevalent complication in this study was diabetic foot ulcer at 6%. Of the patients with diabetic foot ulcer, 25% were amputated (p=0.000).

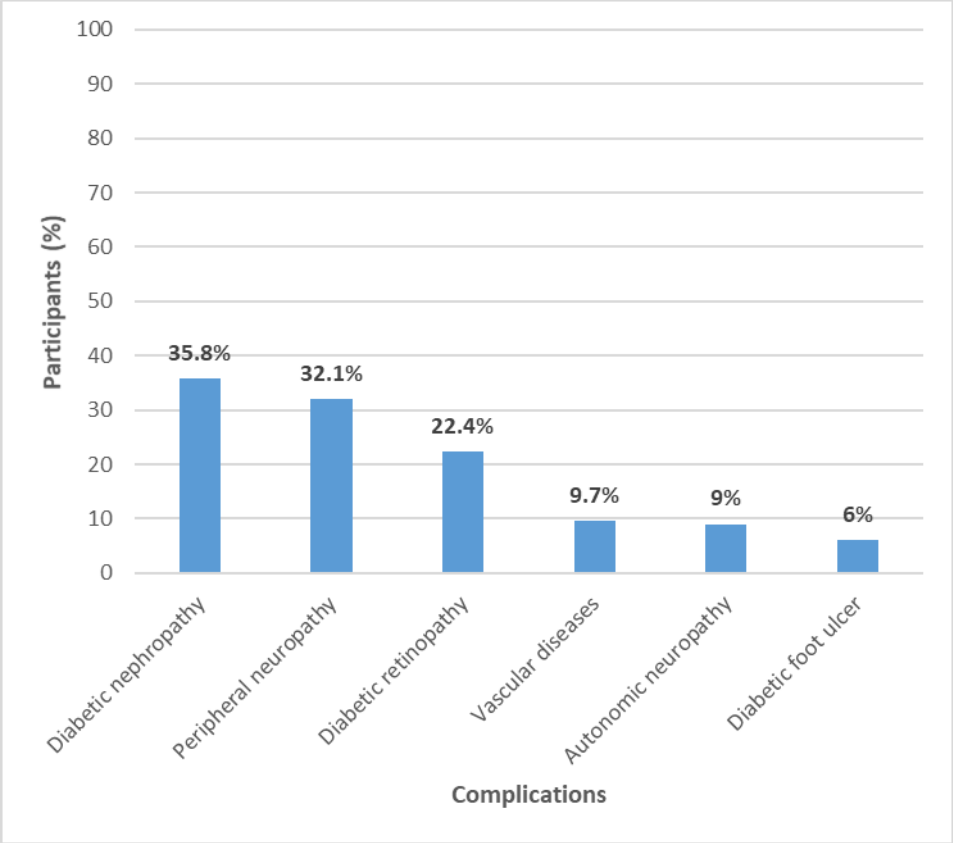

Figure 4.4 Prevalence of individual DM complications

4.6.5 Yearly prevalence of complications

The results portrayed in figure 4.5 show a continued increase in the prevalence of DM complications from year 1 through year 5. Year 1 had a prevalence rate of 20.9% while year 5 had a prevalence rate of 67.2%. The prevalence increase from year 1 to year 5 might be because of the increased duration of DM, which increases the risk of complication (Nathan, 2014). The greatest increase in the prevalence rates was between year 2 and year 3 with a 16.4% increase from 33.6% to 50%, whilst the smallest increase was recorded between year 4 and year 5 with an 8.2% increase from 59%.

The prevalence rate of complications in this study was higher in males as compared to their female counterparts in the first two years. In year 1, male patients had a prevalence rate of 25% as compared to their female counterparts who had a prevalence rate of 19.1%. An increase in prevalence was recorded in both males and females where they increased to 35% and 33% in year 2, respectively. However, the increase in females was high at 13.9% as compared to 10% in males. In year 3, the prevalence of complications in female patients was higher than in males (51.1% vs. 47.5%). This pattern was observed in the preceding 2 years. Females recorded 61.7% and 68.1% vs. 52.5% and 65% for males in year 4 and year 5 respectively. In the overall prevalence of complications (in year 5), the prevalence of complications in males versus females was 65% vs. 68.1% (p = 0.728). This shows an insignificant difference between the prevalence of complications in males and females.

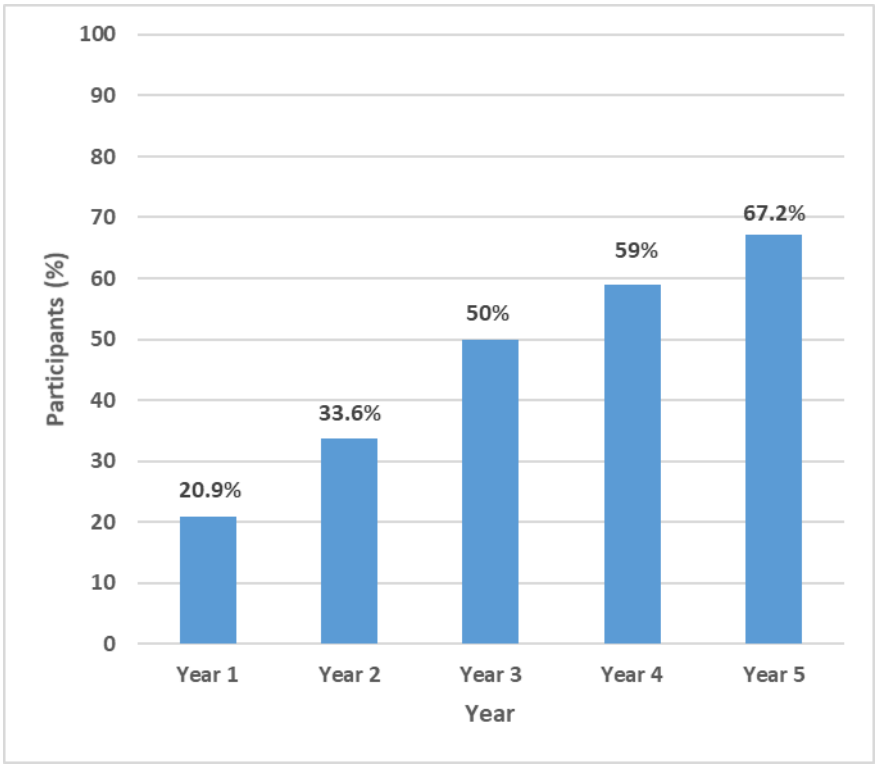

Figure 4.5 Yearly prevalence of DM complications

4.7 DISCUSSION

In this study, more than 80% of the patients were above the age of 50 years. As expected, 82.8% of the patients had T2DM. Ageing population is considered one of the several factors associated with a high prevalence in T2DM (Pheiffer, Pillay-van Wyk, Joubert, Levitt, Nglazi & Bradshaw, 2018). Not surprisingly, the aged population in this study might have contributed to the high prevalence of T2DM. These results did not deviate much from the global estimated T2DM prevalence of around 90% (Georgoulis *et al*., 2014; Cho *et al.*, 2018). The prevalence of DM was significantly high in females. This was not surprising as the risk factors for DM which include physical inactivity and obesity are high in females than males (World Health Organization, 2016).

Hypertension is one of the most common comorbidities amongst patients with DM (Pantalone, Hobbs, Wells, Kong, Kattan, Bouchard, Yu, Sakurada, Milinovich, Weng, Bauman & Zimmerman, 2015). Long & Dagogo-Jack, (2011), revealed that a majority of patients with DM have concomittant hypertension. Similarly, findings from this research revealed that hypertension was the most (94.8%) prevalent comorbidity. People with DM are at a higher risk of developing hypertension than the

general population (Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). This high prevalence could be also as a result of a higher proportion of the aged population in this study as the risk of developing hypertension increases with age.

Globally, the prevalence of DM complications range from 21% to 89% (Litwak, Goh, Hussein, Malek, Prusty & Khamseh, 2013). The findings of this study revealed that an overall prevalence of DM complications over a five-year period was 67.2%. In this study, the prevalence of complications increased with time (20.9%, 33.6%, 50%, 59% and 67.2%) from year one through year five respectively. Based on this study, the patients under study were on DM treatment for at least five years. Therefore, the the high prevalence of DM complications could be attributed to long duration of DM, which has been established to be a major factor in the development of complications (Nathan, 2014). The other reason could be because of the fact that Mankweng Hospital is a tertiary hospital serving as a referral base for level one and two facilities. On the contrary, a recent study conducted in India, revealed a higher prevalence of DM complications of 84.4% (Simi, Thangamani & Radhakrishnan, 2017). These differences could be as a result of different levels of DM care, patient demographics and lifestyle. Another study conducted in Ethiopia showed an overall DM complications prevalence of 59.7% (Abejew, Belay & Kerie, 2015). In contrast, findings from another study showed a lower (50.2%) prevalence of complications as compared to the current study (Stanifer, Cleland, Makuka, Egger, Maro, Maro, Karia, Patel, Burton & Phillipin, 2016).

It was evident from this study that in the early stages of DM, the main factor related to the occurrence of complications was poor glycaemic control but as the duration increases, glycaemic control becomes insignificant. It can be concluded that poor glycaemic control is related to the development of DM complications in the early stages but is insignificant as the duration increases. As the duration of DM increases, both controlled and uncontrolled patients have the same probability of developing complications. In support of this view, Stolar (2010) indicated that certain complications may develop even in patients who are controlled.

The estimated prevalence of diabetic nephropathy in SA ranges from 14-16% (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017).

However, the prevalence of diabetic nephropathy in this study was found to be 35.8%. Comparable to this finding is another local study which reported a prevalence of 33.6% (Ngassa, Van Zyl & Rheeder, 2015). Furthermore, these findings were within the range (32-57%) of diabetic nephropathy prevalence in Africa (Mbanya & Sobngwi, 2003). Nonetheless, there is need for further studies to confirm these observations since SEMDSA estimates were lower than findings from these studies. Findings from a study conducted in Germany revealed a lower (10%) prevalence of diabetic nephropathy as compared to the current study (Heller, Blum, Spraul & Wolf *et al*., 2014). On the other hand, two previous studies reported higher prevalence of diabetic nephropathy than the current study showing 46.8% and 64.6% (Maniarasu & Muthunarayanan, 2017; Simi *et al.*, 2017) respectively. These variations with the current study could be credited to the differences in the population and sample sizes and racial susceptibility to develop nephropathy. In addition, the results obtained in this study showed a prevalence of diabetic nephropathy in patients with T1DM and T2DM at 34.8% and 36% respectively. There was no difference in the prevalence of diabetic nephropathy between T1DM and T2DM in the current study. These results however differ from the ones obtained by Ngassa et al. (2015), who reported a higher prevalence of diabetic nephropathy in T1DM. Sample size and the proportions of T1DM to T2DM patients in the study populations could have contributed to these differences in the two studies.

The second highest prevalent complication in this study was peripheral neuropathy at 32.1%. These findings align with results from a local epidemiological study which found the prevalence of diabetic peripheral neuropathy to be 30.3% (Jacovides, Bogoshi, Distiller, Mahgoub, Omar, Tarek & Wajsbrot, 2014). Similarly, Kuate-tegueu *et al.*, (2015) observed a 33.3% prevalence of peripheral neuropathy in a Cameroonian population. In contrast, the overall prevalence of diabetic peripheral neuropathy in the Middle East and North Africa region was higher than the results obtained in this study at 43.2% (Garoushi *et al*., 2018). Variations in the prevalence of peripheral neuropathy is attributed to diagnostic criteria, geographical and population contributions (Aslam, 2014). Moreover, the results revealed a higher prevalence in female patients as compared to their male counterparts (37.2% vs. 20.0%). Abbott, Malik, van Ross, Kulkarni & Boulton, (2011) also obtained a similar pattern showing higher prevalence in females than in males having 38% vs. 31%.

Women have been reported to have a 50% increased risk of developing peripheral neuropathy than men after age and DM duration adjustments. In the present study, it was also established that peripheral neuropathy was a significant risk factor for the development of diabetic foot ulcer. Of all the patients with diabetic foot ulcer, 75% also had peripheral neuropathy. This aligns with previous studies, which revealed that peripheral neuropathy is a strong independent factor for diabetic foot ulcer (Deribe, Woldemichael & Nemera, 2014). It is therefore advisable that efforts must be taken to prevent the development of peripheral neuropathy and thereby reducing the possibility of diabetic foot ulcer and amputations.

The global estimated prevalence of diabetic retinopathy is 34.6% (Ting, Cheung & Wong, 2016; Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017). In the current study, diabetic retinopathy was the third most prevalent complication in this study at 22.4%. Comparable to these findings are those found in two local studies which revealed a diabetic retinopathy prevalence range from 25% to 29% (Webb, Rheeder & Van Zyl, 2015; Webb, Rheeder & Roux, 2016). However, the prevalence of diabetic retinopathy in the Sub-Saharan Africa have shown high degrees of inconsistency, with prevalence ranging from 32.5% to 52% (Glover, Burgess, Cohen, Harding, Hofland, Zijstra & Allain, 2012; Lewis, Hogg, Chandran, Musonda, North, Chakravarthy, Sivaprasad, & Menon, 2018). This range shows higher prevalence rates than the one obtained in the current study. In a recent Indian study by Prakash & Yadav (2018), they reported a diabetic retinopathy prevalence of 74%. These variations could be caused by differences in patient demographics, geographic locations and quality of DM care. There was no statistically significant relationship between the prevalence of diabetic retinopathy in T1DM and T2DM with prevalence of 21.6% and 26.1% respectively. These findings showed a similar pattern to that conducted by Glover *et al.* (2012), showing a slightly higher prevalence of diabetic retinopathy in T2DM. The slightly high prevalence of diabetic retinopathy in T2DM could be as a result of duration of DM, poor glycaemic control and comorbid conditions which include hypertension and hyperlipidaemia.

DM patients are at a higher risk of developing vascular diseases as compared to the general population. The prevalence of vascular diseases in this particular study was 9.7%. Vascular diseases in this study referred to coronary artery disease, cerebrovascular accidents and peripheral vascular diseases. Previous studies have

shown great disparities in the prevalence of vascular diseases in DM patients ranging from 4.4% to 40% (Zhou *et al.*, 2014; Thiruvoipati, Kielhorn & Armstrong, 2015; Al-nozha, Ismail & Al Nozha, 2016). In a study conducted in India, the prevalence of vascular diseases was even higher showing a prevalence of 50.7% (Vaz, Ferreira, Kulkarni, Vaz & Pinto, 2011).

The prevalence of autonomic neuropathy in this study was 9%. Previous studies have shown that the prevalence of autonomic neuropathy ranges from 2.5 to 50% (Tesfaye, Boulton, Dyck, Freeman *et al.*, 2010). These variations are attributed to diagnostic criteria, definition and the population under study (Verrotti, Prezioso, Scattoni & Chiarelli, 2014).

The lifetime risk of developing diabetic foot ulcer has been estimated to be 25% (Ntuli, Lambert & Swart, 2018). The findings of this research however, recorded a much lower diabetic foot ulcer prevalence of 6%. These results were similar to those reported in a meta-analysis study which revealed a global prevalence of 6.3% while an African prevalence was slightly higher at 7.2% (Zhang, Lu, Jing, Tang, Zhu & Bi, 2017). However, Europe and Oceania reported lower (5.1% and 3.0%) prevalence of diabetic foot ulcer as compared to the current study (Zhang *et al.*, 2017). In contrast, the current findings were lower than those obtained in a local study done at a Johannesburg Hospital which had a diabetic foot ulcer prevalence of 12.5% (Mokoena, 2017). In another local study, the prevalence of diabetic foot ulcer was significantly high (28%) as compared to results from this study (Ntuli *et al.*, 2018). The prevalence of diabetic foot ulcer was higher in males (62.5%) than in females.

It is therefore, of paramount importance for the HCPs after knowing about the problems to be able to address them using some of the evidence-based solutions used in other countries. An example of such programmes is the point of care testing that can be used to improve DM management thereby slowing down the progression of complications. A review conducted by Schnell *et al*. (2017), concluded that point of care testing of HbA1c leads to an increase in adherence to testing guidelines, improved therapeutic outcomes and patient fulfilment. Additionally, it was found to be cost effective for both HCPs and patients. However, for this programme to succeed, it has to be fully supported in order to benefit all the stakeholders (Price & St. John, 2019). Findings of a study conducted in Cape Town, here in South Africa showed

that the introduction of a point of care testing in DM management promoted a positive change in clinical practice and improved HbA1c accessibility which is important for the clinical monitoring of the patients (Motta, Shepherd, Brink, Lawson & Rheeder, 2017). This shows that the programme can be adopted and successfully implemented provided it is given all the support it requires to benefit all the stakeholders.

4.8 SUMMARY

In summary, it is evident that SA compares very well with other African countries in terms of the prevalence of DM complications. However, when compared to European countries, the prevalence of DM complications in general is higher in SA. SA is however performing fairly well than Asian countries as the prevalence of complications in SA was relatively lower. These variations could be attributed to similarities or differences in demographics and socio-economic status amongst the study populations, geographical location and, quality of DM care.

The current study also confirmed that the risk of developing complications increases with the duration of DM as evidenced by a continuous increase in the prevalence of complications from year one to year five within the study population. This therefore, highlights the need for constant clinical follow-up using evidence based guidelines. This should be done by a multidisciplinary team that has received specific training in DM care to ensure proper management of the patients. Systems audits and quality improvement strategies should form part of DM care.

CHAPTER 5

CROSS-SECTIONAL STUDY RESULTS AND DISCUSSION

5.1 INTRODUCTION

This chapter presents the results obtained from the cross-sectional study on the management of DM complications at Mankweng Hospital. The data obtained were presented in tables and graphs, and the results were discussed and compared with the existing literature from previous studies.

5.2 HEALTHCARE PROFFESIONALS DEMOGRAPHICS

5.2.1 Gender and age

The healthcare professionals (HCPs) demographics are presented in table 5.1. A total of 47 HCPs were given a self-administered questionnaire with a response rate of 87.2% (n=41). Female participants constituted more than half of the population (65.9%). Furthermore, a majority (63.4%) of the participants was within the age group 26-35 years. The age group that had the second most population was those within 36-45 years range with 19.5% (n=8). These two groups show that most of the participants were in the middle aged group as compared to the old aged group that contributed the least with 2.4%.

Table 5.1: Participants by age and gender (n=41)

		Gender		Total	Percent
		Male	Female		
Age	25 years and below	1(7.1%)	5(18.5%)	6	14.6%
	26 - 35 years	10(71.4%)	16(59.3%)	26	63.4%
	36 - 45 years	3(21.4%)	5(18.5%)	8	19.5%
	46 - 55 years	0(0%)	1(3.7%)	1	2.4%
Total		14(100%)	27(100%)	41	100.0%
Percent		34.1%	65.9%	100.0%	

5.2.2 Occupation

Figure 5.1 shows the occupation frequencies obtained from this study. Pharmacists contributed the most (41.5%) number of participants in the current study. Professional nurses and physiotherapists contributed 17.1% each, while optometrists and doctors contributed 12.2% and 9.8% respectively. The occupation that contributed the least to the sample population was podiatrist(s) with 2.4% (n=1). This is because there is only one podiatrist at Mankweng Hospital.

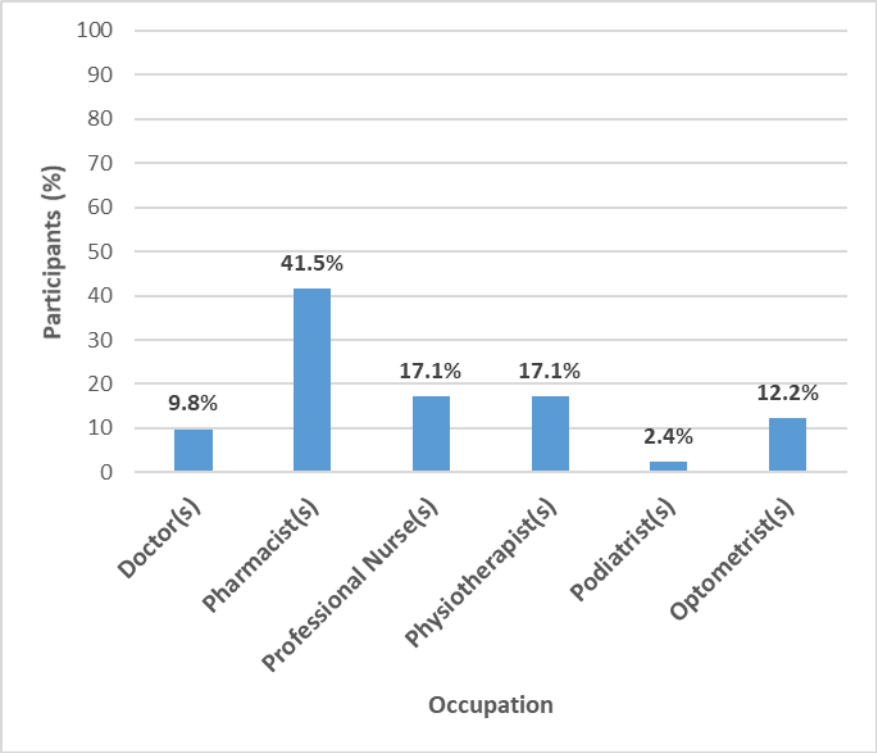

Figure 5.1: Occupation of participants

5.2.3 Duration of service

The frequency of duration of service for each category obtained from the sample population is shown in figure 5.2. The category that had most of the participants was 2 – 5 years with 46%, while < 2 years had 17%, 5 – 10 years 15%, 10 – 15 years 12% and > 15 years had the least number of participants at 10%. These findings revealed that 37% of the participants had worked for 5 years and above. It is assumed that with a longer duration of service comes an improved expertise in the performance of one's duties.

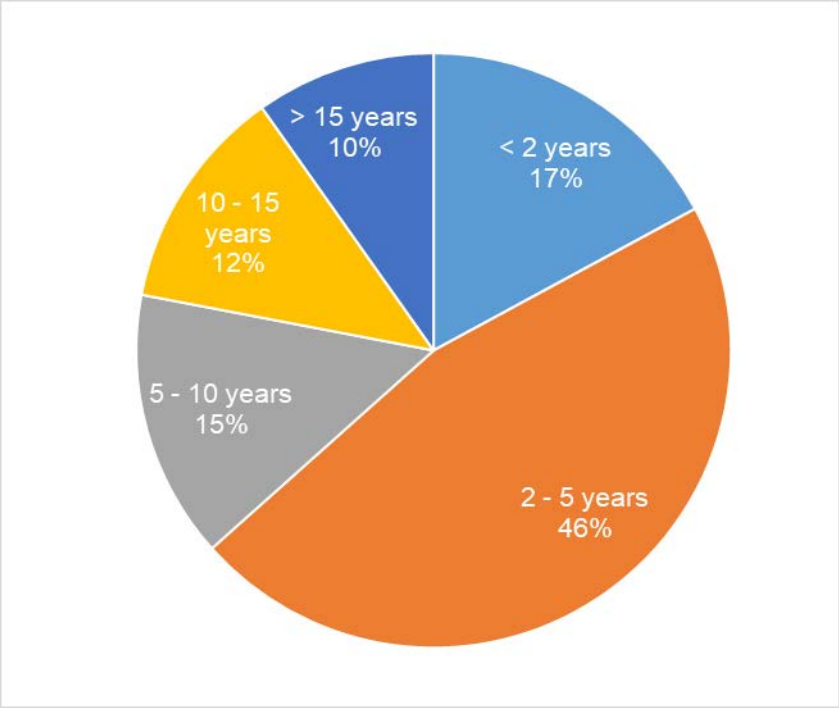

Figure 5.2: Duration of service

5.3 MANAGEMENT OF DIABETIC PATIENTS WITH COMPLICATIONS

To fulfil objective number 2, to evaluate the management of diabetic patients with DM complications at Mankweng Hospital, the researcher had questions to check how often some monitoring tests and examinations were done on these patients. Optimum management of DM involves lifestyle management, proper monitoring and screening for complications, and individualised adjustments of drug doses depending on the condition of the patient.

5.3.1 Patient reviews

Patient reviews are done to check if the therapeutic goals are being met or not and to screen for the development of complications. However, the frequency of reviews is determined by the patient's health status and progress. If the patient has complications or if there is no adequate progress towards the goals of therapy, the frequency of reviewing the patient must be increased so as to closely monitor and adjust wherever possible the management to suit the patient's clinical needs. This applies to all medical conditions, including DM.

Figure 5.3, shows the results that were obtained from a question that needed the HCPs to indicate the frequency of reviews on patients with complications and those without. The results revealed that a majority (82.6%) of the HCPs indicated that patients with DM complications are reviewed on a monthly basis as compared to 33.3% who indicated that they are supposed to be done monthly in patients without complications. Some (8.7%) of the HCPs indicated that patient reviews should be done daily on the same group of patients. These were responses from professional nurses from medical and surgical wards which corresponds with their scope of practice that requires them to review their patients on a daily basis. Furthermore, 41.7% of the HCPs revealed that patient reviews should be done every six months in patients without complications.

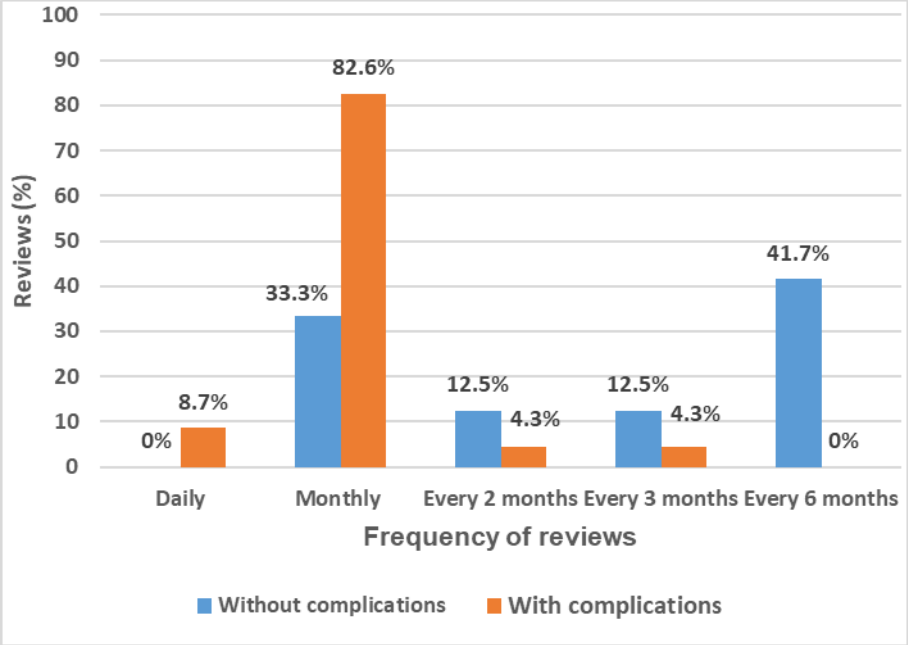

Figure 5.3: Frequency of reviews

5.3.2 Frequency of RBG tests

The results on frequency of RBG tests from this study are displayed in figure 5.4. A majority (92.6%) of the HCPs indicated that RBG tests should be done every month on patients with complications. The other 7.4% indicated that RBG tests should be done every six months. All professional nurses, doctors and physiotherapists indicated that RBG should be done on a monthly basis in this group of patients as compared to only 93.3% of the pharmacists and 50% of the optometrists.

The findings further revealed that a majority (70.4%) of all the HCPs indicated that RBG tests should be done on a monthly basis in patients without complications. In this section all of the professional nurses and physiotherapists indicated that RBG tests should be done monthly in patients without complications as compared to 73.3% of the pharmacists and 50% of the doctors. None of the optometrists indicated that RBG tests should be done monthly in patients without complications. The results showed a statistically significant relationship between occupation and frequency of RBG tests within patients without complications (p=0.001).

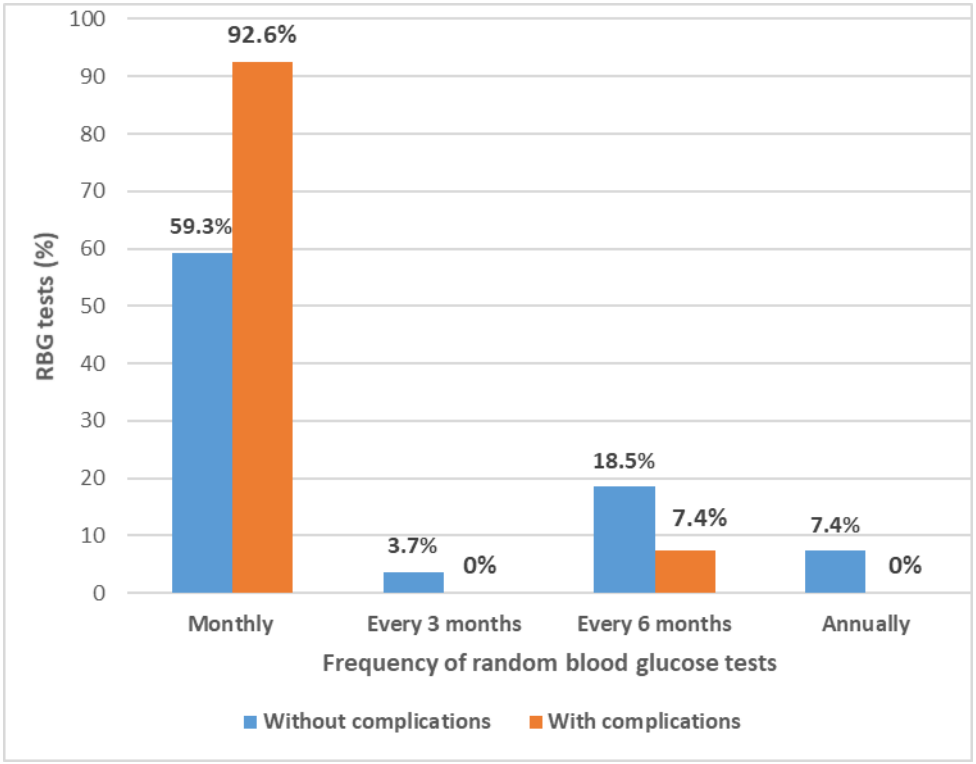

Figure 5.4: Frequency of RBG tests

5.3.3 Foot examination

Findings regarding foot examinations are summarised in figure 5.5. An overwhelming majority (88.9%) of the HCPs indicated that foot examinations should be done monthly in patients with complications as compared to 22.2% for patients without complications. Only 75% of the pharmacists revealed that foot examinations should be done on a monthly basis in patients with complications as compared 100% of doctors, professional nurses, physiotherapists and podiatrists indicating the same.

On the other hand, 50% of the HCPs indicated that foot examinations should be performed biannually in patients without complications as compared to 5.6% on patients with complications. There was no significant relationship between occupation and frequency of foot examinations in both patients with and those without complications (p=0.946 and p=0.208) respectively.

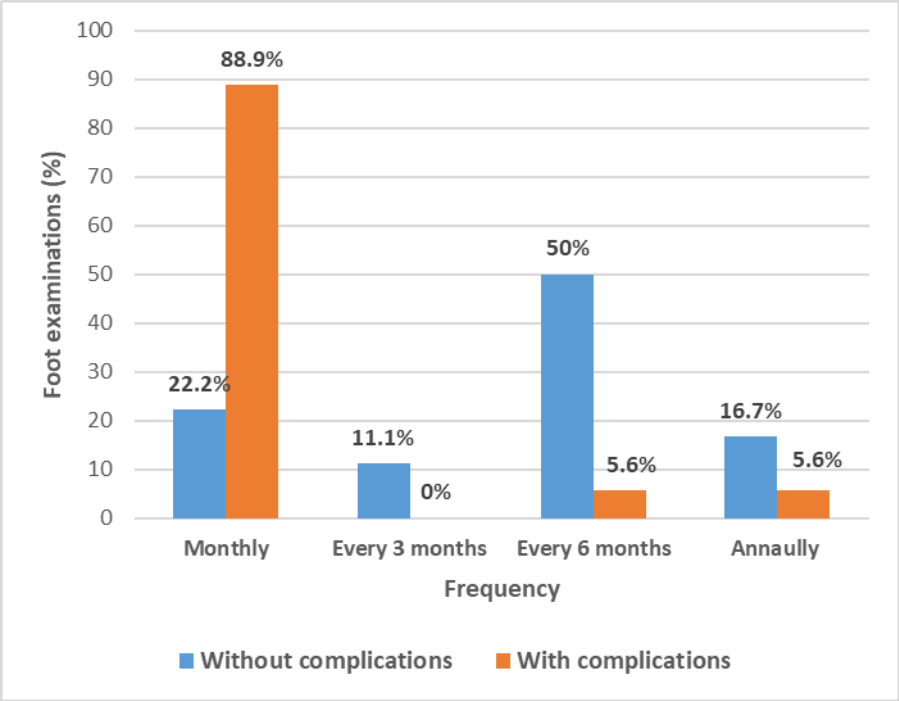

Figure 5.5: Frequency of foot examinations

5.3.4 Eye examination

As shown in figure 5.6, a majority (75%) of the HCPs indicated that patients with complications should have their eyes examined on a monthly basis as opposed to 27.2% for patients without complications. All the doctors, 75% of the professional nurses, 75% of the optometrists and 72.7% of the pharmacists indicated that eye examinations should be done monthly in patients with complications with none of the physiotherapists indicating the same. Chi-square tests indicated significant relationship between occupation and frequency of eye examinations in patients with complications (p=0.005).

For the patients without complications, most (40.9%) of the HCPs indicated that these patients should be examined biannually while 8.3% indicated that patients with complications should also be examined biannually. No significant relationship was

found between occupation and frequency of eye examinations amongst patients without complications (p=0.204).

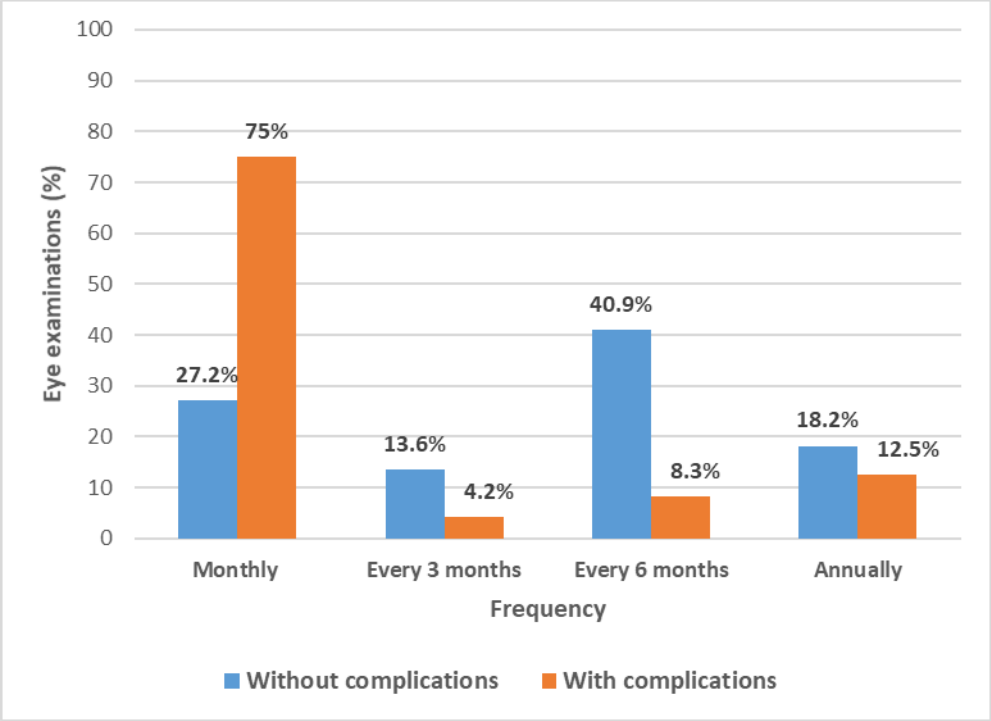

Figure 5.6: Frequency of eye examinations

5.3.5 Renal function tests

Findings from the current study for the frequency of renal function tests are presented in figure 5.7. A majority (73.7%) of the HCPs specified that renal function tests should be conducted every month in patients with complications as opposed to 40% for patients without complications. For patients with complications, all of the professional nurses and physiotherapists, 75% of the doctors and 63.6% of the pharmacists indicated that renal functions tests should be done monthly.

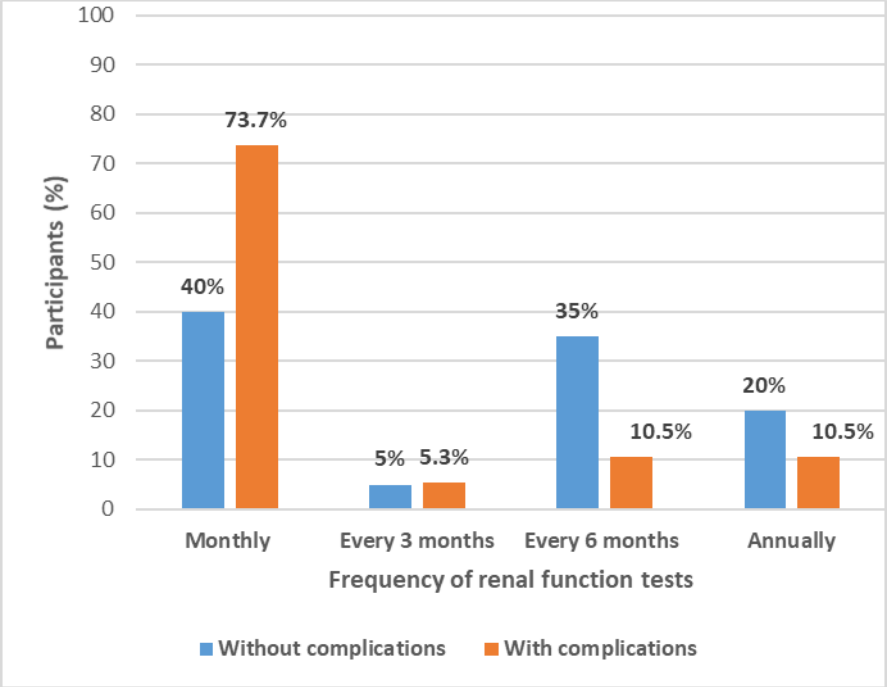

Figure 5.7: Frequency of renal function tests

5.3.6 HbA1c

On the frequency of HbA1c tests, the question required the HCPs to select the provided options for both patients with and those without complications. As summarised in figure 5.8, most (44.4%) of the HCPs revealed that HbA1c tests should be performed every six months and 27.8% indicated that they should be done on a monthly basis in patients with complications. Conversely, a majority (57.9%) of the participants reported that the tests should be conducted monthly in patients without complications.

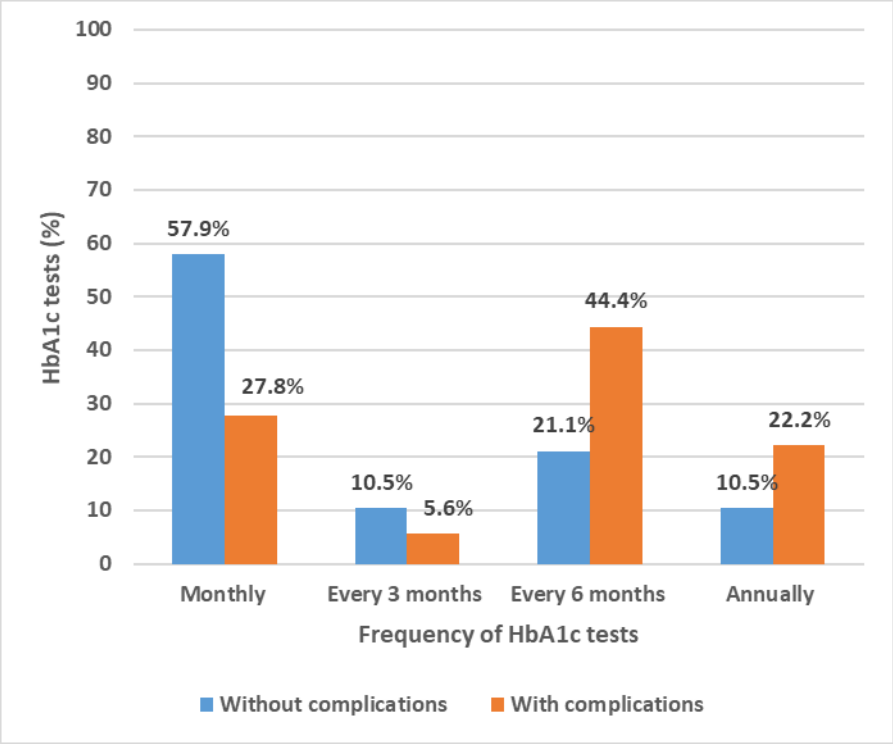

Figure 5.8: Frequency of HbA1c tests

5.3.7 BP checks

HCPs were required to give the frequency of BP check in in patients with and/or without DM complications. Figure 5.9, shows the results obtained from the current study. A majority (84.6%) of the HCPs revealed that BP checks should be done monthly on patients with complications. All of the professional nurses, 92.9% of the pharmacists, 75% of the doctors and 50% of the optometrists indicated that BP checks should be done on a monthly basis in patients with complications. Chi-square tests showed a significant relationship between occupation and frequency of BP checks amongst patients with complications (p=0.005).

On the other hand, 75% of the HCPs revealed that BP checks should be performed every month on patients without complications. All (100%) of the professional nurses and physiotherapists, 87.5% of the pharmacists and 25% of the doctors indicated that BP checks should be done on a monthly basis in patients without complications. There was a significant relationship between occupation and the frequency of BP checks within patients without complications (p=0.000).

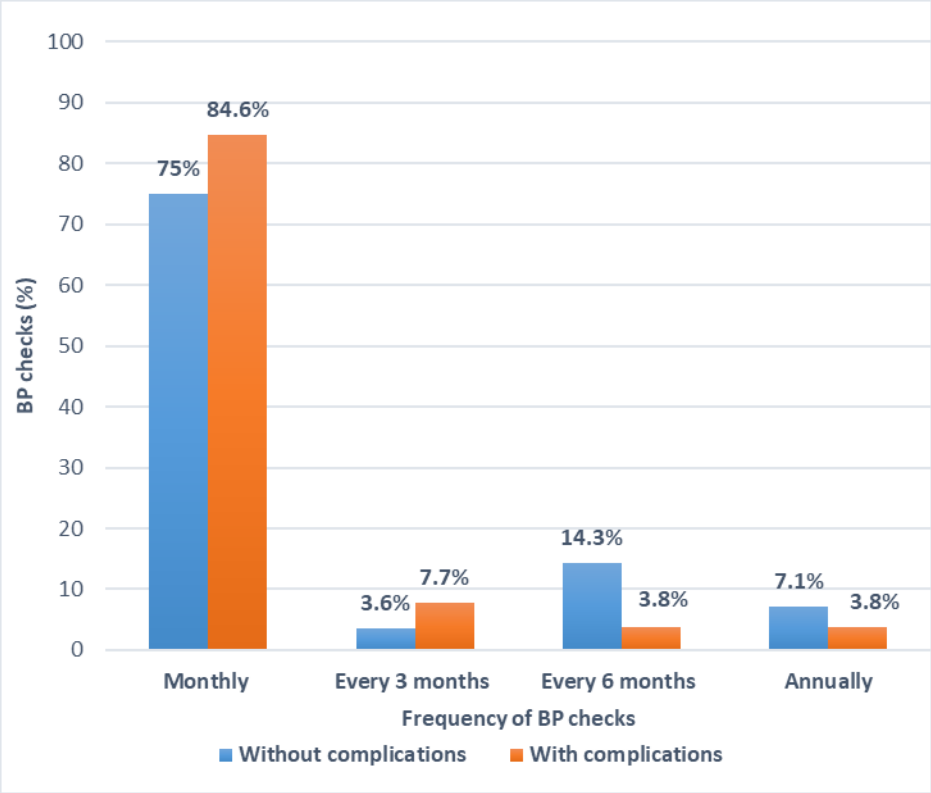

Figure 5.9: Frequency of BP checks

5.3.8 Lipogram tests

Figure 5.10 reflects the frequency of lipogram tests as obtained from the data collected. Half of the HCPs stated that lipogram should be performed every month amongst patients with complications as opposed to 28.6% for patients without complications. On another note, most (38.1%) of the HCPs indicated that the test should be done every six months in patients without complications as compared to 22.7% for patients with complications.

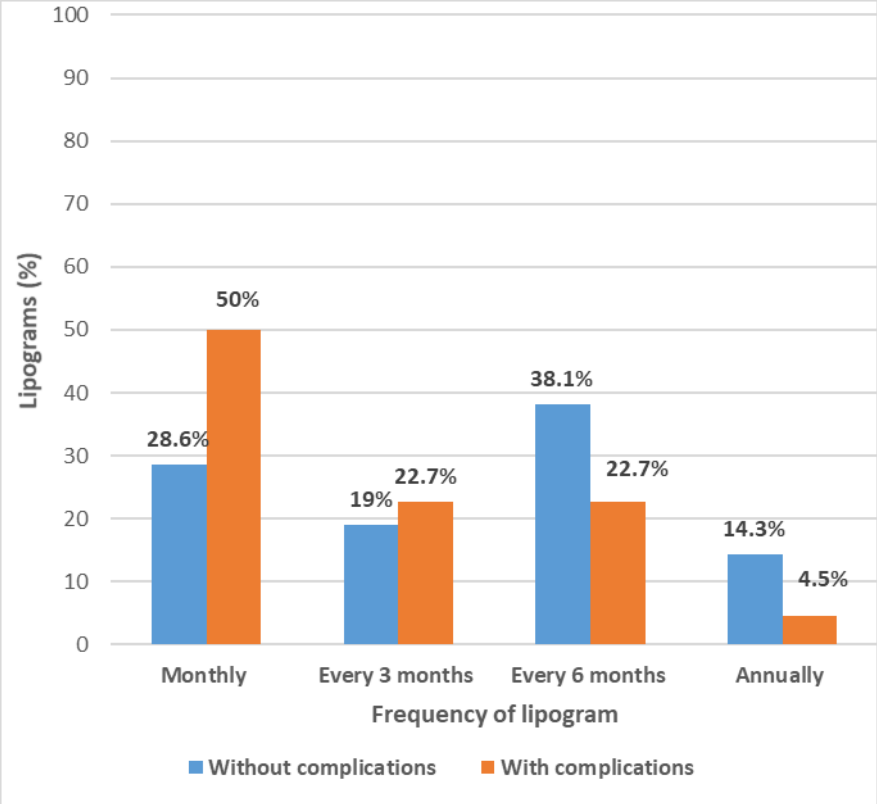

Figure 5.10: Frequency of lipogram

5.3.9 Clinical monitoring from patient files

The aspect of clinical monitoring looks at the tests and examinations that were done and recorded in the patients' files. The researcher looked at whether all the tests and examinations that were supposed to be done were done at the frequency recommended by the National Department of Health (NDoH). On each clinical parameter, the researcher checked for compliance with the NDoH guidelines throughout the five-year period in terms of the frequency of the tests. According to the SEMDSA 2017, the use of a DM consultation template is of paramount importance to ensure that no assessments and processes of care are omitted.

Clinical monitoring of DM patients through performance of various tests and examinations must be done to achieve the desired outcomes. These tests and examinations should be done in accordance with the evidence-based guidelines. However, in Canada studies revealed that there was a care gap between the DM management guidelines and the actual clinical practice (Clement, Filteau, Harvey, Jin, Laubscher, Mukerji & Sherifali, 2018).

Table 5.2 shows the data extrapolated from the patient files for the five-year period. The results reveal high compliance rates with BP checks (92.5%) and RBG tests (71.6%). However, to achieve better therapeutic outcomes there is need for 100% compliance with the evidence-based guidelines. The results further show very low compliance rates with albumin-creatinine ratio (20.9%), HbA1c (17.2%), cholesterol (15.7%) and eye examination (2.2%). None of the medical records had foot examination and body mass index complied with.

Table 5.2 Compliance with clinical monitoring guidelines

Test	**Compliance rate (%)**
Random blood glucose (RBG)	71.6%
HbA1c	17.2%
Foot examination	0%
Eye examination	2.2%
Albumin-creatinine ratio	20.9%
Blood pressure	92.5%
Lipogram	15.7%
Body mass index	0%

5.4 FACTORS ASSOCIATED WITH DM COMPLICATIONS

A list of eighteen factors was compiled and the HCPs were asked to rate them according to how much they contribute to the development of complications. They were asked to rate them according to least, moderate and most. Figure 5.11, shows a summary of the results obtained.

The results obtained in this study revealed a very strong agreement amongst the HCPs that diet, non-compliance, route of administration and physical inactivity are the most contributory factors to the development of complications. On diet, it can be seen that a majority (87.2%) of the HCPs agreed that diet is the most contributory

factor to the development of complications in patients with DM. Non-compliance amongst DM patients was also regarded as the second most contributory factors to the development of complications at 76.3%. The third most contributory factor was indicated to be route of administration with 73.7% of the HCPs indicating that it contributes to the development of complications the most. A majority (69.2%) of the HCPs also rated physical inactivity among DM patients as one of the most contributory factor leading to the development of DM complications. However, other factors like multiple medication that are hard to follow, lack of financial resources to buy monitoring equipments, tobacco smoking, medication stockouts and alcohol consumption had most of the participants indicating that they contribute the most to the development of complications but there was no strong consensus to that effect between the HCPs.

The results further revealed that the factors that were rated as moderately contributing to the development of complications in DM patients included; information provided in a way not understood by the patients (47.5%), lack of financial resources to attend appointements (46.2%), adverse effects of antidiabetics (43.6%) and lack of adequate time to educate the patients during review (42.5%). Lack of coordinated multidisciplinary teamwork was also revealed to be one of the factors moderately contributing to the development of complications with 37.5% indicating such. Only 30% indicated that it contributed the most to the development of complicatios. A majority of the professional nurses (83.3%) and optometrists (60%) indicated lack of coordinated multidisciplinary teamwork as the least contributing factor to the development of complications while a majority (75%) of the doctors rated it as moderate and most pharmacists (47.1%) and physiotherapists (42.9%) rated it as the most contributing factor. Chi-square indicated a significant relationship between occupation and lack of coordinated multidisciplinary teamwork (p=0.043). Although these factors had most participants indicating that they moderately contribute to the development of DM complications, there was no strong agreement between the HCPs.

Medication taste is one of the factors that HCPs strongly agreed that it contributes the least to the development of complications with 65.8% agreeing to that effect. Lack of adequate suitably qualified personnel was also rated as one of the least contributing factor to the development of complications as indicated by 52.6% of the

HCPs. Sixty-six percent (66%) of the professional nurses, 62.5% of the pharmacists, 50% of the doctors and 42.9% of the physiotherapists indicated lack of adequate suitably qualified personnel as the least contributing factor to the development of complications.

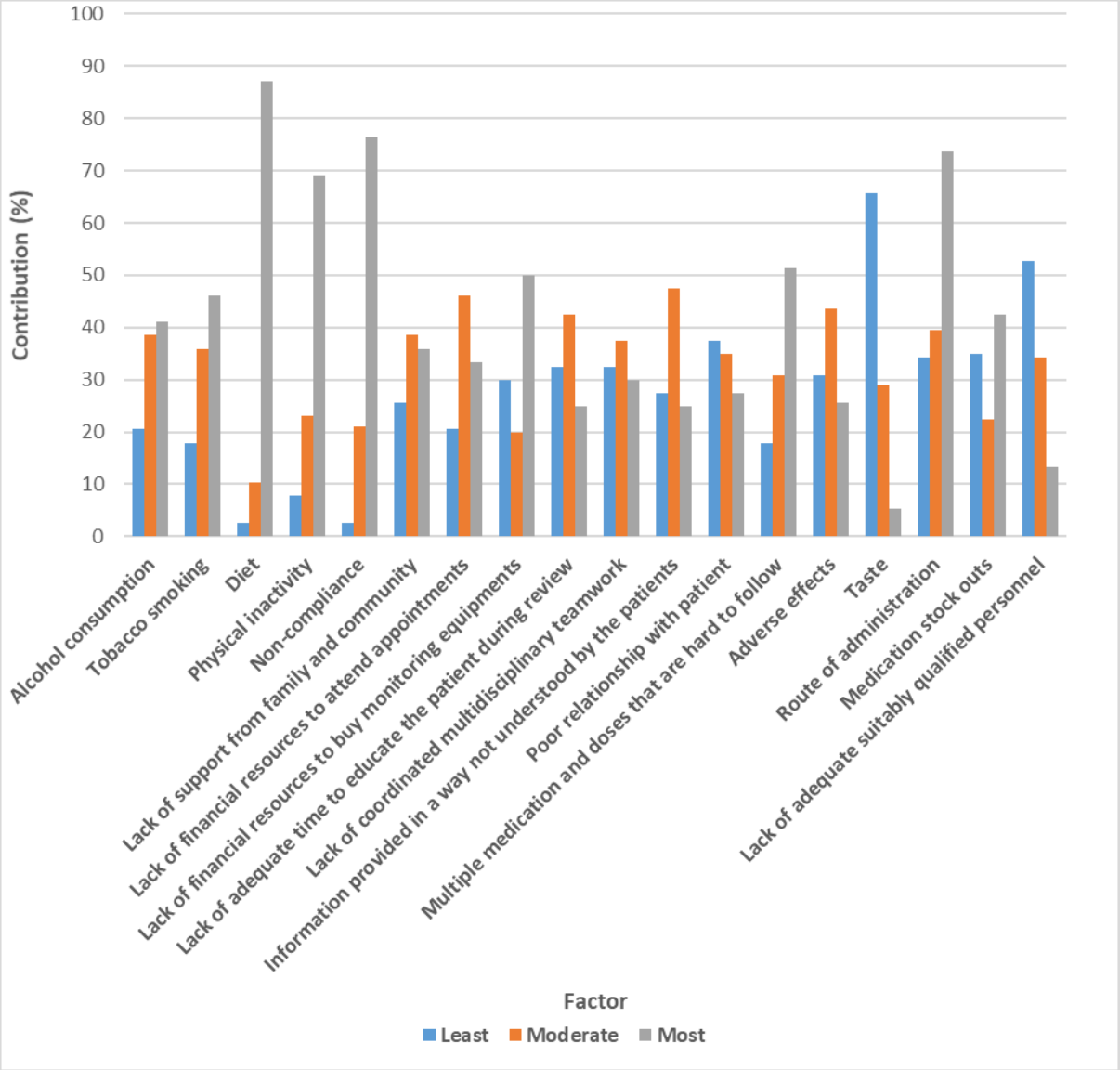

Figure 5.11: Factors contributing to the development of complications

Factor groups

The factors discussed above were then grouped into five major classes; patient, socio-economic, healthcare team, medication and health system related factors. All these factors affect the quality of DM care and in turn have an impact on slowing down the progression of DM complications. The HCPs were asked to rate the five

major classes of factors according to how much they contribute to the development of complications using a Likert scale from 1 to 5 (1 being least and 5 being most). The results obtained from this question are portrayed in figure 5.12.

From the findings obtained in this study, 56.4% of the HCPs indicated that patient related factors contribute the most to the development of DM complications with 75% of doctors, 75% of optometrists, 66.7% of physiotherapists and 58.8% of pharmacists indicating such. None of the HCPs indicated least while 5.1%, 12.8% and 25.6% indicated neither least nor moderate, moderate and neither moderate nor most respectively. This shows that most of the HCPs agree that patient factors contribute that most to the development of complications. However, Chi-square tests did not indicate a statistically significant relationship between occupation and patient related factors (p=0.089).

Socio-economic and medication related factors were rated as moderately contributing to the occurrence of complications within DM patients. Most (36.1%) of the HCPs rated socio-economic factors as moderate in terms of how much they contribute to the development of complications. Only 8.3% rated the socio-economic factors the least while 16.7% rated them the most contributory factors to the occurrence of complications. Twenty-nine percent (29%) of the HCPs rated medication related factors as moderately contributory factor to the development of DM complications. However, 22.6% rated health related factors the least while only 9.7% rated them the most contributory factors to the development of complications among DM patients.

Findings from the current study revealed that health system and healthcare team related factors were rated as the least contributory factors leading to the development of complications in DM patients. Most (33.3%) of the HCPs indicated that health system related factors contribute the least to the development of DM complications while only 16.7% indicated that they contribute the most. The results further revealed that most (32.4%) of the HCPs rated healthcare team related factors as the least while 2.9% rated them the most contributory factors to the development of complications.

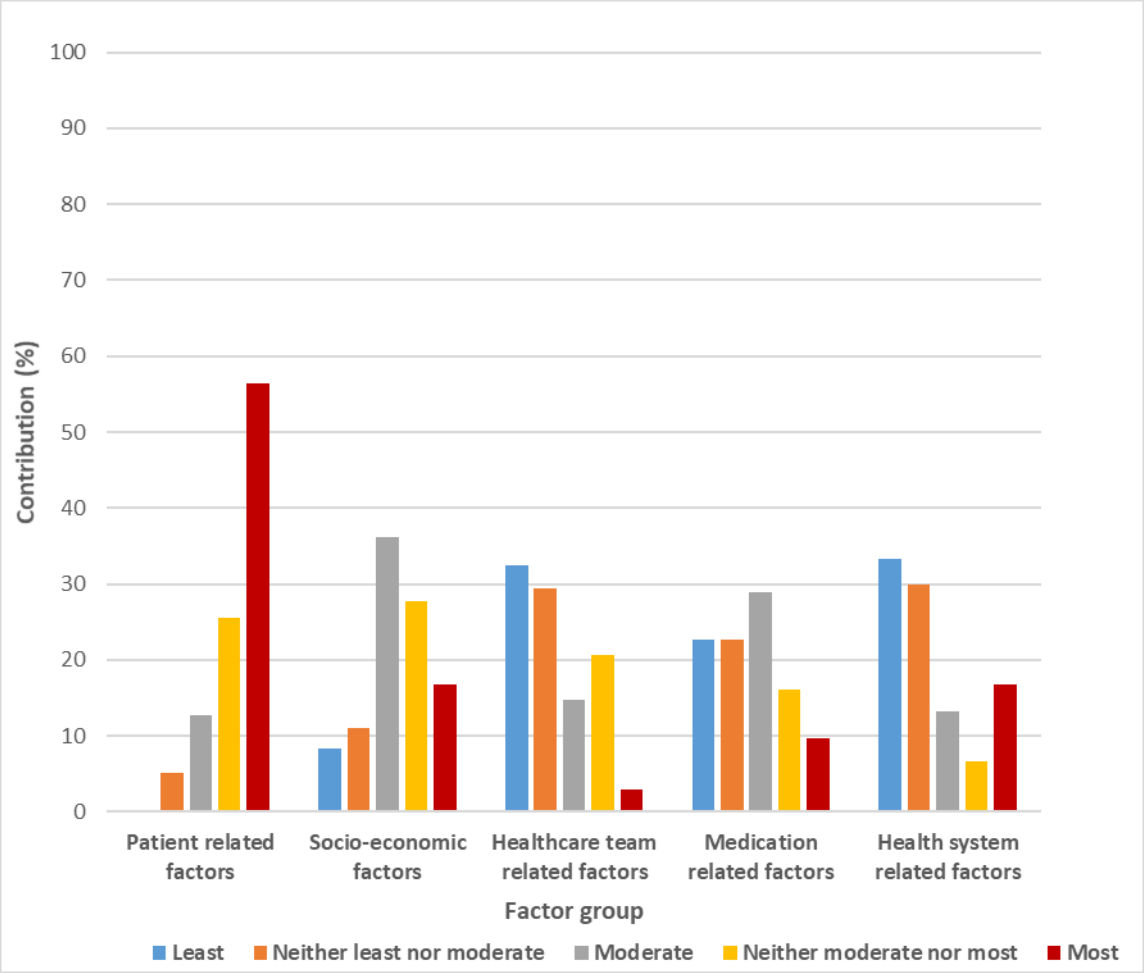

Figure 5.12: Factor groups contributing to the development of complications

5.5 METHODS OF PATIENT FOLLOW-UP

The HCPs were given four methods of patient follow-up where they were required to choose either one or more methods. Figure 5.13 shows the results obtained from the current study. The results revealed that the widely used method of patient follow-up was patient reviews with 68.4% of the HCPs indicating that they use this method of patient follow-up. Furthermore, the results also indicated that the HCPs also used diabetes report cards (18.9%) and community outreach (18.9%) as part of their patient follow-up methods. The least used method of patient follow-up was diabetes self-care booklet/log sheet with only 8.1% of the HCPs using it.

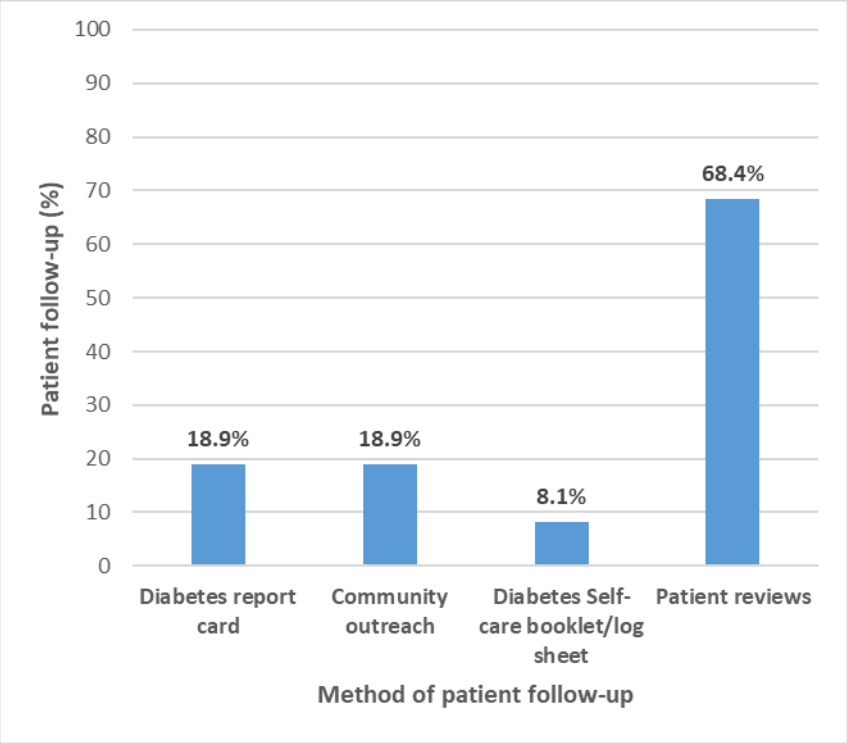

Figure 5.13: Methods of patient follow-up

5.6 STANDARD GUIDELINES

The HCPs were asked to indicated if they follow any standard protocol in the management of people with DM complications. Figure 5.14 displays the results obtained from the question. Only 68.4% of the HCPs indicated that there was a standard guideline that they follow when treating patients with DM complications. This shows that a significant fraction (31.6%) of HCPs did not follow any guidelines which in overall affects the standards of DM care.

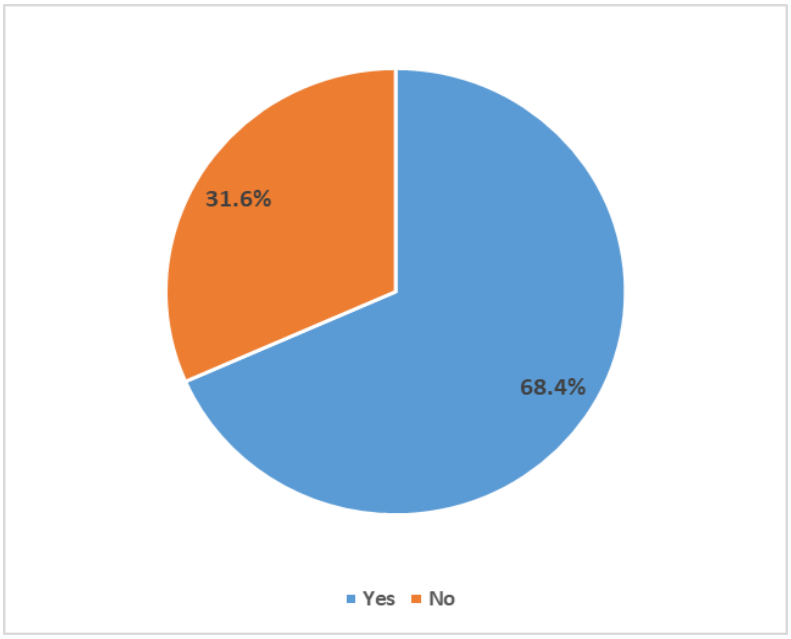

Figure 5.14: Standard guidelines followed

5.7 TYPE OF DM AND PREVALENCE OF COMPLICATIONS

Figure 5.15 displays the results obtained from the current study. The results revealed that a majority (83%) of the HCPs indicated that T2DM is associated with a higher prevalence of complications as compared to T1DM. However, 17% of the HCPs indicated that T1DM is associated with a higher prevalence of complications.

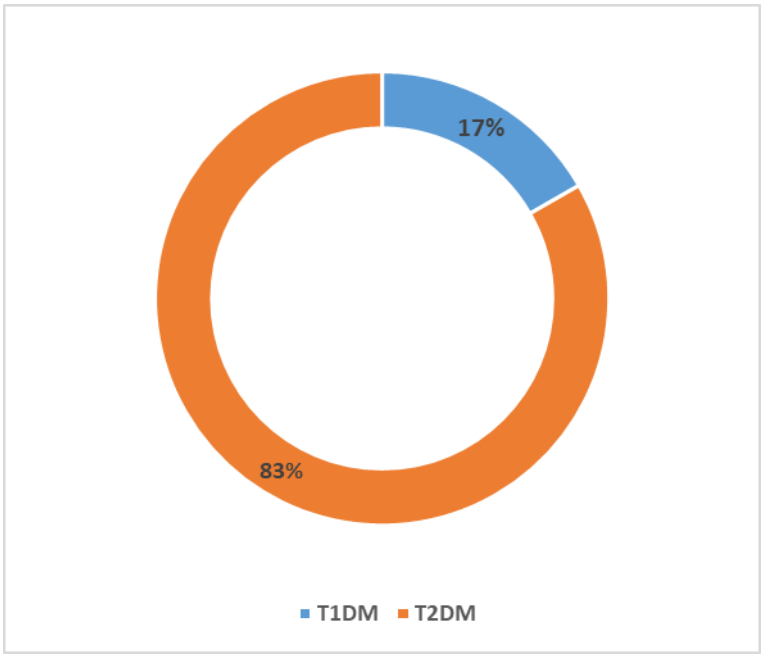

Figure 5.15: Type of DM with the highest prevalence of complications

5.8 THE MANAGEMENT OF DM PATIENTS WITH AND THOSE WITHOUT COMPLICATIONS

The management of people with or without DM complications differs from patient to patient depending on their health status. The data presented in figure 5.16, was obtained after asking the HCPs if there were any differences in the management of patients with and those without complications. A majority (73.7%) of the HCPs indicated that there were differences in the management of the two groups of patients. The other HCPs (26.3%), indicated that there are no differences existing between the management of patients with and those without complications.

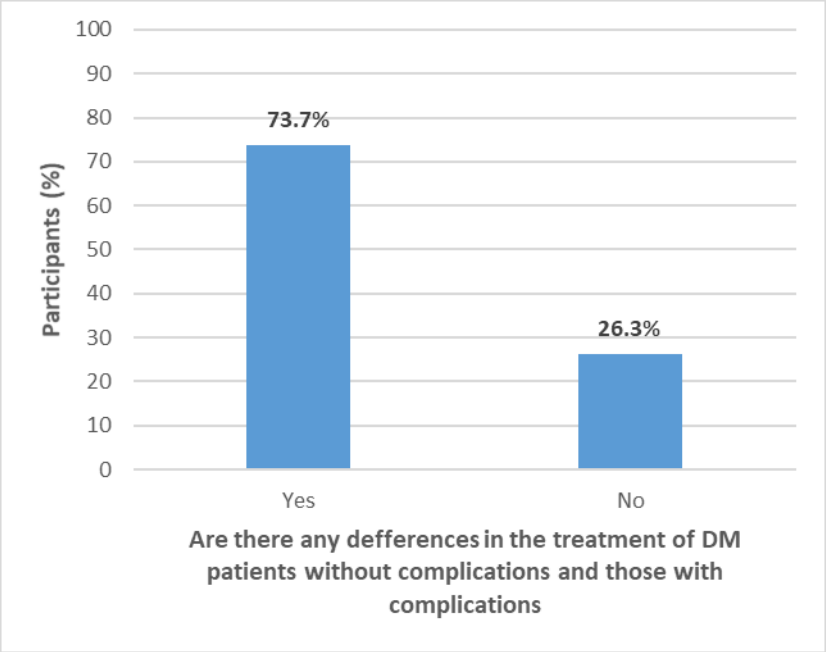

Figure 5.16: Differences in the management of DM patients with and without complications

5.9 SPECIAL ATTENTION TO PATIENTS WITH COMPLICATIONS

On this question, participants were asked if there was any special attention needed to be paid to patients with complications. Results obtained from this study are displayed in figure 5.17. Most (75.7%) of the HCPs indicated that there is need to pay special attention to patients with complications while 24.3% indicated otherwise.

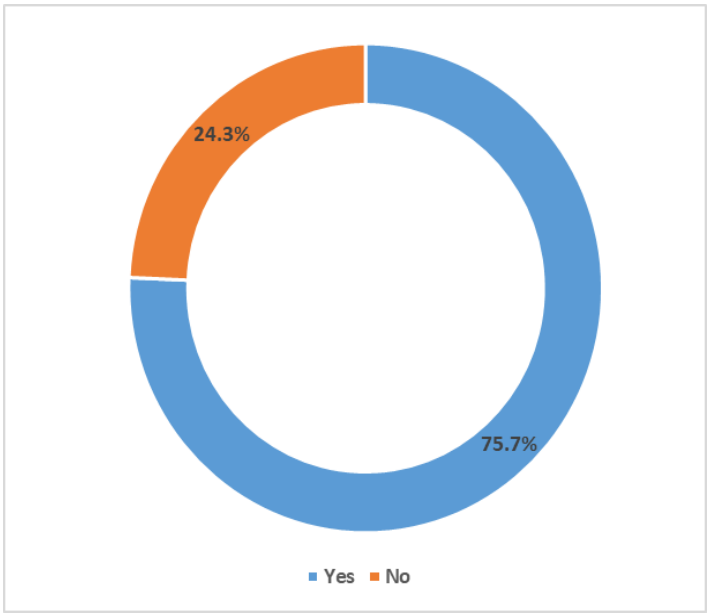

Figure 5.17: Shows if there was any need to pay special attention to patients with complications

5.10 MULTIDISCIPLINARY TEAM AND PREVENTION OF COMPLICATIONS

Figure 5.18, shows the results obtained from asking the HCPs if a multidisciplinary approach in DM management can help delay or prevent the development of complications. Majority (97.4%) of the HCPs agreed that using a multidisciplinary approach helps in the prevention of complications.

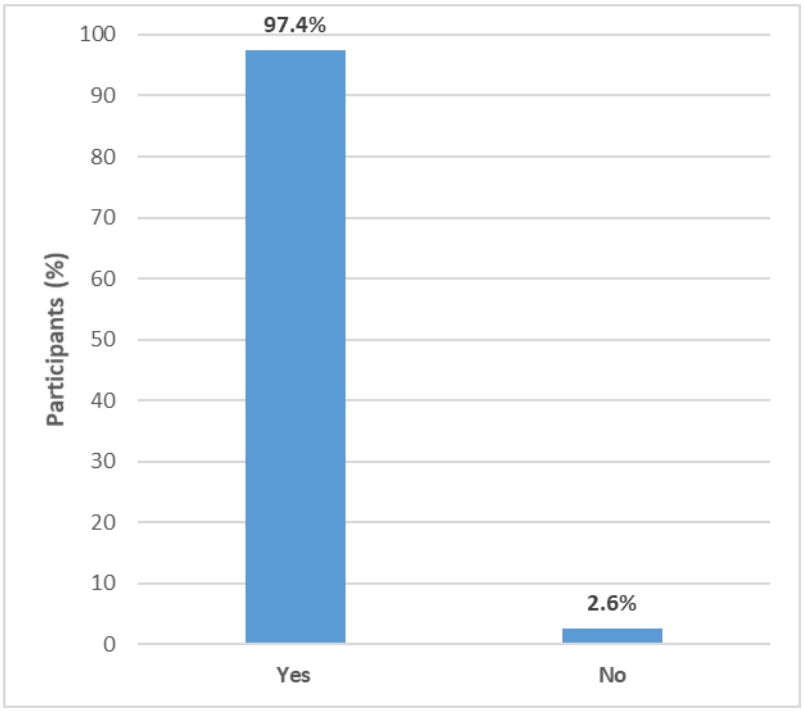

Figure 5.18: Does the management of DM patients by a multidisciplinary team help in the prevention of complications

5.11 CHALLENGES WHEN MANAGING PEOPLE WITH DM COMPLICATIONS

The presence and severity of DM complications present challenges in the management of patients with DM. This population requires special attention in order to manage DM, its complications and comorbidities. As shown in figure 5.19, a majority (81.6%) of the HCPs agreed that there were challenges in managing patients with DM who present with complications.

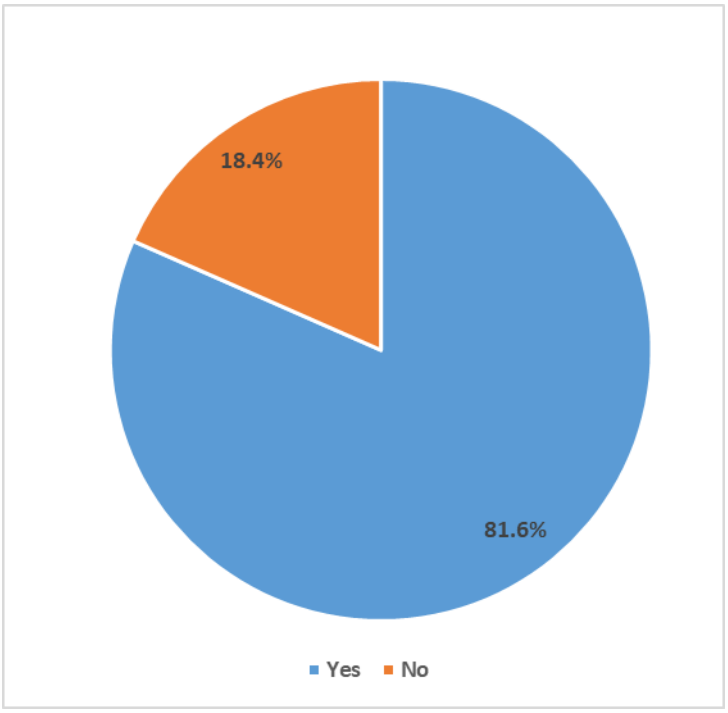

Figure 5.19: Presence of challenges when managing DM patients with complications

5.12 DISCUSSION

As expected, findings from this study showed that a majority (65%) of the HCPs were females. This confirms estimates of the World Health Organisation, that a bulk of the HCPs in many countries are females (WHO Department of Human Resources for Health, 2008). The results further showed that seventy-eight percent of the HCPs were below the age of 35 years, suggesting that the majority of the participants were young adults. Moreover, this was reflected in the duration of service, where also 78% of the HCPs indicated that they had worked for at most ten years. Most (41.5%) of the participants were pharmacists, followed by professional nurses and physiotherapists at 17.1% each. Most of the HCPs were pharmacists because all of the pharmacists at the hospital were involved in the study with a high turnout of questionnaires.

Frequency of Patient reviews

This study revealed that DM patients with complications are reviewed more often than those without. A majority (82.6%) of the HCPs indicated that patients with complications should be reviewed on a monthly basis as compared to 33.3% of the HCPs who indicated that patients without complications should be reviewed monthly.

This therefore, will have a major economic impact on patients with complications as they will have to take leave days every month for their monthly reviews. However, the frequency of patient reviews depends on a lot of factors. These include the health status of the patient, results from examinations and laboratory tests, whether the medication has been switched or not, response to medication and the local guidelines. According to these factors, it is justified for the HCPs to review patients with complications more frequently.

Frequency of RBG

In this study, an overwhelming majority (92.6%) of the HCPs indicated that RBG tests should be done on a monthly basis in patients with complications. This indicate that HCPs are aware of the guidelines related to RBG tests. However, only 71.6% of the patient records had RBG tests done in accordance with the clinical guidelines. According to the NDoH (2014), blood glucose is one of the biochemistry tests that should be done on the time of diagnosis and per every subsequent follow-up visit regardless of presence or absence of complications. The main aim for RBG tests is to perform therapeutic evaluation to ascertain if the goals of therapy are being met. It is of great importance to perform continuous glucose monitoring coupled with usual DM care as it results in improved therapeutic outcomes (Beck, Riddlesworth, Ruedy, Ahmann, Bergenstal, Haller, Kolmann, Kruger, Mcgill, Polonsky, Toschi, Wolpert & Price, 2017).

HbA1c tests

In this study, the HCPs indicated that HbA1c tests should be conducted more frequently than the recommendations of the guidelines, reflecting that the healthcare professionals are not complying with the guidelines. Most (44.4%) of the HCPs indicated that HbA1c tests should be conducted every six months in patients with complications while 22.2% indicated that the tests should be conducted annually in the same population. Furthermore, patient files showed that only 17.2% patients had HbA1c tests done as per the guidelines. The frequency of HbA1c test in individuals with normal levels (≤ 7%) should be once annually while the frequency is increased for those with higher levels and after treatment adjustments to every three to six months (National Department of Health, 2014; Ohde, Deshpande, Yokomichi, Takahashi, Fukui, & Yamgata, 2018). The SEMDSA (2017), however, recommends

a biannual test interval for patients with stable control and a three-month interval for those with uncontrolled glycaemia. Similarly, a study conducted in the United Kingdom revealed that a three-monthly testing interval was associated with a 3.8% reduction in HbA1c (Driskell, Holland, Waldron, Ford, Scargill, Heald, Tran, Hanna, Jones, Pemberton & Fryer, 2014).

Screening for complications

The screening tests and examinations that were included in this study comprised of foot examinations, eye examinations, renal function tests, BP checks and lipogram tests. Generally, most of the HCPs in this study revealed that most of the tests and examinations should be performed more often in patients with complications than in those without. The HCPs indicated that foot examinations, eye examinations, renal function tests and lipogram tests should be done monthly in patients with complications.

According to SEMDSA (2017), foot examinations forms an integral part of DM management to identify patients at risk of developing foot ulcers and amputations. A majority (88.9%) of the HCPs in this study indicated that foot examinations should be done on a monthly basis in patients with complications. This indicate that HCPs fully comprehend the risk of developing diabetic foot ulcers in patients who already have complications. Foot examinations should be done annually as a must in all asymptomatic patients and frequency must be increased in patients at risk of developing diabetic foot ulcers (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017; American Diabetes Association, 2018). However, people with moderate and high-risk profile and, those with diabetic foot disease must have foot examinations done every visit (Society of Endocrinology, Metabolism and Diabetes of South Africa, 2017).

Results from this study further indicated that 75% of the HCPs revealed that eye examinations should be done on a monthly basis in patients with complications as opposed to 27.5% for patients without complications. Regular eye examinations should be done to screen for diabetic retinopathy. However, the frequency depends on the patient's age and type of DM. Diabetic retinopathy usually goes unnoticed until vision loss occurs. Nonetheless, regular eye screening, optimal glycaemic control and early treatment reduces vision loss. Screening should therefore, be

initiated at the time of diagnosis on all patients with T2DM and after 5 years after diagnosis in all T1DM patients 15 years and older (Altomare *et al.*, 2018). According to the SEMDSA, (2017), follow-up screening every two years in patients without any sign of visual impairment and have good glycaemic control has been found to be cost-effective especially in resource limited areas. However, annual follow-up screening is recommended for patients without any sign of diabetic retinopathy. If there is a sign of diabetic retinopathy, then follow-up tests and examinations should be done more frequently.

Findings from this study reveal that 10.5% and 20% of the HCPs indicated that renal function tests should be performed annually on patients with and those without complications respectively. Screening for diabetic nephropathy is recommended to be done annually or it can be repeated twice or once within three months for abnormal albumin-to-creatinine ratio or estimated glomerular filtrate respectively (National Department of Health, 2014; McFarlane *et al.*, 2018).

This study further reveals a poor adherence by the HCPs to the national guidelines in terms of the frequency of monitoring tests and examinations. The compliance rate with BP monitoring in this study was 92.5%. Similarly, these findings correspond with the ones found in a study conducted in KwaZulu Natal where BP monitoring compliance rate was found to be 91.6% (Igbojiaku, Harbor & Ross, 2013). However, this study shows a higher compliance rate as compared to the one obtained from another South African study that recorded a BP monitoring compliance rate of 66.8% (Webb *et al.*, 2015).

The results further indicate that the frequency of RBG tests were complied with in 71.6% of the patients' medical records. Similarly, Webb and colleagues (2015) also found that 70.3% of their patients' records had the frequency of RBG tests complied with. Another study that was conducted in SA, found that 100% of the medical records had RBG tests done according to the guidelines (Rampersad, Rangiah & Kendon, 2018).

The results obtained in this study further indicated that albumin-creatinine ratio had a compliance rate of 20.9%. These findings showed a higher compliance rate as compared to the one done by Rampersad *et al.,* (2018), which obtained an albumin-creatinine ratio compliance rate of 10.4%. The findings are also higher to those

obtained from a study conducted in Asia which also had a 10% compliance rate to the albumin-creatinine ratio tests (Alam, Syamala, Al Hamadi, George, Kunnunmal, Abdelfattah, Chinamma & Al-Sulaiti, 2017).

HbA1c tests frequency was performed as per the national guidelines in 17.2% of the patients in this study. These findings falls within the range that was obtained in another study that revealed a 13.2% to 29.2% range (Rampersad *et al*., 2018). The results also showed less compliance rate as the one found in two other studies that revealed compliance rates with HbA1c tests of 24% and 53% (Igbojiaku *et al*., 2013; Alam *et al.*, 2017).

None of the patients with the reviewed records had their feet examined as often as recommended by the SA guidelines. However, in two other studies, the compliance rates were 6.1% and 7.8% (Igbojiaku, Harbor & Ross, 2013; Rampersad *et al*., 2018). According to Sutkowska, Sokolowski, Zdrojowy & Dragan, (2016), inadequate foot examinations by healthcare professionals is the main hindrance to the prevention of diabetic foot. Their study revealed that only 17.6% of their participants had their foot examined. The variations in the findings from this and other studies could be reflective of the HCPs' different levels of dedication to comply with the available guidelines and the level of DM care.

Factors contributing to the development of DM complications

This study reveals that the HCPs strongly agreed that diet, non-compliance, physical inactivity and route of administration contribute the most to the development of complications.

Diet was revealed to be the most contributing factor to the development of complications in this study, with 87.2% of the HCPs indicating it as such. It is of paramount importance to incorporate medical dietary therapy in the management of DM and prevention of its complications. Previous studies have established that high sodium and carbohydrates intake are associated with DM complications while the intake of a Mediterranean diet and dietary fibre provides protection from developing diabetic retinopathy (Wong, Man, Fenwick, Gupta, Li, van Dam, Chong & Lamoureux, 2018). Although glycaemic control is a major clinical goal, the reason for hyperglycaemia is a high carbohydrate diet and DM complications are chiefly

driven by glucose metabolism (Mobbs, Mastaitis, Isoda & Poplawski, 2013). Therefore, carbohydrate intake should be moderated to slow down or prevent DM complications. However, as noted by Forouhi, Misra, Mohan, Taylor & Yancy, (2018), diet is one of the most contentious and difficult aspects of the management of DM. This therefore, makes diet one of the factors contributing the most to the development of complications amongst DM patients.

Findings from this study revealed that a majority (76.3%) of the HCPs reported non-compliance as the most contributing factor to the development of complications. Likewise, it has been established that non-compliance is strongly associated with poor glycaemic control, increased morbidity and premature mortality (Polonsky & Henry, 2016). Therefore, non-compliance is one of the major factors leading to the development of DM complications. This consequently requires the HCPs to try and meet the growing need to actively involve the patients in decision making of their health as it helps improve compliance by fitting in all the health care plans into their lifestyle without disturbing it than forcing the plans onto the patients.

Physical inactivity has been noted to be one of the leading causes of diseases and disability while physical activity is associated with improved glycaemic control (World Health Organization, 2010; Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). This results in a reduction in the risk of developing DM complications. However, physical activity should be mild in patients with diabetic retinopathy, peripheral neuropathy, autonomic neuropathy and diabetic nephropathy as it may worsen these complications if done excessively (Sigal *et al.*, 2018).

The current study showed some disagreements on rating lack of coordinated multidisciplinary teamwork amongst the HCPs with only 32.5%, 37.5% and 30% of the them rating it as the least, moderate and most contributor to the development of complications respectively. However, there was a significant relationship between the occupation of the participants and the rating of lack of coordinated multidisciplinary teamwork ($p=0.043$). The findings from this study show that pharmacists and physiotherapists considered it as the most contributory factor. The reason for this might be because they felt left out in DM care. However, professional nurses, doctors and optometrists rated it least and moderate maybe because they feel comfortable working alone in DM management.

In this study, patient related factors had most (56.4%) of the HCPs agree that they are a major contributor to the development of DM complications. They constituted 75% of the factors that the HCPs rated as the most contributory factors to the development of DM complications. The link between a prescribed regimen and therapeutic outcomes critically depends on the patient's behaviour. These factors include alcohol abuse, the patient's comprehension of the disease and its consequences, acceptance of the disease and awareness of the dangers posed by the disease (Inamdar, Kulkarni, Karajgi, Manvi, Ganachari & Kumar, 2013).

Most (36.1%) of the HCPs in the current study rated socio-economic factors as moderate contributors to the development of complications in DM patients. Low socio-economic status in DM patients is associated with poor health outcomes (Saydah, Imperatore & Beckles, 2013). In a study conducted in Japan, it was established that low education, patients on public assistance, irregular or unemployment and low income levels were associated with higher risks of developing diabetic retinopathy and nephropathy (Funakoshi, Azami, Matsumoto, Ikota, Ito, Okimoto, Shimizu, Tsujimura, Fukuda, Miyagi, Osawa & Miura, 2017). Medication related factors were also rated as moderate contributors to the development of complications. Most of the medication related factors lead to non-compliance which results in uncontrolled hyperglycaemia and progression to complications. DM is associated with other chronic comorbid conditions which force HCPs to prescribe multiple medication and sometimes doses that are hard to follow (Alwhaibi, Balkhi, Alhawassi, Alkofide, Alduhaim, Alabdulali, Drweesh & Sambamoorthi, 2018).

This study revealed health system and healthcare team related factors as the least contributory factors to the development of complications amongst DM patients. Health system related factors in this study referred to medication stock outs and lack of adequate suitably qualified personnel. Previous studies established that increased availability of medication and personnel motivation are related to better health outcomes in DM patients (Alberti, Boudriga & Nabli, 2007). As such, the development of DM complications is slowed down or prevented. The use of a multidisciplinary team has been found to be related to significant reduction in HbA1c levels when compared to usual physician provided DM care (McGill, Blonde, Chan,

Khunti, Lavalle & Bailey, 2017). This results in a reduced DM complications risk profile.

Guidelines

A majority (68.4%) of the HCPs in this study indicated that they follow guidelines when treating DM patients with complications. Standards of care provide the HCPs with a reference guide on a step by step basis involved in DM care process. This therefore, provides a checklist where a healthcare provider checks if they have done things accordingly. Clinical practice guidelines have an important benefit in healthcare, which is their potential to improve both quality or process of care and therapeutic outcomes (Graham & Harrison, 2005). Adherence to the clinical practice guidelines may be achieved through customising the guidelines to a particular organisation with the active involvement of the end-users (Kredo, Bernhardsson, Machingaidze, Young, Louw, Ochodo & Grimmer, 2016). As DM management is a complex process, the approach to the organisation of care provided by guidelines is essential (National Department of Health, 2014). However, many countries have to adopt and contextualise their guidelines from many and sometimes contradictory guidelines. Further complications come from the availability of questionable guidelines. Adoption of these guidelines may lead to ineffective interventions and use of scarce resources, and sometimes harm to patients (Harrison, Legare, Graham & Fervers, 2010).

Type of DM and prevalence of complications

As expected, 83% of the HCPs revealed that T2DM is associated with a high prevalence of complications as compared to T1DM. Song (2015), noted that although the complication burden increases with duration in both types of DM, T2DM is associated with a high prevalence of chronic complications which also occur at an earlier stage than in T1DM.

Management of patients with and those without complications

Findings from this study reveal that a majority (73.7%) of the HCPs indicated that the management of patients with and those without complications is different. The study however, did not establish the type of differences but the literature shows that patients with complications are monitored more often than those without (National

Department of Health, 2014; Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). Furthermore, more than 75% of the HCPs indicated that there was need to pay special attention to patients with complications. The reason for this could be to slow down or halt the progression of complications thereby reducing morbidity and premature mortality. The other reason could be the need to improve the health outcomes of the patients and therefore, the need for specialist care more frequently and frequent monitoring tests.

Multidisciplinary team in prevention of complications

A majority (97.4%) of the HCPs indicated that using a multidisciplinary approach helps in the prevention of DM complications. This team approach to DM care can effectively assist in prevention of DM complications (Centres for Disease Control, 2013). In another study conducted in the United Arab Emirates, it was discovered that a multidisciplinary paediatric team approach provided improved metabolic outcomes and delaying or preventing the development of complications (Asma, Salima, Hana, Layla, Shanker & Mary, 2016).

Challenges when managing DM patients with complications

It is important to note that in the current study, 81.6% of the HCPs acknowledged facing challenges when managing DM patients with complications. Due to the increase in the number of medications to be taken by patients with complications apart from their DM medication, there is bound to be non-compliance on the patients' side. Some patient related factors lead to some of the challenges faced in managing people with DM complications. These range from lack of SMBG practices, non-compliance to medication and lifestyle modifications and often, lack of trust in western medicine. Patients end up consulting both western health practitioners and traditional health practitioners, while some traditional health practitioners regard DM as curable and sometimes do not refer patients. The other existing challenge is that there are low health budget allocations in low-medium income countries and also non-communicable conditions like DM are on the least in terms of priorities (Levitt, 2008). All these factors present as challenges to the healthcare professionals when managing patients with complications. The other challenges include lack of adequate trained staff dedicated for the DM clinic is also a challenge as workload ends up being absorbed by a small number of staff members. Lack of specialist practitioners

who are essential in the management of people with DM management results in a number of challenges. An example is the shortage of podiatrists, with only one podiatrist found at Mankweng Hospital.

5.13 SUMMARY

This chapter presented data that was obtained through questionnaires for HCPs and patient records from Mankweng Hospital. The data were presented as figures and tables and Chi-square tests were performed to check for any correlation between individual variables. The key findings are that there were indications of non-compliance to the standards of DM care set out in the local evidence-based guidelines, which was consistent with other existing literature from previous studies. These findings were discussed and compared to the existing literature so as to draw appropriate conclusions. The following chapter presents a summary and conclusion, as well as pointing out the limitations of the study, and recommendations for further studies.

CHAPTER 6

SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 INTRODUCTION

In this chapter, the summary of the study will be discussed together with the conclusion. The recommendations will be drawn from the results obtained. Limitations of the current study will also be outlined.

6.2 SUMMARY OF RESULTS

6.2.1 Summary of the retrospective study results

Prevalence of complications

- The results obtained from this study showed a very high prevalence of DM complications 67.2% in contrast to 28.8% of those patients without complications.
- The prevalence of individual complications ranged from 6% to 35.8%. Diabetic nephropathy was the most prevalent complication at 35.8%, followed by diabetic neuropathy and retinopathy with 32.1% and 22.4% prevalence respectively. The least prevalent complication was diabetic foot ulcer.

Management of patients with DM

- The compliance to the clinical monitoring guidelines as specified by the NDoH had a range from 0% to 92.5%. Body mass index and foot examination had the least compliance rates, both at 0% while blood pressure monitoring was the most complied with, with a compliance rate of 92.5%. Random blood glucose tests had a compliance rate of 71.6% while HbA1c tests had a compliance rate of 17.2%. This signifies very low compliance rates to the most important clinical tests in DM management.
- Glycaemic control was determined using the results from random blood glucose and HbA1c tests. Both the tests revealed that consistently less than 50% of the

patients achieved target glycaemic control. The patients who reached target random blood glucose levels ranged from 36.2% to 48.8% throughout the five-year period under study. The HbA1c tests had patients ranging from 24% to 35.6% achieving the target levels.

6.2.2 Summary of the cross-sectional study results

Management of patients with DM complications

- According to the healthcare professionals, the review of patients with DM complications is done more frequently on a monthly basis. Of all the participants, 82.6% indicated that the frequency of reviews is done monthly in this population.

- The majority (92.6%) of HCPs indicated that RBG tests are done per every visit in patients with complications. However, it should be known by all the HCPs that according to the guidelines blood glucose tests should be done per every visit for all the patients regardless of whether they have complications or not. As with HbA1c, most (44.4%) of the HCPs indicated that the tests should be done every six months for patients with complications.

- The frequency of conducting other tests like foot examination, eye examination, renal function tests, BP checks and lipogram was also investigated. Most (83.3%) of the HCPs indicated that foot examinations should be done per every visit in patients with DM complications. However, according to the guidelines, foot examination should be done annually in patients without complications and more frequent in patients with complications ranging from once every one to three months or once every six months depending on the severity of diabetic foot complication. Foot inspection is however, supposed to be done per every visit. According to the NDoH guidelines, eye examination should be done more frequently (every three or six months) if there is loss of visual acuity or significant retinopathy. However, only 4.2% and 8.3% of the HCPs indicated that eye examination should be done four times and twice a year, respectively. Renal function tests are supposed to be done every three months in patients with abnormal values, but from the results obtained in this study, only 5.3% indicated the correct frequency of renal function tests. Most (84.6% vs. 75%) of the HCPs indicated that BP checks should be done per every visit in both patients with

complications and those without, respectively. Lipogram should be done annually, if the results are satisfactory and every three months in those with abnormal levels. From the present study only 22.7% of the HCPs indicated that lipogram should be done every three months in patients with complications and those at risk of developing cardiovascular complications.

Factors contributing to the development of DM complications

- Patient related factors were rated to be the most contributory factors to the development of complications in patients with DM. A majority (56.4%) of the HCPs indicated that patient related factors in general, are the most contributory factors. Amongst the patient related factors, diet, non-compliance and physical inactivity were found to be the most contributory patient related factors to the development of complications (87.2% vs. 76.3% vs. 69.2%, respectively).

- Socio-economic and medication related factors were rated to moderately contribute to the development of complications amongst people with DM. Most (36.1% and 29%) of the participants rated socio-economic and medication related factors as moderate in terms of how much they contribute to the development of complications. Lack of financial resources to buy self-monitoring equipment was found to contribute the most, with 50% of the participants. Under medication related factors, route of administration, and multiple medication and doses that are hard to follow were selected as the most contributory (73.7% vs. 51.3% respectively) to the development of complications.

- Healthcare team and health system related factors were rated as the least contributory factors to the development of complications by the HCPs.

6.3 CONCLUSION

DM crisis, most importantly complications are a challenge to healthcare HCPs, patients with DM, policy makers and healthcare planners worldwide. The overall findings of this study indicated the need to emphasize on DM standards of care in order to prevent or slow down the development of complications amongst people with DM.

Non-compliance with the local evidence-based DM guidelines in terms of patient monitoring might be the reason for a very high prevalence of complications. The results obtained from the patient files showed that the monitoring tests were conducted erratically as compared to the recommendations from the guidelines. This therefore, compromises the quality of care in people with DM. These results were consistent with the ones obtained from the HCPs, where they were asked about the frequency of clinical monitoring tests conducted in DM care. Therefore, there is a need to have workshops as refresher courses with all the stakeholders involved in DM care whenever there are new or revised guidelines so that they comprehend the importance of complying with the guidelines. Also quality audits must be conducted often times to check if the guidelines are being correctly implemented and adhered to.

It was noted from the results obtained that the HCPs were over monitoring the patients as compared to the guidelines. This therefore, has a negative impact on the budget which may in-turn affect the availability of resources at the hospital. It also has some negative implications on the patients as they have to take leave days and also travel to the hospitals for their appointments. On a different note, over monitoring may help the HCPs to make early informed therapeutic decisions depending on the results obtained to improve the patient's health outcomes. It may be beneficial to the patient as it might slow down or prevent the development of complications.

6.4 RECOMMENDATIONS

The following recommendations are made based on the results of the study:

- There is need for a larger scale community-based study to ascertain the prevalence and impact of DM complications as this study looked at a small sample derived from one tertiary hospital.
- There is need to evaluate the knowledge of HCPs on evidence-based guidelines for the standards of DM care available in South Africa.

- There is need to introduce the teaching of the standardised guidelines in universities to improve the competences of healthcare professionals upon completion of their studies towards DM patient care.
- Conducting workshops focusing on evidence-based DM management to improve patient outcomes.
- Cultivate ethos of distinction, where quality improvement through system reviews and audits are done to check if the standards of DM care through evidence-based guidelines are being implemented.
- Development and implementation of institutional quality improvement programs where regular audits of the processes and outcomes are monitored by all the stakeholders involved in DM patient care.
- Patient empowerment through the introduction and maintenance of Diabetes Self-Management Education and Support (DSME/S) principles.
- There is need for researches to compare the management of DM and its complications between the private and public sector, to highlight if there are any differences.
- Pharmacists should be actively involved in the clinical aspects of DM management and slowing down of its complications as they see the patients more often. This can help with early detection of complications and treatment adjustments accordingly.

6.5 LIMITATIONS OF THE STUDY

The study was conducted on one hospital and therefore, results may not be generalised in other health settings across South Africa. Retrospective study data was collected from patient records and therefore, the researcher entirely relied on what was written in the records and if some relevant information was skipped, the researcher could not know. DM patients were decentralised to clinics, and some of the relevant clinical information was at the clinics making some of the files not suitable for inclusion in this study. This therefore, reduced the number of files to be included in the study. The researcher did not take into account the severity of the

complications and therefore those with severe and less severe complications were classified as one.

The target population of the HCPs was very small, and not everyone participated in the study making it even smaller. This therefore, makes the results not generalizable. Most of the HCPs cited time constrains and therefore were reluctant to participate in the study.

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APPENDICES

Appendix 1: Diabetes Complications Checklist

Demographic information

Patient Number

1. Gender:

Male	1	Female	2

2. Date of Birth:

dd - mm - yyyy
- -

3. Age:

4. Race:

5. Type of diabetes mellitus:

Type 1		Type 2	

6. Treatment:

1	Insulin	
2	Metformin	
3	Metformin + Glibenclamide	

4	Metformin + Gliclazide	
5	Metformin + Glimepiride	
6	Metformin + Glibenclamide + Insulin	
7	Metformin + Gliclazide + Insulin	
8	Metformin + Glimepiride + Insulin	
9	Other (specify)	

7. When was diabetes diagnosed?

…… (Month and year)

8. Which comorbidities does the patient have?

1	Hypertension	
2	Dyslipidaemia	
3	Obesity	
4	Coronary artery disease	
5	Chronic kidney disease	
6	Other (Please specify)	

9. Are there any pre-existing diabetes mellitus complication/(s)?

Yes		No	

DIABETES COMPLICATIONS CHECKLIST

CORONARY ARTERY DISEASE	**Yes**	**No**	**When**
1. Has the patient been diagnosed with coronary artery disease?			
2. Has the patient complained of any chest pain?			
3. Has the patient suffered a heart attack?			
CEREBROVASCULAR DISEASE			
4. Is there any history of stroke for the patient?			
5. Has the patient suffered a transient ischaemic attack?			
PERIPHERAL VASCULAR DISEASE			
6. Has the patient been diagnosed of blockage of blood vessels of the legs?			
NEUROPATHY			
Peripheral neuropathy			
7. Has the patient ever complained of no feeling or numbness before?			
Autonomic neuropathy			
8. Has the patient complained of loss of bowel control or diarrhoea while asleep?			
FOOT PROBLEMS			
9. Has the patient ever developed an ulcer on his/her toe, feet or lower legs?			
10. Has the patient developed gangrene on the toes?			
11. Was any of the patient's toe or feet amputated?			

EYE PROBLEMS			
12. Has the patient complained of any vision problem?			
13. Has the patient developed a cataract?			
14. Has the patient been diagnosed of retinopathy?			
KIDNEY PROBLEMS			
15. Has the patient presented with microalbuminuria?			
16. Was the patient diagnosed with nephropathy?			

Monitoring and tests done per hospital visit

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
Date											
Random blood glucose											
HbA1c											
Foot examination											
Eye examination											
Urinary albumin											
Blood pressure											
Cholesterol											
Other test (specify)											

Appendix 2: Questionnaire for healthcare professionals

(Please answer the questions that apply to your practice)

SECTION A: BIOGRAPHICAL DATA

1. Gender:

Male	1	Female	2

2. Age:

3. What is your occupation? *(please tick the relevant profession and provide speciality where applicable)*

	Profession	**Specify Speciality**	
1	Medical Doctor		
2	Pharmacist		
3	Professional nurse		
4	Occupational therapist		
5	Physiotherapist		
6	Podiatrist		
7	Optometrist		
8	Dietitian		
9	Ophthalmologist		
10	Other		

4. How long have you been working?

1	< 2 years	
2	2-5 years	
3	5-10 years	
4	10-15 years	
5	> 15 years	

SECTION B: DIABETES MELLITUS COMPLICATIONS MANAGEMENT.

5. How often should reviews be done on patients with diabetes mellitus?

		Without complications	**With complications**
1	Every month		
2	Every 2 months		
3	Every 3 months		
4	Every 6 months		
5	Other (specify)		

6. How often should the following tests and examinations be done on DM patients?

		Monthly	Every 3 months	Every 6 months	Annually	Other (please specify)
Random blood glucose	With complications					
	Without complications					
Foot examination	With complications					
	Without complications					
Eye examination	With complications					
	Without complications					
Urinary albumin	With complications					
	Without complications					
HbA1c	With complications					

	Without complications					
Blood pressure	With complications					
	Without complications					
Lipid profile	With complications					
	Without complications					

7. Which of the following could be the contributory factors leading to the development of complications in diabetic patients? *(Please tick the most appropriate factor(s))*

PATIENT RELATED FACTORS	
Alcohol consumption	
Tobacco smoking	
Diet	
Physical inactivity	
Non-compliance	
Other (Please specify)	
SOCIO-ECONOMIC FACTORS	
Lack of support from the family and community	
Lack of financial resources to attend appointments	
Lack of financial resources to buy monitoring equipments e.g. glucometer and strips	
Other (Please specify)	
HEALTHCARE TEAM RELATED FACTORS	
Lack of adequate time to educate the patient during review	
Lack of coordinated multidisciplinary teamwork	
Information provided in a way not understood by the patients	
Poor relationship with patient	

Other (Please specify)	
MEDICATION RELATED FACTORS	
Multiple medication and doses that are hard to follow	
Adverse effects	
Taste	
Route of administration	
Other (Please specify)	
HEALTH SYSTEM FACTORS	
Medication stock outs	
Lack of adequate suitably qualified personnel	
Other (Please specify)	

8. **How would you rate the following factors in terms of how much they contribute to the development of complications?** *(Please tick the number in the column that best describes how much each factor contributes to the development of DM complications)*

Factor	**Least**	**Moderate**	**Most**
Patient related factors	1	2	3
Socio-economic factors	1	2	3
Healthcare team related factors	1	2	3
Medication related factors	1	2	3
Health system related factors	1	2	3

9. How do you keep track of patients with diabetes mellitus? *(Please tick most appropriate strategy or strategies)*

Diabetes report card	
Community outreach	
Diabetes Self-care booklet/log sheet	
Patient visits/Reviews	
Other (specify)	

10. Is there any standard protocol that you follow when treating patients with complicated diabetes mellitus?

Yes		No	

If your answer is yes, please specify…….....

11. Which type of diabetes mellitus patients present with the highest prevalence of complications?

Type 1		Type 2	

Please explain

……
……
……
……
……
……
……

12. Are there any differences in the treatment of diabetes mellitus patients without complications and those with complications?

Yes		No	

If your answer is yes, please explain

……
……
……
……
……
……
……

13. Is there a specific type of counselling for patients with complicated DM?

Yes		No	

Please explain your answer

……
……
……
……
……
……

14. Do you think there is need to pay special attention to patients with complications?

Yes		No	

Explain your answer

……
……
……
……
……
……

15. Do you think the management of DM patients by a multi-disciplinary team would help in the prevention of complications?

Yes		No	

Please explain your answer

……
……
……
……
……
……

16. Are there any challenges you face when managing DM patients with complications?

Yes		No	

Please explain your answer

……

……

……

……..

Appendix 3: Consent form

PROJECT TITLE: THE PREVALENCE AND MANAGEMENT OF DIABETES MELLITUS COMPLICATIONS AT MANKWENG HOSPITAL, LIMPOPO PROVINCE

NYAMAZANA T.

SUPERVISOR: Mr MANYAMA T.L.

I, …… hereby voluntarily consent to participate in the above-mentioned project. I have been invited to participate in the study. I have had the opportunity to ask additional questions and have been answered satisfactorily. I have been given enough time to decide about participation. I understand that:

1. The study deals with the investigation of the prevalence of diabetes complications and management.

2. The Turfloop Research Ethics Committee has approved that individuals may be approached to participate in the study.

3. The research project, i.e. the extent, aims and methods of the research, have been explained to me. Any questions that I may have regarding the research, or related matters, will be answered by the researcher/s.

4. Participation in this research is voluntary and I can withdraw my participation at any stage. I have been assured that the information obtained from me will remain anonymous and confidential and to be solely used for the purpose of this research.

Signature of participant……

Signature of witness……

Signature of investigator …….

Signed at_____ this ____ day of _____ 20__

Appendix 4: TREC Clearance certificate

University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 2212, Fax: (015) 268 2306, Email:noko.monene@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE CLEARANCE CERTIFICATE

MEETING:	**31 August 2017**
PROJECT NUMBER:	**TREC/239/2017: PG**
PROJECT:	
Title:	The prevalence and management of diabetes mellitus complications at Mankweng Hospital, Limpopo Province
Researcher:	T Nyamazana
Supervisor:	Mr TL Manyama
Co-Supervisor:	Mr RM Tshitake
School:	Health Care Sciences
Degree:	Masters in Pharmacy

PROF TAB MASHEGO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

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

Note:
i) **Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.**
ii) **The budget for the research will be considered separately from the protocol.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

Finding solutions for Africa

Appendix 5: Permission from Department of Health Limpopo Province

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Enquiries: Stols M.L (015 293 6169) Ref:4/2/2

Nyamazana T(LP2017 09 007)
University of the Limpopo
Private Bag X1106
Sovenga
0727

Greetings,

RE: The prevalence and management of Diabetes Mellitus complications at Mankweng Hospital, Limpopo Province

The above matter refers.

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

Your cooperation will be highly appreciated.

Head of Department

Date 13/10/2017

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

Appendix 6: Permission from Mankweng Hospital

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

MANKWENG HOSPITAL

Ref: S5/3/1/2

Enq: Makola M.M

From: HR Utilization and Capacity Development

Date: 16 November 2017

TO: Nyamazana T
University of Limpopo
Turfloop Campus

REQUEST FOR PERMISSION TO CONDUCT RESEARCH AT MANKWENG HOSPITAL

1. The above matter has reference.
2. This is to confirm that **Nyamazana T** has been granted permission to conduct research on" **The Prevalence and Management of Diabetes Millitus Complications at Mankweng Hospital ,Limpopo Province.**"
3. He will be conducting research as from 23 November 2017 to October 2020.
4. Attached please find her application letter,approval from Provincial Office,Turfloop Research Ethics Committee Clearance Certificate, Research Proposal and Questionnaire.

Thanking you in advance

..... 2017/11/16
Chief Executive Officer Date

DEPARTMENT OF HEALTH
Mankweng Hospital
PRIVATE BAG X1117
SOVENGA 0727
Tel. 015 286 1000
LIMPOPO PROVINCE