MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A DISTRICT HOSPITAL IN GAUTENG

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DECLARATION

I, Shingairai Dewah, student number 2389344, declare that this research report is my own work and that I contributed adequately towards research findings published in the article stated below which are included in my research report. It is being submitted for the degree of Master of Science in Medicine (Clinical Pharmacy) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or exam at any other university.

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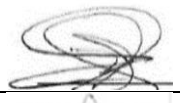
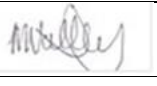
2nd Author	Ané Orchard		26/03/2024
3rd Author	Muhammed Vally		28/03/2024
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ABSTRACT

Background:

Diabetes mellitus (DM) is a major health concern in South Africa and worldwide. Type 2 diabetes mellitus (T2DM) is the most prevalent type of diabetes in sub-Saharan Africa. The management of patients with chronic conditions are guided by the Standard Treatment Guidelines (STGs) of South Africa. This study aimed to investigate whether there was compliance to the STGs by health care professionals, in the management of patients with T2DM attending a district hospital in Gauteng and to determine the extent of glycaemic control for these patients.

Methods:

A retrospective review of 153 medical records of patients with T2DM was conducted. Records from the outpatient department (OPD) were randomly selected by systematic sampling. Patients with T2DM who accessed care between June 2022 and May 2023 were included. Demographic and clinical data was recorded.

Results:

During the one-year period under study, glycated haemoglobin (HbA1c) was measured once in 69.3% of the patients. Of these patients, only 16% achieved glycaemic targets. Random blood glucose levels and hypertension were checked at each clinic visit. Serum creatinine and serum potassium were done on 79.1% and 79.7% of patients respectively. Eye and foot examinations were performed on 15% and 8.5% of patients, respectively. Exclusive oral hypoglycaemic treatment and exclusive insulin therapy was prescribed in 57.5% and 5.9% of patients respectively. Metformin was the most prescribed oral medication, 93.5% of patients were prescribed metformin as monotherapy or combination therapy with another oral agent with or without insulin.

Conclusion:

The study demonstrates poor compliance to treatment guidelines. This highlights the need to review the implementation of the treatment guidelines in public sector facilities in South Africa.

Keywords:

Diabetes mellitus, glycated haemoglobin, public sector, glycaemic control.

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LIST OF ABBREVIATIONS

ACE	Angiotensin Converting Enzyme
BMI	Body Mass Index
BP	Blood Pressure
CCB	Calcium Channel Blocker
CHC	Community Health Centre
CVD	Cardiovascular disease
DKA	Diabetic Ketoacidosis
DM	Diabetes Mellitus
ECG	Electrocardiogram
HbA1c	Glycated haemoglobin
HHS	Hyperglycaemic Hyperosmolar Syndrome
HoD	Head of Department
HREC	Human Research Ethics Committee
IDF	International Diabetes Federation
IQR	Interquartile Range
NAD	No abnormalities detected
NDoH	National Department of Health
OPD	Outpatients Department
PHC	Primary Health Care
RBG	Random blood glucose
STGs	Standard Treatment Guidelines
TB	Tuberculosis
T2DM	Type 2 Diabetes Mellitus

PUBLICATION

At the time of submission, the article had been submitted to the Pan African Medical Journal and is presented in its submissible format.

MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A DISTRICT HOSPITAL IN GAUTENG

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1. INTRODUCTION

South Africa has tiered levels of healthcare provision in the public sector. District health services comprising of primary healthcare (PHC) clinics, community health centres (CHCs), and district hospitals are commonly the points of first entry with referral to regional and tertiary hospitals (National Department of Health, 2020). District hospitals are key players in the healthcare referral system in South Africa, bridging the gap between PHC clinics, CHCs, and higher regional and tertiary levels of healthcare (Mojaki *et al.*, 2011). The treatment and management of prevalent health conditions in the South African public healthcare sector are standardised through the implementation and use of Standard Treatment Guidelines (STGs) (Govender *et al.*, 2021). The STGs of South Africa were introduced in 1996 and rolled out across the public healthcare system, with the purpose of providing therapeutic guidance for the treatment of common health conditions (Perumal-Pillay and Suleman, 2021). These evidence-based guidelines emphasize effective strategies for monitoring and treating priority diseases afflicting the population (Govender *et al.*, 2021). Diabetes mellitus (DM) is one of these priority health conditions.

Diabetes mellitus (DM) is a metabolic disease affecting an estimated 537 million people worldwide (Magliano and Boyko, 2021). According to the International Diabetes Federation (IDF), it is estimated that 10.5% of the world's population aged between 20 and 79 years was living with diabetes (Magliano and Boyko, 2021). On a global scale, the prevalence of DM is growing at an alarming rate (Magliano and Boyko, 2021). It is projected that this population would increase to 11.3% by 2030 and increase by a further 0.9% by 2045 (Magliano and Boyko, 2021). In South Africa, the number of people with diabetes has more than doubled from 1.9 million in 2011 to an estimated 4.2 million in 2021, with a prevalence of 10.8% of the adult population aged 20 to 79 years (Magliano and Boyko, 2021). The escalating prevalence of DM in South Africa is attributed to increased urbanisation, unhealthy diets which are high in sugar and fats, coupled with inactive lifestyles (Duro *et al.*, 2023). Type 2 Diabetes Mellitus (T2DM) is the most prevalent type of diabetes, attributing to a more than 90% incidence in sub-Saharan Africa (Masuku *et al.*, 2022). It is reported that DM is among the leading causes of mortality and morbidity in the South African population (Okaiyeto and Oguntibeju, 2021). Diabetes Mellitus is the second highest natural cause of death in South Africa (26 879 deaths in 2018), only surpassed by tuberculosis (TB) (27 450 deaths in 2018), with a consistent increase in the

proportions of death due to DM over the three-year period between 2016 to 2018 (Statistics South Africa, 2018).

The complications of DM are serious and are classified as microvascular and macrovascular complications (Powers and D'Alessio, 2023). Microvascular complications cause damage to the small blood vessels and include diabetic neuropathy, retinopathy, and nephropathy (Powers and D'Alessio, 2023). Macrovascular complications cause damage to large blood vessels and lead to cardiovascular complications such as heart failure, coronary artery disease, peripheral arterial disease, arrythmias and stroke (Viigimaa *et al.*, 2019). Cardiovascular diseases (CVDs) contribute to the burden of disease in South Africa, and is one of the major causes of death in patients with T2DM (Duro *et al.*, 2023). Previous studies on the incidence of cardiovascular events indicate that, in comparison with individuals with no diabetes, individuals with DM are at an increased risk of developing CVDs (Duro *et al.*, 2023). In men, this risk is increased two to three fold and in women, it is increased three to five fold, compared to people without diabetes (Amod *et al.*, 2017). Therefore, the consequences of these serious complications pose major health challenges (Owolabi *et al.*, 2022), as well as socio-economic challenges on a South African health system that is already plagued by lack of resources (Pheiffer *et al.*, 2021).

The early detection of DM, appropriate diagnosis, treatment, constant access to suitable medications, effective management of co-morbidities, consistent screening, and early identification of diabetic complications, are all crucial factors in the management of diabetes (Bulbulia *et al.*, 2020). In order to minimise diabetes-related morbidity and mortality, it is imperative to ensure good control of blood glucose levels, blood pressure (BP) and serum cholesterol levels (Kok *et al.*, 2021). The extent of glycaemic control may be established from an individual's serum glycated haemoglobin (HbA1c) level (Kerr, 2019). The HbA1c test measures the proportion of haemoglobin which is bound to glucose and provides an average glycaemic level over the past 3 months of treatment (Duro *et al.*, 2023).

One major risk factor in the development of diabetic complications is hypertension, which is characterised by consistently elevated levels of BP. Blood pressure control in patients with T2DM significantly reduces the risk of developing macrovascular and microvascular disease (National Department of Health, 2014). Previous meta-analyses revealed that a reduction in systolic BP by 10 mmHg lowers the risk of CVD events by 20%, coronary heart disease is

lowered by 17% and the risk of stroke and heart failure is reduced by 27% and 28% respectively (Akalu *et al.*, 2022). Similarly constant monitoring of cholesterol and treatment of lipid abnormalities in patients with T2DM reduces the risk of CVDs (National Department of Health-South Africa, 2014).

Adherence to treatment guidelines, by healthcare providers, when managing patients with DM reduces the burden of complications due to the disease as well as reducing the cost of care (Igbojiaku *et al*., 2013). Adherence can be classified as adherence to monitoring assessments and adherence to pharmacological treatment (Igbojiaku *et al*., 2013). In order to comply with the STGs of South Africa for monitoring, nine assessments must be conducted annually on all patients with T2DM, and four tests, blood glucose measurements, blood pressure (BP) measurements, waist circumference and body mass index (BMI) measurements, must be done at every patient visit to the clinic. The recommended annual investigations include the estimated Glomerular Filtration Rate (eGFR) and levels of serum creatinine, eye examination to check for retinopathy, checking for signs of peripheral neuropathy, assessment for macrovascular disease by measuring blood lipids (total cholesterol, triglycerides, high density lipoprotein and low density lipoprotein), urine protein by dipstick, resting electrocardiogram (ECG), oral and dental examination, serum potassium concentration and foot examination (National Department of Health, 2019). Point of care blood glucose and BP measurement, waist circumference, BMI, and weight measurements should be done at every visit (National Department of Health, 2019). The pharmacological treatment guidelines as per the STGs of South Africa are illustrated in Figure 1.

Determining the extent of glycaemic control in patients with T2DM at a district hospital level of care is imperative to reduce the burden and cost of care in South Africa. Insight into the management of patients with T2DM could have a positive impact on how T2DM is treated and managed at this level of care. Thus, this study aimed to assess whether recommended treatment and monitoring practices are adhered to by health care professionals, for patients with T2DM, in a district hospital in Gauteng (South Africa).

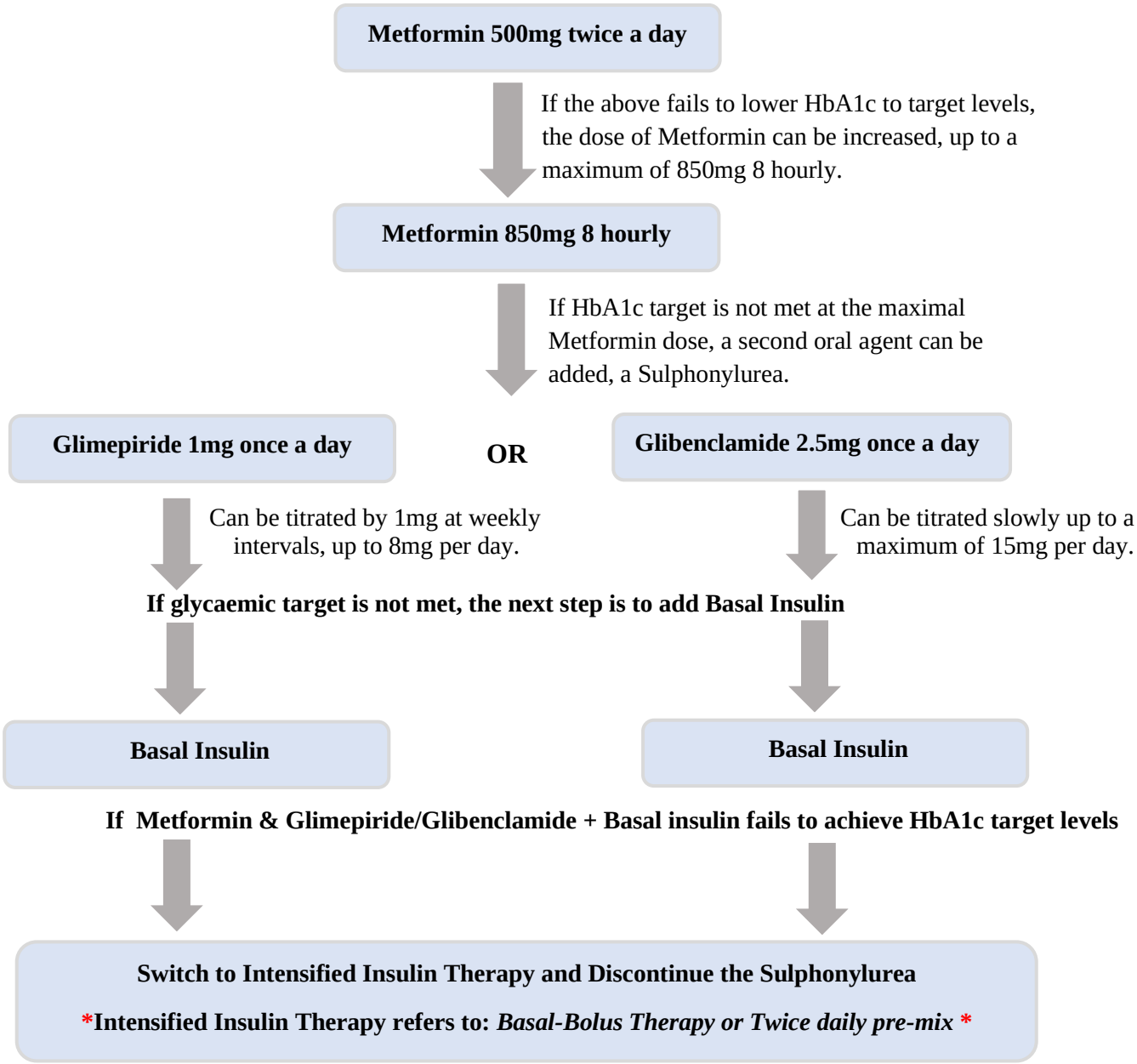

Figure 1: Pharmacological treatment of type 2 Diabetes Mellitus (STG and EML for South Africa Hospital Level, Adults 2019 Edition).

2. METHODS

2.1 Study design and setting

A quantitative, retrospective record review of medical files of patients with established T2DM was undertaken, to determine whether the management of patients at a district hospital was aligned to the STGs of South Africa. The study site is a 300 bedded level 1 district hospital situated in Germiston, in the Ekurhuleni Metro Municipality in Gauteng.

2.2 Sample size calculation

The selected study site has an average head count of 226 patients with type 2 DM per month. A minimum sample of 143 patient records will be randomly selected for this research. The sample size was derived by using the electronic sample size calculator software Raosoft®. The margin of error is calculated at 5% with a confidence level of 95%. The formula that was used in the calculation is as follows: $n = {}^{N\,x}/_{[(N-1)\,E^2 + x].}$ Where:

- *n* is the sample size, which is the point of interest.
- E is the margin of error.
- N is the population size and
- *x* is the observed sample mean.

Calculation of sample size

Equation 1 below is used to obtain the value of *x.*

$$x = Z({}^{c}/_{100})^2 r(1-r)$$

Where:

- $Z({}^{c}/_{100})$ is the critical value for the confidence level=1.96
- *r* is the fraction of responses we are interested in= 50% (0.5)

$x = (1.96)^2 \times 0.5 \times (1-0.5)$

$x =$ **0.96**

Equation 2 below is used to obtain the value of *n*, which is the sample size.

$$n = {}^{N\,x}/_{[(N-1)\,E^2 + x].}$$

$$n = {}^{226 \times 0.96}/_{[(226-1)\,0.05^2 + 0.96].}$$

$$n = {}^{216.96}/_{1.52}$$

$n =$ **142.7**

Therefore, a minimum of 143 patient records was calculated for this study. The estimated sample size was adjusted, to factor in incomplete data from patient medical records. A total of 156 patient medical records were randomly selected for this study.

2.3 Participants and data collection

Medical records of all patients with a diagnosis of T2DM who received care at the Outpatients Department (OPD), were identified and selected. A total of 156 patient medical records were randomly selected for this study, using a systematic sampling technique, where every third patient record was selected until the desired sample size was achieved.

Ethical approval for the study was obtained from the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (Clearance Certificate Number M230665 MED23-05-105). Written approvals were obtained from the Head of Department (HoD) of the OPD, the clinical manager of the hospital, and the District Research Committee.

Demographic data including sex, age, clinical and laboratory measurements were collected from the physical patient medical records and recorded onto a predesigned data collection tool, (Appendix I). No patient names or file numbers were used in the recording of the data, instead each data collection sheet was numbered sequentially until the sample size was achieved. Clinical data included random blood glucose (RBG) levels, BP measurement, weight, BMI, HbA1c, waist circumference, serum creatinine and potassium levels. The values of the blood lipid tests were documented in the patient medical records as high or normal. Those results were recorded onto the data collection tool as high, or no abnormalities detected (NAD). The measurements recorded were readings from any three consecutive clinic visits, recorded in the patient medical files between 01 June 2022 and 31 May 2023. Pharmacological treatment regimens for the same period were also recorded.

2.4 Data analysis

Statistical analysis of the data was done using Statistica® version 14.0.1. Data was checked for completeness and cleaned using Microsoft Excel®. Data from three patient medical records were excluded from the analysis. One was due to duplication and the other two due to incomplete data, with no single test recorded. Statistical analysis of the results was presented as frequencies and percentages, for categorical variables. Continuous variables were presented as means and standard deviations, where data was normally distributed, and as medians and interquartile ranges for data that presented with a skewed distribution.

The respective targets for control of T2DM as set out in the STGs of South Africa were used as the standard of reference. A complete list of the respective targets is shown in Table 1.

Table 1: Glycaemic and non-glycaemic targets for control of T2DM (STG and EML for South Africa Hospital Level, Adults 2019 Edition).

Category of patients	Target HbA1c (%)	Fasting glucose levels (mmol/L)	BMI (kg/m^2)	B. P. (mmHg)
Young, low risk patient with no CVD.	< 6.5	4.0 -7.0	≤ 25	≤ 140/90 and ≥ 120/70
Elderly, high-risk patients with poor short-term prognosis	< 7.5	4.0 -7.0	≤ 25	≤ 140/90 and ≥ 120/70
Majority of the patients	< 7.0	4.0 -7.0	≤ 25	≤ 140/90 and ≥ 120/70

3 RESULTS

3.1 Demographic data

A total of 153 (67.7%, N=226) medical records of patients with T2DM was reviewed retrospectively for this study. The patients were between 27 to 90 years old, with a mean age of 59.3 years (± 12.4). Females made up the majority of patients 85, (55.6%). Only 6 patients, (3.9%), had no co-morbid conditions and the remaining 147 patients, (96.1%) had at least one or more co-morbidities. Of these patients, 49 (32.1%) had one co-morbid condition, 83 (54.2%) had two co-morbid conditions and 15 (9.8%) had three co-morbidities.

Hypertension and hypercholesterolemia were the most common co-morbidities, with 133 (86.9%) of the study population presenting with hypertension and 86 (56.2%) presenting with hypercholesterolemia as documented in the patient medical records. Hypothyroidism was recorded for 9 (5.8%) of the patients, while chronic kidney disease (CKD) was recorded for 8 (5.2%) of the patients. Heart failure was recorded for 5 (3.3%) and aortic stenosis was recorded for one patient (0.65%), of which the cause was not stated in the medical record. Chronic Obstructive Pulmonary Disease (COPD) was recorded for 3 (1.9%) of the patients.

3.2 Medications

A total of 88 (57.5%) patients were exclusively on oral medication, nine patients (5.9%) were on insulin only therapy, and the remaining 56 patients (36.6%) were treated with a combination of oral medication and insulin. The patients using insulin exclusively had a mean HbA1c of 12.3%. One patient met the recommended HbA1c target for the majority of patients of < 7%, one had no recorded measurement of HbA1c, and the remaining patients had HbA1c levels ranging between 9.5% to 15.8%.

According to the STGs, all oral medication apart from metformin must be discontinued once biphasic insulin is added to the treatment regimen. Metformin is recommended because it reduces insulin resistance, resulting in the reduction of the required insulin dose (National Department of Health, 2014). One patient was prescribed biphasic insulin with a sulphonylurea, an approach that is not in line with the STGs. The mean HbA1c level was 16.9% and average plasma glucose levels, based on three consecutive readings taken at one-month intervals was 15.5% for this patient.

Metformin was prescribed for 143 (93.5%) of the patients, as monotherapy or combination therapy including a sulphonylurea with or without insulin. The sulphonylurea prescribed was glimepiride and the 4 mg strength most commonly prescribed, for 21 (47.7%) patients out of the total 44 (28.8%) patients on glimepiride. Second line treatment of metformin with a sulphonylurea was prescribed for 39 (25.5%) of patients. Insulin was prescribed for 65 (42.5%) patients. The following insulin regimens were used: intermediate-acting insulin (Protaphane®) eight (5.2%) of patients, and biphasic insulin (30/70 mix), 57 (37.3%) of patients. Pharmacological management of T2DM is set out in the STGs in a stepwise approach. The study results show that treatment guidelines were adhered to in 138 (90.2%) patients.

The most common co-prescribed medicines included diuretics, lipid lowering agents, angiotensin converting enzyme inhibitors (ACE-inhibitors), calcium channel blockers (CCB), aspirin and beta blockers. Lipid lowering agents were prescribed for 118 (77%) of the patients (simvastatin 58% and atorvastatin 19%), and 82 (69.5%) of those patients had a documented diagnosis of hypercholesterolemia in the patient medical records. The remainder of the patients, 36 (30.5%), were on either one of the two lipid lowering agents, however, with no documented diagnosis of hypercholesterolemia.

The proportion of patients receiving at least one diuretic was 125 (82%), hydrochlorothiazide 58 (38%), furosemide 45 (29.4%) and spironolactone 22 (14.4%). A calcium channel blocker was prescribed for 72 (47%) of the patients and amlodipine was the only CCB used in the patients. The proportion of patients who received an ACE-inhibitor (enalapril) was 75 (49%) The proportion of patients who received BP medication was as follows (n=130): those that were on one BP medication, 19 (14.6%), on two BP medications, 45 (34.6%), on three BP medications, 55 (42.3%), on four medications, 10 (7.7%) and those on five BP medications, one (0.8%). Beta blockers were used for 36 (24%) of the patients, (atenolol 6.5% and carvedilol 17.0%). A complete list of the co-prescribed medicines is shown in Figure 2.

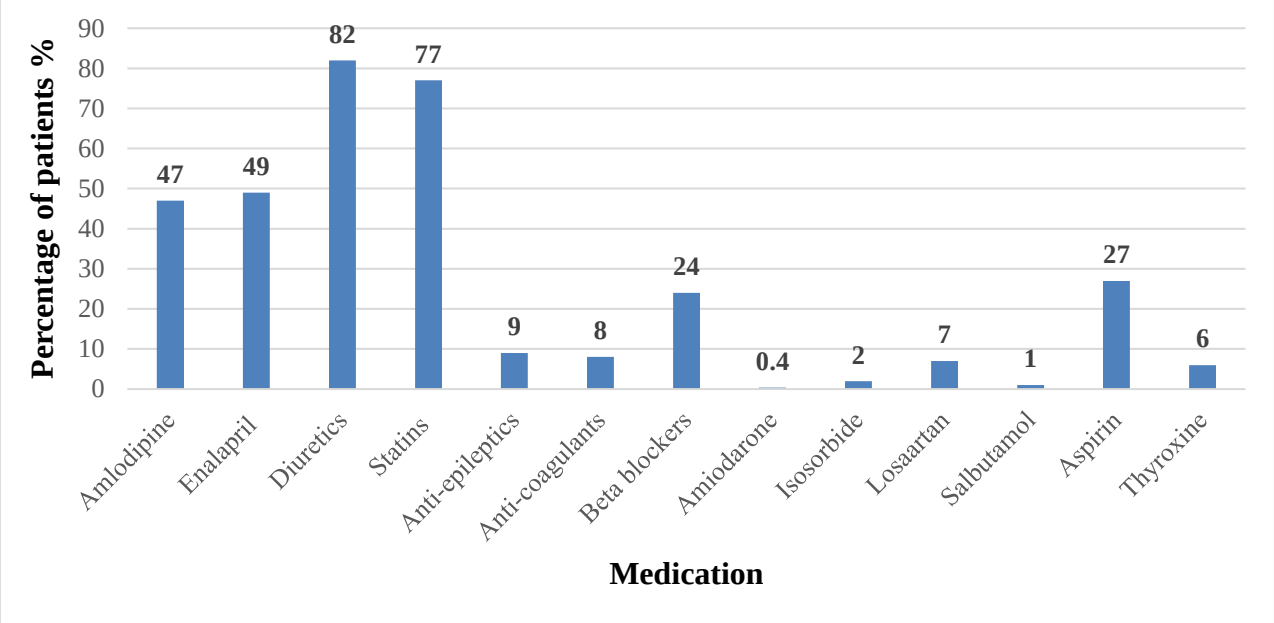

Figure 2: Co-prescribed medications among patients with T2DM.

3.3 Clinical and laboratory data

The HbA1c levels for 106 (69.3%) patients were recorded. Patients with HbA1c levels available at the first visit during the study period had a mean HbA1c of 10.7% (± 3.8), a median of 9.6%, and Interquartile range (IQR) of (7.7, 13.4). Figure 3 depicts the ranges of the first HbA1c levels taken for all 106 patients, at the first visit.

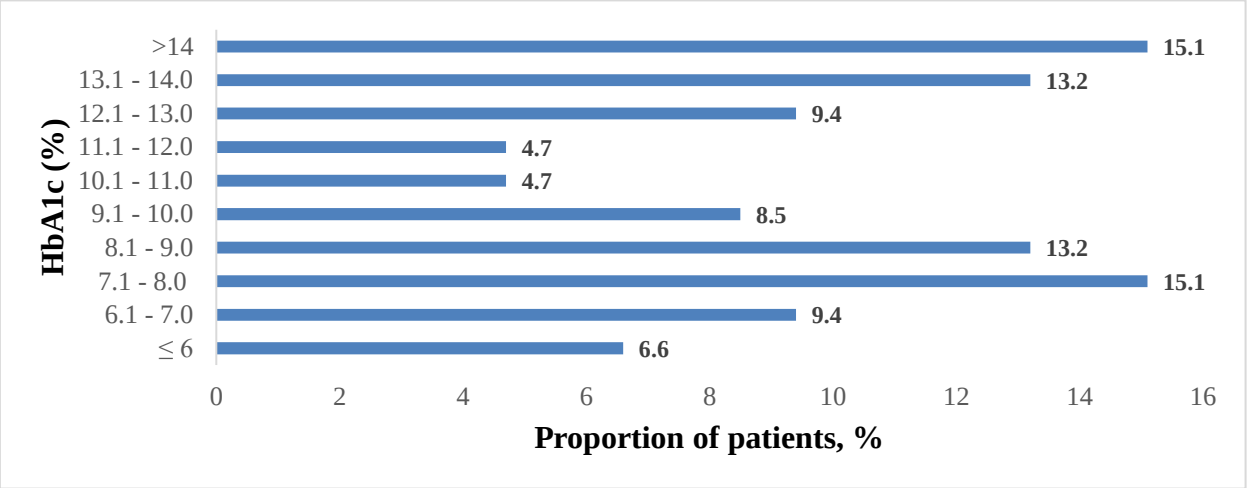

Figure 3: HbA1c values among patients with T2DM.

The patients were classified according to patient type, as stipulated in the STGs, as follows, the young low-risk patients with no CVD (n=8), the elderly high-risk patient (n=50) and the majority of the patients (n=48). The proportion of patients who did not achieve their HbA1c targets were 89 (84%) and the proportion of patients that achieved glycaemic targets (HbA1c) were as follows: the young, low risk patients, 1 (12.5%) achieved the target of < 6.5%, the elderly high-risk patients, 11 (22%) achieved the target of < 7.5% and only 5 (10.4%) of the patients, that do not fall into the two categories mentioned, achieved the glycaemic target of less than 7%, which is the recommended target for the majority of patients. Of these 106 patients, only 21 (19.8%) had a second HbA1c level available in the medical records, taken within 12 months of the first, during the one-year study period under review. Table 2 presents the HbA1c results of the patients, classified according to patient type.

Table 2: HbA1c results of patients with T2DM.

Category of patients	n	Target HbA1c (%)	Proportion of patients achieving target HbA1c
Young, low risk	8	< 6.5	1 (12.5%)
Elderly, high risk	50	< 7.5	11 (22.0%)
Majority of the patients	48	< 7.0	5 (10.4%)
Total patients with HbA1c result	106		17 (16.0%)

All 153 patient medical records had three consecutive random blood glucose levels available, which were taken at each clinic visit, as is required in the STGs. The mean RBG levels were 11.7 mmol/L, 10.9 mmol/L and 11.1 mmol/L for the first, second and third visits, respectively.

Body Mass Index values were recorded in 25 patient medical records, 23 (15%) recorded at the first visit and two (1.3%) recorded during the third visit. The average BMI for the first-visit records was 32.3 kg/m^2 (± 8.4). Of these, only six patients (26%) met the target BMI of ≤ 25kg/m^2. Blood pressure measurements were available for all 153 patient medical records. Only seven patients (4.6%) achieved the recommended BP target of ≤ 140/90 mmHg and ≥ 120/70 mmHg, based on the average of the three consecutive measurements, each of which had to be within the target range.

Serum potassium levels were measured once in 80% of patients during the one-year study period. Average serum potassium levels were 4.29 mmol/L (± 0.65). Blood lipid profiles were done for 114 (74.5%) patients, once during the one-year study period. The blood lipid level was recorded as high or normal in the medical records of which 6 patients (5.3%) had high blood lipid levels and 108 (94.7%) had satisfactory results. The complete clinical and laboratory data is shown in Table 3.

Table 3: Clinical and laboratory data

Variable	1st Visit	2nd Visit	3rd Visit
Random blood glucose (mmol/L) (n=153)			
Mean ± SD[1]	11.7 ± 5.27	10.9 ± 5.21	11.1 ± 4.4
Median (IQR)[2]	10.9 (7.3, 15.2)	9.8 (7.2, 13.8)	10.4 (7.8, 13.5)
BMI[3] (kg/m^2) (n = 25)			
Mean ± SD	32.3 ± 8.4		24.3 ± 1.63
Median (IQR)	31.4 (25.7, 38.2)		24.3 (23.1, 25.4)
Not recorded	130	153	151
Systolic BP[4] (mmHg) (n = 153)			
Mean ± SD	143 ± 21.4	141 ± 21.0	142 ± 19.9
Median (IQR)	142 (126, 154)	140 (125, 152)	
Diastolic BP (mmHg) (n = 153)			
Mean ± SD	83 ± 13.8	85 ± 13.1	83 ± 12.1
Median (IQR)	82 (74, 92)	84 (77, 92)	84 (76, 90)
HbA1c[5] (%) (n = 106)			
Mean ± SD	10.7 ± 3.8	9.4 ± 2.7	
Median (IQR)	9.6 (7.7, 13.4)	9.2 (7.4, 10.5)	
Not recorded	47	132	153

Variable	1st Visit	2nd Visit	3rd Visit
	Annual value		
Serum Potassium (mmol/L) (n = 122)			
Mean ± SD	4.29 ± 0.65		
Median (IQR)	4.2 (4.0, 4.5)		
Not recorded	31		

[1]SD., standard deviation; [2]IQR., interquartile range; [3]BMI., body mass index; [4]BP., blood pressure; [5]HbA1c., glycated haemoglobin

3.4 Clinical assessments

Annual assessments were recorded in the patient medical records. The assessments that were done for the majority of the patients were serum creatinine 121 (79.1%), serum potassium 122 (79.7%), and blood lipid profiles 114 (74.5%). Other assessments that were recorded were foot examination, which was done on 13 (8.5%) of the patients, and a resting ECG which was done on 60 (39.2%) of the patients. Urinalysis findings were documented in 82 (53.6%) patient medical records. Glycosuria was recorded for 22 (27.2%) of patients, while ketonuria was documented for 2 patients (2.5%). Only 3 patients (2%) had an oral and dental examination performed within the twelve months of the study period. Eye examination was recorded in 23 (15%) patients. Assessment for peripheral neuropathy was done on 28 (18.3%) patients. According to the STGs of South Africa, a total of nine assessments must be done annually as part of monitoring patients with T2DM, for microvascular and macrovascular complications. The results indicate that none of the 153 patients had all nine assessments performed in the twelve-month study period (Table 4). Majority of patients, 39 (25.5%), had an average of four assessments done and 9 (5.9%) had no single assessment done in the twelve-month study period.

Table 4: Number of annual assessments done for patients with T2DM

No. of assessments done	No. of patients	Percentage (%)
0	9	5.9
1	9	5.9
2	5	3.3
3	12	7.8
4	39	25.5
5	33	21.6
6	27	17.6
7	15	9.8
8	4	2.6
9	0	0
TOTAL	153	100

4. DISCUSSION

This retrospective study set out to assess the adherence by healthcare professionals, to treatment and monitoring guidelines, as set out in the STGs of South Africa, in the management of adult patients with T2DM receiving care at a district hospital and the extent of glycaemic control among patients with T2DM. Adherence to the STGs for the treatment of diabetes was demonstrated by the healthcare personnel. The results indicate that pharmacological treatment was in line with the STGs of South Africa for 138 (90.2%) of the patient prescriptions. However, clinical management, including monitoring assessments, indicated poor adherence to the STGs, identifying several areas for improvement. Poor adherence to screening and testing protocols by medical personnel amplifies the risk of patients developing diabetic complications (Igbojiaku *et al.*,2013).

The recommendation according to the available treatment guidelines, is for the majority of patients with T2DM, to be controlled at HbA1c levels of < 7%. The HbA1c levels of patients with DM should be checked on a regular basis, as it is a good indicator for glycaemic control and enables healthcare providers to predict complications (Pastakia *et al.*, 2018). In patients who meet treatment goals, HbA1c levels must be checked every six months and in patients whose control is sub-optimal or if therapy has been changed, it must be checked every three months, until the patient is stable (National Department of Health, 2019). The data indicates that only 16% of the patients achieved the recommended targets for glycaemic control, using HbA1c as a measure. These results support existing evidence that glycaemic control is generally poor in South Africa (Piotie *et al*., 2021). Other studies from South Africa have similarly reported such disappointing findings, with as few as 15.6% or less of patients achieving the target of HbA1c < 7% (Pinchevsky *et al.*, 2017). Pillay *et al*., 2015 also found that only 11.8% of the patients with T2DM achieved optimal blood glucose control.

Achieving good glycaemic control is of paramount importance. Evidence exists that shows a 2.5 to 5-fold increase in the risk of developing microvascular complications in patients with T2DM with HbA1c values greater than 7.5% (National Department of Health, 2014). In the same patients, the risk of developing peripheral arterial disease shows a 5-fold greater risk (National Department of Health, 2014). The entire study population was receiving the recommended pharmacotherapy of glucose-lowering agents; however, glycaemic control was poor. The results from this population emphasize that glycaemic control is not determined by

adequate access to pharmacotherapy only (Piotie *et al.*, 2021). Poor glycaemic control could be indicative of patient related factors such as compliance issues to prescribed dietary and lifestyle modifications (Wyett *et al.*, 2019). This highlights the need by medical professionals to strengthen medication education and look closely into issues that inform patient compliance, such as medication side effects and patient preferences, outside the scope of this study (Wyett *et al*., 2019).

Hydrochlorothiazide, a type of thiazide diuretic, was the most commonly prescribed diuretic among the patients, yet the main side effects of thiazide diuretics are metabolic effects, such as hypokalaemia and most importantly, hyperglycaemia (Weber *et al.*, 2014). If not closely monitored, this could be a contributing factor to poorly controlled blood glucose levels.

Glycaemic control is not the only goal in the treatment of DM, treatment and control of other cardiovascular risk factors is also crucial (Bulbulia *et al*., 2020). Hypertension is one of the most serious, life threatening risk factor for the development of cardiovascular disease (Pinchevsky *et al.*, 2017). In this study 133 (86.9%) patients had documented hypertension. These results are similar to other local studies, Pinchevsky et al. had 88.4% (Johannesburg, South Africa) and Piotie et al, had 82.7% (Tshwane, South Africa) of patients with documented hypertension. Despite receiving BP lowering medication, the results from this study indicate that treatment goals were only met in seven (4.6%) patients.

Blood glucose levels and blood pressure measurements were performed routinely in every patient, at each clinic visit, by the nursing staff. However, waist circumference, height, weight, and BMI were seldomly done and according to the STGs, these should be checked at each clinic visit. Findings indicate that only one patient had a documented waist circumference measurement at all clinic visits. There was no plausible reason found as to why waist circumference could not be routinely measured in every patient at each clinic visit. Possible reasons for omitting this measure could be attributed to the healthcare professionals' lack of understanding of the guidelines, and significance of an increased waist circumference in patients with diabetes (Rampersad *et al.*, 2019). The only documented reason identified from some of the patient medical records, for not performing weight checks, was that the scale was non-functional at the time of consultation with the patients.

Other examinations as per the guidelines, such as oral and dental examination, 3 (2%), eye

examination 23 (15%), assessment for peripheral neuropathy 28 (18.3%) and foot examination 13 (8.5%), were performed in a small number of patients during the one-year study period. Available guidelines recommend that these assessments be performed annually in all patients (National Department of Health, 2019). The findings from this study are similar to a 2018 study performed at a district hospital in Kwa-Zulu Natal which showed only 7.8% of the patients had a foot examination conducted (Rampersad *et al.,* 2019). Building onto this evidence of poor foot examination in patients with DM, Amod *et al*., 2017 found that only 6% of the patients had a documented foot examination. This is concerning considering the guidelines clearly stipulate that all patients with T2DM should have a foot examination performed annually, to determine their risk of developing foot ulcers (Amod *et al*., 2017). Previous studies have also shown that diabetic foot ulcers account for approximately 85% of amputations, attributed to DM (Manickum *et al.,* 2022). Similarly, a 2023 retrospective study of all amputations conducted across Gauteng's central and provincial hospitals revealed that 75.3% of the first amputations were as a result of an infected ulcer and 88% of second amputations were preceded by a diagnosis of infected foot ulcer (Ntuli and Letswalo, 2023). The high incidence of amputations, largely due to DM, pose a financial burden on the health care system, and also poses psychological burden on the patients and their families (Manickum *et al*., 2021). In order to minimise the risk to the patients, it is crucial for healthcare professionals to perform regular foot examinations on all patients with DM.

Oral and dental examination was sub-optimal considering these monitoring tests are clearly stipulated in the STGs. There could possibly be a lack of understanding of the relationship that exists between hyperglycaemia and oral health. People with DM are generally at a greater risk of developing oral diseases and this risk is further increased in patients with poorly controlled DM (Borgnakke, 2019). Some of the oral conditions that may develop in patients with DM include, periodontitis, dental caries, and an increased rate of tooth loss (Borgnakke, 2019). More attention is needed towards the oral health of patients with DM, in order to improve their quality of life.

The medication of choice as first line therapy in the treatment of T2DM is metformin, owing to its cost-effectiveness, efficacy in lowering blood glucose levels and its minimal likelihood to cause hypoglycaemia (Hinnen and Kruger, 2019). The majority of patients being treated with metformin 143 (93.5%) as monotherapy or combination therapy, which is in line with the current STGs in diabetes management indicates adherence by prescribers to the stepwise

approach in the pharmacological management of patients with T2DM. The recommended second line approach of metformin with added sulphonylurea was seen in 39 (25.5%) of patients. The addition of insulin is not recommended unless the two oral agents fail to achieve the HbA1c target (Kok *et al.*, 2021). Therefore the preferred sequence of agents is to use metformin first, followed by the addition of a sulphonylurea, in this case, glimepiride and lastly the addition of basal insulin (National Department of Health, 2019). In this study 55 (36%) were prescribed metformin plus insulin with or without glimepiride, depending on the type of insulin added. Although this is in line with the guidelines, where the addition of bi-phasic insulin to metformin, must be followed by the removal of the sulphonylurea (National Department of Health, 2019), it was difficult to determine for those patients that were on metformin and bi-phasic insulin, whether they had been on metformin and a sulphonylurea previously, before the addition of insulin and removal of glimepiride. Medical records of some patients date back many years, and the entire patient medical history would not have been available at the time of the study to make this determination.

One patient was prescribed biphasic insulin with a sulphonylurea, glimepiride. A serious adverse effect of sulphonylureas is hypoglycaemia (National Department of Health, 2014). It has also been reported that the most common adverse effect of insulin is hypoglycaemia (Trujillo and Haines, 2023). Biphasic insulin which consists of intermediate and rapid-acting insulin in a fixed ratio has a greater potential to cause hypoglycaemia (Silver *et al.*, 2018), hence the risk of hypoglycaemia is increased when a sulphonylurea is used in combination with biphasic insulin.

Lipid lowering therapy, in particular, statins should be used in all patients with T2DM presenting with other cardiovascular risk factors, for the primary prevention of macrovascular complications (Costa *et al.*, 2006). According to the guide for the management of type 2 diabetes in adults, published by the National Department of Health (NDoH, January 2014), all patients with T2DM with existing CVD, CKD and are older than 40 years with one or more cardiovascular risk factor, such as hypertension, should have statin therapy added to lifestyle therapy regardless of their baseline lipid levels (National Department of Health, 2014). In this study population, 8 patients (5.2%) had documented CKD, hypertension and were over the age of 40. All these patients except one (12.5%) were on statin therapy, (simvastatin or atorvastatin), in line with the recommendations. Deviations from this recommendation are evident in the group of patients that had documented CVDs (heart failure), hypertension and were above the

age of 40 years, where 5 (3.3%) of patients had all the above conditions, but only 3 (60%) were on either one of the two statins available. A proportion of patients were prescribed statins but with no documented evidence of hypercholesterolemia. These patients had documented hypertension in addition to T2DM and were all above the age of 40 years. Although they did not have existing CVDs or CKD, they presented with at least one cardiovascular risk (hypertension). This approach is in line with the recommendations and is supported by existing evidence that is in favour of the primary prevention of cardiovascular events (Pinchevsky, 2012).

Limitations

Some of the medical records had missing data on weight, BMI, and waist circumference. The study was conducted in one district hospital in an urban setting and therefore the results may not necessarily be applicable to all patients with T2DM across the whole of South Africa.

Recommendations

A multi-disciplinary approach to be implemented in the management of patients with T2DM, which includes dentists or oral hygienists, podiatrists, ophthalmologists, pharmacists, dieticians, doctors and nurses. Systematic processes must be in place for the smooth management of patients with DM. The hospital has a 'chronic patient annual record' form that indicates the types of tests and interventions to be made and the frequency thereof. This form must be used with every patient with a diagnosis of DM, it must be attached to the patient's medical record and used at each hospital visit.

Reasons for poor adherence to recommended treatment guidelines by the healthcare providers need to be investigated and strategies to improve and maintain adherence must be implemented. Healthcare professional managing patients with DM should receive medical education on an ongoing basis, with emphasis on the STGs of South Africa. The quality and level of communication between patients and healthcare providers must be assessed and where strengthening is needed, this must be implemented, to ensure successful management of chronic diseases, such as DM. Existing patient education programmes must be assessed, to determine whether they are effective in empowering patients with information about DM. Where the programmes are lacking in effectiveness, there is a need to intensify the education strategies.

A reliable scale is needed in each consulting room, to weigh the patients at each hospital visit.

In order to maintain accuracy, this scale must be calibrated accordingly as per manufacturer's instructions. In addition, tape measures and stadiometers to measure waist circumference and height respectively must be available at all times and used accordingly.

Similar studies that focus on the compliance to the STGs of South Africa, need to be conducted in other district hospitals across Gauteng. This will contribute to an in-depth understanding of how healthcare professionals interpret and implement treatment guidelines.

5. CONCLUSION

The study assessed adherence to the recommended Standard Treatment Guidelines of South Africa, by healthcare personnel, in the treatment and management of patients with T2DM and the extent of glycaemic control in patients with DM being managed in a public healthcare setting. The study demonstrates poor compliance to treatment guidelines. The findings also indicate poor adherence to monitoring interventions recommended in the STGs. This highlights the need to review the implementation of the treatment guidelines in public sector facilities in South Africa. If diabetic complications are to be minimised and health outcomes improved, vigorous monitoring and screening strategies need to be implemented. This study also supports the postulation that access to the correct pharmacological treatment does not automatically translate into optimal glycaemic control. A myriad of other factors may impact achieving the recommended targets, worthy of further investigation.

What is known about this topic

Adherence to monitoring strategies by healthcare personnel in the management of patients with DM are not satisfactory. Glycaemic control in South Africa is generally poor.

What this study adds

It adds to the evidence that treatment guidelines are not being adhered to in the management of patients with chronic conditions in public healthcare facilities. The non-adherence to recommended guidelines may translate to consequences for patients. Continuous professional education, for healthcare personnel, in the management of chronic conditions can have a positive impact on health outcomes of patients with T2DM.

Competing interests

The authors declare that there are no competing interests.

Authors' contributions

Razeeya Khan, Amber Cheng, Ané Orchard, and Muhammed Vally conceptualised the idea and supervised Shingairai Dewah. Data collection, data analysis, interpretation of results and drafting the original article was undertaken by Shingairai Dewah. Razeeya Khan, Amber Cheng, Ané Orchard, and Muhammed Vally reviewed the article.

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APPENDICES

Appendix I: Data Collection Tool

Data Collection Tool

Parameter	Response		
Sample Number			
Gender			
Age			
Current weight (Kg)			
Other chronic conditions			
***Random blood glucose levels**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***Waist circumference (cm)**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***BMI measurements**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***Blood pressure measurements**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***HbA1c levels**	Lapsed period to visit	Level	Comment(s)
	1st:		
	2nd:		
	3rd:		
***Serum Creatinine measured**	Yes	No	Comment(s)

Parameter	Response		
***Eye examination done**	Yes	No	Comment(s)
***Urine dip stick done**	Yes	No	Comment(s)
***Serum potassium levels measured**	Yes	No	Comment(s)
***Assessment for peripheral neuropathy**	Yes	No	Comment(s)
***Foot examination done**	Yes	No	Comment(s)
***Blood lipids done**	Yes	No	Comment(s)
***Oral and dental examination done**	Yes	No	Comment(s)
***Resting ECG done**	Yes	No	Comment(s)
Treatment regimen	**On Insulin**: *Circle Response Yes		No
	Medication	Dose	Dosing Interval
	1.		
	2.		
	3.		
	4.		
	5.		
	6.		
	7.		
	STGs followed: *Circle Response		
	a) Treatment	Yes	No
	b) Monitoring	Yes	No

***Comments**-where applicable

- High
- Low
- No abnormalities detected (NAD)
- Patient referred for further assessment/intervention

Notes/Additional Items

Appendix II: Approval of Title

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

26 June 2023
Person No: 2389344
PAG

Miss S Dewah
Postnet Suite 44
Private Bag X3
Dalview
1541
South Africa

Dear Miss Shingairai Dewah

Master of Science in Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Management of patients with type 2 Diabetes Mellitus at a district hospital in Gauteng* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix III: Protocol

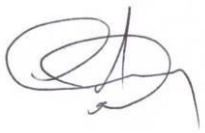
CANDIDATE'S SURNAME: [Please print] DEWAH		FIRST NAME/S: SHINGAIRAI	STUDENT NUMBER: 2389344
CURRENT QUALIFICATIONS: B. Pharm			
TEL: N/A	CELL:067 041 8640	E-MAIL: 2389344@students.wits.ac.za	FAX: N/A
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MSc Med (Pharmacotherapy)			
PART-TIME OR FULL-TIME: PART-TIME			
FIRST REGISTERED FOR THIS DEGREE:	TERM: 1	YEAR: 2021	
DEPARTMENT: Pharmacy and Pharmacology			
TITLE OF PROPOSED RESEARCH: Management of patients with type 2 Diabetes Mellitus at a district hospital in Gauteng.			
CANDIDATE'S SIGNATURE:		DATE: March 2023	
SUPERVISOR 1 (NAME & SURNAME): Mrs Razeeya Khan		25% Supervision	
SUPERVISOR'S QUALIFICATIONS: B. Pharm, MSc, PCDT, AHMP			
SUPERVISOR'S DEPARTMENT: Pharmacy and Pharmacology			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: University of Witwatersrand, Medical School, Faculty of Health Sciences. 7 York Rd, Parktown, Johannesburg 2193, South Africa. **TEL**: 011 717 2578 **E-mail**: Razeeya.Khan@wits.ac.za			
SUPERVISOR 2 (NAME & SURNAME): Miss Amber Cheng		25% Supervision	
SUPERVISOR'S QUALIFICATIONS: B. Pharm, M. Pharm			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: University of Witwatersrand, Medical School, Faculty of Health Sciences. 7 York Rd, Parktown, Johannesburg 2193, South Africa. **TEL:** 011 717 2552 **E-MAIL:** Amber.Cheng@wits.ac.za			
SUPERVISOR 3 (NAME & SURNAME): Mr Muhammed Vally		25% Supervision	
SUPERVISOR'S QUALIFICATIONS: B. Pharm, MSc (Med), Pg Dip Diabetes, Pg Dip PVCM, PCDT			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: University of Witwatersrand, Medical School, Faculty of Health Sciences. 7 York Rd, Parktown, Johannesburg 2193, South Africa. **TEL:** 011 717 2042 **E-MAIL:** Muhammed.Vally@wits.ac.za			
SUPERVISOR 4 (NAME & SURNAME): Dr Ané Orchard		25% Supervision	
SUPERVISOR'S QUALIFICATIONS: B. Pharm, PhD, Pg Dip HSE			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: University of Witwatersrand, Medical School, Faculty of Health Sciences. 7 York Rd, Parktown, Johannesburg 2193, South Africa. **TEL:** 011 717 2317 **E-MAIL:** Ane.Orchard@wits.ac.za			

WITS ETHICS NOT REQUIRED: WITS ETHICS PENDING: WITS ETHICS APPROVED: (Circle appropriate symbol) * ***Please note the final human ethics clearance certificate or animal ethics certificate must be available prior to starting research**	Yes (No) (Yes) No Yes (No)	IF Y SUPPLY ETHICS CLEARANCE CERTIFICATE AS ATTACHMENT AND INCLUDE ETHICS NUMBER HERE:

SYNOPSIS OF THE RESEARCH

Diabetes mellitus (DM) is a metabolic disorder which is characterised by chronic hyperglycaemia and a disturbance of carbohydrate, fat, and protein metabolism because of insulin deficiency or the inability of insulin to perform its functions in the body. The most common types of DM are type 1 and type 2 DM. Other types of diabetes that exist are gestational diabetes and latent autoimmune diabetes (LADA). Ineffective management of DM can result in major complications and possibly lead to death. However, if effectively managed, the outcomes of diabetic patients can greatly improve. This research aims to investigate whether the treatment and management of type 2 DM patients in a public hospital is aligned to the Standard Treatment Guidelines (STGs) of South Africa. Evidence of glycaemic control will be checked and analysed in type 2 DM patients. A retrospective review of patients' hospital records or files will be conducted over a four-week period. A systematic sampling technique will be used to select the patients' records until the sample size is achieved. The research will be conducted to examine the treatment and monitoring of type 2 DM patients, to identify areas of success and areas of improvement. It is important for a study of this nature to be conducted to help improve the treatment outcomes and the quality of life of patients with type 2 DM, by ensuring that their condition is effectively managed.

As supervisor/s, I/we confirm that I have read the protocol which has been submitted for assessment.

SIGNATURE OF SUPERVISOR/S:		
HOD signature		
SIGNATURE PG OFFICE STAFF ……..	REGISTERED YES…. NO….	STAMP

1. Introduction

Diabetes mellitus (DM) is a chronic endocrine disorder characterised by persistently elevated blood sugar levels, as well as abnormal metabolism of carbohydrates, fats, and proteins (Schwinghammer *et al*., 2021). The most common types of DM are type 1 and type 2 DM. Other types of diabetes include gestational diabetes and latent autoimmune diabetes (LADA), among others. In type 1 DM, there is an absolute deficiency of insulin, and this could be due to the destruction of the β-cells which are found in the pancreas, whose primary role is to produce insulin. Type 2 DM is characterised by impaired insulin secretion because of β-cell dysfunction and the failure of these β-cells is progressive (Schwinghammer *et al*., 2021). The β-cell dysfunction is coupled with some degree of insulin resistance and excess abdominal fat is a major contributing factor (Trujillo & Haines 2021).

Diabetes mellitus is listed among the leading causes of mortality within the South African population (Okaiyeto & Oguntibeju 2021). According to a 2018 report published by Statistics SA, DM is listed as the second highest natural cause of death in South Africa, after tuberculosis. In addition, it poses major public health challenges as well as socio-economic challenges (Amod *et al*., 2017), despite it being a non-communicable disease that is preventable and treatable. Diabetes mellitus can also be linked to or lead to other major diseases, therefore making it a very important public health issue in South Africa.(Okaiyeto and Oguntibeju, 2021).

Early detection of DM and effective diagnosis of the disease can prevent the development of complications or delay the onset thereof. Diabetes mellitus can lead to significant microvascular and macrovascular complications. Microvascular complications are those that cause damage to the small blood vessels and include diabetic neuropathy, retinopathy, and nephropathy (Powers & D'Alessio 2023). Macrovascular complications will cause damage to large blood vessels and lead to complications such as heart failure, coronary artery disease, peripheral arterial disease, arrythmias and stroke (Viigimaa *et al*., 2019).

Without proper management, DM can lead to a severe clinical acute complication known as diabetic ketoacidosis (DKA), which may lead a patient into a diabetic coma and in the absence of treatment, may result in death (Amod *et al*., 2017). Diabetic ketoacidosis commonly occurs in patients with type 1 diabetes (Funk 2019). Ineffective management of type 2 DM can also result in a condition called Hyperglycaemic Hyperosmolar Syndrome (HHS), which is

characterised by progressive development of significantly high levels of plasma glucose, usually more than 50mmol/L (Amod *et al*., 2017). It also presents with severe dehydration and hyperosmolality and may lead to death if not managed appropriately (Amod *et al*., 2017). Proper management of the disease can greatly improve the outcomes of diabetic patients. According to Pastakia *et al*., (2018), to ensure that diabetes management is effective, appropriate diagnosis, treatment, and measures for monitoring for hyperglycaemia need to be reliably accessible.

An important parameter used to monitor hyperglycaemia is the Haemoglobin A1c (HbA1c) level. This HbA1c evaluates one's blood glucose control over the last two to three months and can be expressed as the estimated average glucose (eAG) (Kerr 2019).

As per the latest Standard Treatment Guidelines (STGs) target HbA1c levels for control of hyperglycaemia have been set at less than 6.5% for young patients who are also at low risk of developing complications, as well as the newly diagnosed DM patients. For the elderly, patients at high risk for complications and those with a poor prognosis in the short term, the target level should be below 7.5% (STG and EML for South Africa Hospital Level, Adults 2019 Edition). The current guidelines according to the STG and EML for South Africa Hospital Level, Adults 2019 Edition, HbA1c levels are measured every 6 months in those patients that meet treatment goals and for those patients that do not meet the treatment goals or if their therapy has been changed, they must be measured every 3 months.

On an annual basis, the following needs to be assessed for type 2 DM patients: (STG and EML for South Africa Hospital Level, Adults 2019 Edition).

i. The estimated Glomerular Filtration Rate (eGFR) and levels of serum creatinine.
ii. Eye examination to check for retinopathy.
iii. Checking for signs of peripheral neuropathy.
iv. Assessment for macrovascular disease.
v. Urine protein by dipstick (to detect the onset of nephropathy or any kidney problems).
vi. Foot examination.
vii. Serum potassium concentration.
viii. Oral and dental examination.
ix. Resting electrocardiogram (ECG).

1.1 Treatment

The primary goal in the treatment of hyperglycaemia in type 2 DM patients is to lower the blood glucose levels well enough to alleviate symptoms of hyperglycaemia however, most importantly to prevent or delay the onset of microvascular and macrovascular complications (Amod *et al*., 2017). The role of pharmacological interventions remains a pivotal part in diabetes management.

Figure 1 shows the stepwise approach for the pharmacological management of type 2 DM (STG and EML for South Africa Hospital Level, Adults 2019 Edition).

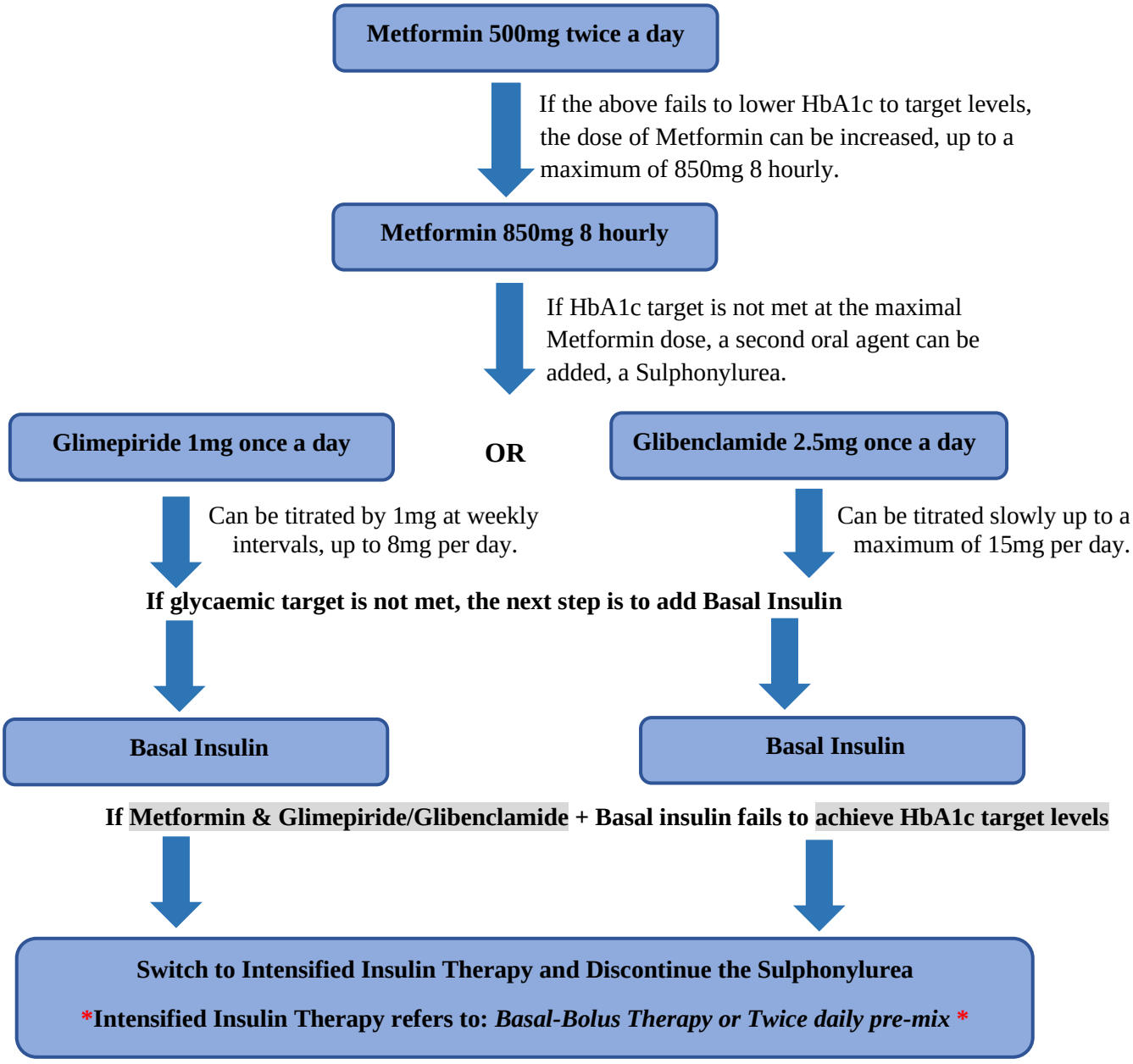


Figure 1 Treatment of type 2 Diabetes Mellitus

It is of importance to note that insulin is only indicated in type 2 DM patients under these circumstances: (STG and EML for South Africa Hospital Level, Adults 2019 Edition).

i. If two oral agents, at maximal doses, fail to control the blood glucose levels.
ii. In the presence of severe kidney and/or liver disease.
iii. For use in temporary situations such as surgery.
iv. Pregnancy

1.2 Problem statement

Diabetes mellitus poses major public health challenges (Okaiyeto & Oguntibeju 2021). If not diagnosed early, treated, and managed, it can lead to severe health complications which can burden the already overburdened South African public healthcare system. One of the critical aspects in the management of type 2 DM is the screening and regular assessment for microvascular and macrovascular disease. A report published by the National Department of Health (NDoH) on type 2 diabetes management in adults (January 2014), states that one of the most common causes of mortality among patients with type 2 DM was cardiovascular disease. According to Pinchevsky *et al*., (2013), as many as 80% of the deaths among patients with type 2 DM is because of cardiovascular disease. Therefore, it is crucial to determine whether a correlation exists, between adherence to STGs in the management and treatment of type 2 DM and optimal glycaemic control coupled with positive health outcomes.

Findings from a recent study conducted by Piotie *et al*., (2021), indicate that there is generally poor or suboptimal control of hyperglycaemia in South Africa. Piotie *et al*., (2021) further discusses some of the concerning consequences of poorly controlled DM in patients, one of which is the need for complex health care interventions should they develop infections such as those caused by viruses. However, this study focused on type 2 DM patients enrolled in the Central Chronic Medicine Dispensing and Distribution (CCMDD) programme, a system that enables public sector patients to collect their monthly medications from an external pick-up point closer to their homes or workplaces. Chronic Central Medicine Dispensing and Distribution enrolled patients undergo clinical assessments every six months at a public healthcare institution (Piotie *et al*., 2021).

The study population of the aforementioned study was focused on patients with type 2 DM receiving treatment and being monitored at clinics and Community Healthcare Centers (CHCs). No studies have been found that focus on the clinical outcomes of type 2 DM patients receiving care at public hospitals and being treated and monitored according to the South African STGs.

It is important to conduct a study that seeks to determine the extent of glycaemic control in patients who collect treatment from a public hospital and have access to clinical assessments monthly. Presenting research-based information of the treatment outcomes of those patients could have a positive impact on how type 2 DM is treated and managed in the future.

2. Research Question

Is the management of patients with type 2 DM in line with the latest STGs and is there evidence indicating glycaemic control in patients treated as per the STG recommendations in a public sector hospital in Ekurhuleni?

3. Aim

To determine whether the pharmacological and clinical management of patients on treatment for type 2 DM in a public healthcare setting is aligned to the Standard Treatment Guidelines of South Africa, as well as to ascertain whether glycaemic control is evident in these patients.

4. Objectives

4.1 To determine whether the monitoring tests for patients with type 2 DM at each hospital visit are being done according to the recommendations in the STGs, by reviewing patient files.

4.2 To evaluate if prescribing patterns for patients with type 2 DM are in line with the Standard Treatment Guidelines for South Africa.

4.3 To determine the extent of glycaemic control in patients with type 2 DM.

5. Methodology

5.1 Study design

This study will be a retrospective record review of patients with type 2 DM attending the outpatients' department at Bertha Gxowa Hospital over a two-month period.

5.2 Study site

The study will be conducted at the out-patient department of Bertha Gxowa Hospital, which is a district hospital situated in Germiston in the Ekurhuleni municipality. District hospitals are the first level of hospital care in the South African public health referral system and are also responsible for the upward referral of patients to higher levels of healthcare services. Therefore, it is important and beneficial to the healthcare system to have well controlled patients at this level of care, hence the choice of this study site.

5.3 Sampling Technique and Sample size

A probabilistic sampling technique will be used to select the patient records. There are several types of probabilistic sampling techniques and for this research, the systematic sampling technique will be used. Records of all patients with type 2 DM will be collected, and samples selected at regular intervals. Every third patient record will be selected. Sampling bias is eliminated because the samples will be evenly spread across the entire population. A sticker will be discretely placed on the rear cover of the patient record to avoid resampling, which will be removed after the study. In the case of resampling, the next unsampled file will be selected.

Bertha Gxowa Hospital has an average head count of 226 patients with type 2 DM per month. A minimum sample of 143 patient records will be randomly selected for this research. The sample size was derived by using the electronic sample size calculator software Raosoft®. The margin of error is calculated at 5% with a confidence level of 95%. The formula that was used in the calculation is as follows: $n = {}^{N\,x}/_{[(N-1)\,E^2 + x].}$ Where:

- *n* is the sample size, which is the point of interest.
- E is the margin of error.
- N is the population size and
- *x* is the observed sample mean.

Calculation of sample size

Equation 1 below is used to obtain the value of *x.*

$$x = Z({}^{c}/_{100})^2 r(1-r)$$

Where:

- $Z({}^{c}/_{100})$ is the critical value for the confidence level=1.96
- *r* is the fraction of responses we are interested in= 50% (0.5)

$x = (1.96)^2 \times 0.5 \times (1-0.5)$

x = **0.96**

Equation 2 below is used to obtain the value of *n*, which is the sample size.

$$n = {}^{N\,x}/_{[(N-1)\,E^2 + x]}.$$

$$n = {}^{226 \times 0.96}/_{[(226-1)\,0.05^2 + 0.96]}.$$

$$n = {}^{216.96}/_{1.52}$$

n = **142.7**

Therefore, a minimum of **143** patient records will be randomly selected for this study.

5.4 Inclusion criteria

The following inclusion criteria will be applied:

i. Data from hospital files of patients who have been receiving type 2 DM treatment at the hospital between 01 June 2022 and 31 May 2023.

5.5 Exclusion criteria:

The following exclusion criteria will be applied:

i. Patient records of patients younger than the age of 18 years.
ii. Patient records of pregnant women presenting with gestational diabetes.
iii. Patient records of patients with type 1 DM.

5.6 Limitations

Incomplete or missing information from records.

Inability to decipher prescriber handwriting.

6. Data collection

6.1 Measurement tool

A data collection tool (Appendix A) will be used to collect the data over a two-month period. A total of 143 samples is required and to achieve the required number of samples, an average of six patient records will be assessed per day for three days in a week, over eight weeks. A set of clinical outcomes will be collected from the patient files and recorded onto the tool.

6.2 Data management

The information gathered using the data collection tool will be transferred onto a Microsoft

Excel® spreadsheet. This information will be stored onto the researcher's personal laptop which is password protected and only the researcher has access to the laptop. Back-up information of the data will be stored on a USB memory stick which will only be accessed by the researcher and the supervisors. Once all the information from the data collection tool has been stored and transferred electronically, all the raw data sheets will be disposed of using a shredding machine, to keep in line with the provisions of the Protection of Personal Information Act, Act 4 of 2013 (POPI Act).

7. Data analysis

The data will be cleaned using Microsoft Excel® prior to transferring it to a statistical analysis software. Statistical analysis will be performed using statistical software, Stata 17. Categorical data will be described using frequency tables and percentages. Continuous data will be described using standard deviations and means or medians and Interquartile Ranges (IQR), depending on the distribution of the data. Comparisons between categorical variables will be done using the chi-squared test of association. Comparisons between continuous variables will be done using t-tests or Mann-Whitney U test, depending on the distribution of the data.

Table 1 illustrates how the data will be analysed to fulfil each objective.

Table 1 Data analysis

Objective	**Variables**	**Analysis methods**
To determine whether the monitoring tests for patients with type 2 DM at each hospital visit are being done according to the recommendations in the STGs.	Random blood glucose Blood pressure Body Mass Index	Means and standard deviations. Medians and Interquartile Ranges (IQR).
Objective	**Variables**	**Analysis methods**
To evaluate if prescribing patterns for patients with type 2 DM are in line with the Standard Treatment Guidelines for South Africa.	Treatment regimen	Frequency tables and percentages.
To determine the extent of glycaemic control in patients with type 2 DM.	HbA1c	Means and Standard deviations. Medians and IQR.

8. Ethical considerations

Permission will be requested from Bertha Gxowa management, to conduct the research at the Facility (Appendix B). Thereafter approval for ethics clearance will be sought from the Human Research Ethics Committee (HREC) Medical, from the University of the Witwatersrand. An application will be made to the Ekurhuleni Health District Research Committee, which will allow the research to be conducted within a public institution in Ekurhuleni, preliminary approval has been granted (Appendix C). This will be done by submitting the protocol, ethics clearance certificate from the HREC as well as the permission letter from the facility.

Patient confidentiality will be a priority. No patient identifiers will be collected. Each record will be numbered sequentially until the sample size is achieved. All information collected will not be used for any other purpose except for the purposes of this research.

9. Dissemination of results

Findings of the research will be shared with the clinical staff at the research site, which is a public facility, together with any gaps that would have been identified, to improve the health outcomes of the patients living with type 2 DM being managed at the facility.

10. What will the study add?

This study will add to the evidence for the management of patients with chronic conditions in public healthcare facilities.

11. Budget

Description	**Cost (Rands)**
Electronic storage: USB 16 GB	80.00
Data bundles (External Wi-fi), for internet research: 10 GB	150.00
Photocopies: ▪ Data Collection Tool: (143 copies of 2 pages each), @ R2.00 ea.	572.00
Total	**802.00**

12. Funding

An application for funding will be made to the National Research Foundation (NRF).

13. Timeline

The timeline that will be used to conduct this research project will be shown in the table below.

Table 2 Research Report timeline

	2022			2023											2024		
Research Timeline	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
Literature review																		
Permission request: Bertha Gxowa																		
Protocol write-up																		
Protocol submission																		
Ethics submission																		
Data collection																		
Data analysis																		
Write-up																		
Final submission																		

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APPENDICES

Appendix A: Data Collection Tool

Data Collection Tool

Parameter	Response		
Sample Number			
Gender			
Age			
Current weight (Kg)			
Other chronic conditions			
***Random blood glucose levels**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***Waist circumference (cm)**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***BMI measurements**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd
***Blood pressure measurements**		*Lapsed period to visit*	*Lapsed period to visit*
	▪1st	▪2nd	▪3rd

***HbA1c levels**	Lapsed period to visit	Level	Comment(s)
	1st:		
	2nd:		
	3rd:		
***Serum Creatinine measured**	Yes	No	Comment(s)

Parameter	Response		
***Eye examination done**	Yes	No	Comment(s)
***Urine dip stick done**	Yes	No	Comment(s)
***Serum potassium levels measured**	Yes	No	Comment(s)
***Assessment for peripheral neuropathy**	Yes	No	Comment(s)
***Foot examination done**	Yes	No	Comment(s)
***Blood lipids done**	Yes	No	Comment(s)
***Oral and dental examination done**	Yes	No	Comment(s)
***Resting ECG done**	Yes	No	Comment(s)
Treatment regimen	**On Insulin**: *Circle Response Yes No		
	Medication	Dose	Dosing Interval
	1.		
	2.		
	3.		
	4.		
	5.		
	6.		
	7.		
	STGs followed: *Circle Response		
	a) Treatment	Yes	No
	b) Monitoring	Yes	No

***Comments**-where applicable

- High
- Low
- No abnormalities detected (NAD)
- Patient referred for further assessment/intervention

Notes/Additional Items

Appendix B: Permission Letter from Research Site

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

EKURHULENI HEALTH DISTRICT
BERTHA GXOWA HOSPITAL
OFFICE OF THE ACTING CLINICAL MANAGER
Enquiries: Dr. MR. Thoka
Tel no: 011 278 - 7600
Email: Rufus.Thoka@gauteng.gov.za

To: Shingairai Dewah

MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A DISTRICT HOSPITAL IN GAUTENG.

Permission is hereby granted for you to conduct the above mentioned study as described in your request provided:

1. Bertha Gxowa Hospital will not in any way incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall always be observed.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / Not supported / Supported with amendments

Dr. MR Thoka
Clinical Manager
Date: 2019/12/19

Approved / Not approved / Approved with amendments

Ms. LP Khumalo
Chief Executive Officer
Date: 22/12/2019

Private Bag x 1035, Germiston 1400 – C/O Angus and Joubert Street – Germiston 1400

Appendix C: In-Principle Letter from Ekurhuleni District

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

EKURHULENI HEALTH DISTRICT
PUBLIC HEALTH UNIT

Enquiries: Mpho Manamela
Tel no: +27 11 878 8617
Fax no: +27 11 878 8587
E-mail: Mpho.Manamela@gauteng.gov.za

26 May 2023

To: Ethics Committee, University of the Witwatersrand

SUBJECT: IN-PRINCIPLE PERMISSION TO CONDUCT RESEARCH BY SHINGAIRAI DEWAH AT EKURHULENI DISTRICT, GAUTENG.

In-principle permission is granted to Shingairai Dewah from University of the Witwatersrand to conduct research in Ekurhuleni district for the following research topic: **Management of patients with type 2 Diabetes Mellitus at a district hospital in Gauteng.**

AIMS

To determine whether the pharmacological and clinical management of patients on treatment for type 2 DM in a public healthcare setting is aligned to the Standard Treatment Guidelines of South Africa, as well as to ascertain whether glycemic control is evident in these patients.

OBJECTIVE

1. To determine whether the monitoring tests for patients with type 2 DM at each hospital visit are being done according to the recommendations in the STGs, by reviewing patient files.
2. To evaluate if prescribing patterns for patients with type 2 DM are in line with the Standard Treatment Guidelines for South Africa.
3. To determine the extent of glycaemic control in patients with type 2 DM.

Data collection tool

A retrospective review of patients' hospital records or files will be conducted over a four-week period.

Ekurhuleni District Research Committee will review the proposal and will only give permission once we have received the final ethical clearance.

Yours sincerely,

Dr Ronel Kellerman EKURHULENI DISTRICT RESEARCH COMMITTEE CHAIRPERSON
Date:29/05/2023

40 Catlin Street, Germiston, 1401 – Private Bag X1005, Germiston, 1400

Appendix IV: Ethics Clearance Certificate

M230665 MED23-05-105

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Miss Shingairai Dewah et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M230665 MED23-05-105

NAME: (Principal Investigator)	Miss Shingairai Dewah et al
DEPARTMENT:	Pharmacy and Pharmacology Bertha Gxowa District Hospital Ekurhuleni Health District
PROJECT TITLE:	Management of patients with type 2 Diabetes Mellitus at a district hospital in Gauteng
DATE CONSIDERED:	30/06/2023
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Mrs R Khan, Mr M Vally, Dr A Orchard and Miss A Cheng
APPROVED BY:	Prof P Ruff, Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/08/2023 **EXPIRY DATE:** 23/08/2028

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

DECLARATION OF INVESTIGATORS

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** in January each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in June and will therefore be due in the month of June each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Email signed copy of this ethics clearance certificate prior to commencing with the study hrec-medical.researchoffice@wits.ac.za

Principal Investigator Signature

25/08/2023
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix V: Turn-it-in Report

Management of Patients with T2DM at a district hospital in Gauteng

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