PATIENT-RELATED FACTORS ASSOCIATED WITH GLYCAEMIC CONTROL IN TYPE-2 DIABETES MELLITUS PATIENTS ATTENDING DAVEYTON MAIN CLINIC IN THE EASTERN SUB-DISTRICT OF EKURHULENI HEALTH DISTRICT, GAUTENG PROVINCE

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of
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I Declaration

I, Bakatuamba Pabu declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in Family Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any other degree or examination at this or any other University.

Signed ……. (Signature of candidate)

Date:

II Dedication

I would like to dedicate this work to my Lord and Saviour Jesus-Christ for the life and Wisdom provided to me. To my lovely wife and children who have been there for me, accepting my absence day and night during the time of my study. To my family who supported me during this challenging time.

III Abstract

Introduction

The World Health Organisation (WHO) indicates that Diabetes Mellitus (DM) is the most common endocrine disease in the world with the burden of the disease increasing. Furthermore, the International Diabetes Federation (IDF) estimates that about 400 million people are living with DM. In South Africa the estimate is 2.7 million.

Aim

The aim of the study was to explore patient-related factors associated with glycaemic control in T2DM patients attending Daveyton Main Clinic (DMC). The objectives were to determine the socio-demographic characteristics, describe patient-related factors associated with good and poor glycaemic control and factors associated with glycaemic control in T2DM patients attending Daveyton Main Clinic.

Methodology

This was a cross-sectional, descriptive study of all T2DM patients attending the DMC for at least a year, willing to participate in the study from March to June 2015. A consecutive sample of 200 T2DM patients was used. A convenience sampling method was used on a first come first serve basis. A patient questionnaire was administered which included socio-demographics, diabetes information, compliance, co-morbidities, complications, global physical activities (GPAQ), depression screening questions (PHQ-2), blood pressure, weight, height and blood collected for HBA_1C.

Results

The results divided patients in two arms namely the good glycaemic control group and poor glycaemic control arm for age range $\leq$ 65 years and above 65 years old. Thirty-six percent (36 % n= 72) of participants had good glycaemic control. Significant findings associated with good glycaemic control were advanced age mean of 65 years (p=0.001), formal housing (p=0.020), employed or recipient of old age pensions (p=0.001), and not statistically significant factors were chronic hypertension (p=0.056), normal weight (p=0.056) and regular physical activities (p=0.059).

Sixty-four percent (64 %, n=128) of participants had poor glycaemic control. Significant findings associated with poor glycaemic control were younger age, mean of 55 years p= 0.001 and informal housing with p=0.020. Depressive symptoms, reported compliance, co-morbidities, and complications were not found to be associated with either good or poor glycaemic control.

Conclusion and recommendations

The conclusion was that older patients who had a decent social economic status (formal housing and earning an income) were more likely to have good glycaemic control compared to younger patients. It is recommended that disease management efforts be focused on younger T2DM patients, encourage diabetes support group meetings and further study of depression and glycaemic control.

IV Acknowledgements

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To the Daveyton Main Clinic staff members involved at the chronic diseases clinic (doctors, nurses and health promotors) and patients who accepted/consented to sacrifice their time and energy for this research to be completed.

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VII List of Acronyms and Abbreviations

ACCORD: Action to control Cardiovascular Risk in most patients with Diabetes

ADA: American Diabetes Association

AIDS: Acquired Immunodeficiency Syndrome

CHC: Community Health Centre

CVD: Cardiovascular Diseases

DCCT: Diabetes Control and Complication Trail

DM: Diabetes Mellitus

DMC: Daveyton Main Clinic

EASD: European Association of Study of Diabetes

HBA_1C: Haemoglobin A1C or Glycosylate Haemoglobin

HIV: Human Immunodeficiency Virus

HREC: Human Research Ethics Committee

IDF: International Diabetes Federation

JEMDSA: Journal of Endocrinology, Metabolism and Diabetes of South Africa

GPAQ: Global Physical Activity Questionnaires

NCD: Non Communicable Disease

PHC: Primary Health Care

PHQ: Primary Health Questionnaires

T2DM: Type 2 Diabetes Mellitus

UKPDS: United Kingdom Prospective Diabetes Study

USA: United States of America

SA: South Africa

SANHANES: South Africa National Health Status and Nutritional Examination Survey

SEMDSA: Society of Endocrinology Metabolism and Diabetes of South Africa

WITS: University of Witwatersrand

WHO: World Health Organisation

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

The study was done in Daveyton Main Clinic (DMC) one of the oldest clinics in Eastern Sub-district in Ekurhuleni Metro. The word, Ekurhuleni means "place of peace" in Tsonga. The Ekurhuleni Metro, previously known as the East Rand is located in the east of Johannesburg, the third Metropolitan of Gauteng and the fourth most populated Metro district in the country with an estimated population of 3.2 million.[1] The level of urbanisation in Ekurhuleni is 90 %. Ekurhuleni is made of previously white Suburbs and Townships. During the Apartheid era, these townships were demarcated for black African people, but are currently still inhabited primarily by the black African population.

The World Health Organisation [2](WHO) indicates that Diabetes Mellitus (DM) is the most common endocrine disease in the world. The DM burden has been increasing, with around two million South African living with the disease. Moreover, it is the seventh most common cause of death in South Africa, with an incidence of 5.5 % among patients aged 30 years or older. It accounts for the majority of non-trauma related amputations and contributes to ischaemic heart disease, blindness and renal disease[3].

The South African Second Demographic and Health Survey of 2003 has estimated that 6.5 % of adults aged between 20 and 79 years have DM.[3] However, the recent SANHANES[4] (South Africa National Health and Nutritional Examination Survey) study indicated the prevalence of DM to be 9.5 %. The study[4] found also that the prevalence of DM was highest in rural informal setting (13.7%) and urban formal setting (10.6%). Daveyton is an urban formal setting with a high number of DM patients considering the headcount of DMC. DM is one of the leading causes of death, with complications claiming 190 000 American lives annually and at an estimated economic cost to the USA in 2012 of $ 245 billion.[5] DM accounted for 4.9 million deaths globally in 2014.[6]

Diabetes Mellitus expenditure reached US $ 612 billion in 2014 globally.[5] The International Diabetes Federation (IDF) estimates that 387 million people are living with DM, 46.3% are undiagnosed and an expectation of 205 million increases by 2035.[6] Of all people living with DM, an estimated 80 % are living in low and middle income countries.

Africa has 22 million people living with DM with an estimated prevalence of 5.1%. In the IDF's[6] latest estimation, SA has 2.7 million people living with DM, 1.2 million are undiagnosed with a prevalence of 8.39%, 68.977,00 related deaths per year which is closer to SANHANES[4] DM prevalence of 9.5% compared to a previous estimate of 6.5%[3]. These statistics indicate a serious challenge and strain to the global economy as most economically active people are affected by the condition, particularly in low and middle income countries such as SA.

1.2 **RATIONALE**

South Africa has quadruple burden of diseases with non-communicable diseases (NCD) leading the way by 33 %: HIV/AIDS with 30 %, infectious diseases with 22 % and injuries and trauma 14 % of death. The non-communicable diseases are: cardiovascular diseases, hypertension, diabetes, cancers, strokes and dyslipidaemia.[7] According to WHO, the epidemics of tomorrow will be chronic diseases such as heart diseases, stroke, diabetes and cancers that are going to take the greatest toll on death and disability in the foreseeable future.[8] T2DM is a global pandemic threatening the economy of many countries particularly low and middle income countries in Africa and Asia[9] Therefore, understanding DM in Ekurhuleni could be useful in helping to tackle head on the challenge of Non Communicable Disease especially DM as there are no studies published on DM in the Ekurhuleni Metro.

The research aimed to identify patient-related factors associated with glycaemic control in adult DM patients attending the DMC. To the best of my knowledge, previous research on the topic has never been done in the Ekurhuleni Health District. Despite well-defined treatment, the disease in the majority of patients is poorly controlled. Therefore, the researcher believed that the study would provide Health care professionals dealing with DM in Daveyton and the Ekurhuleni Health District with some understanding of the factors associated with glycaemic control, consequently providing tools to improve glycaemic control of DM patients attending our clinics and the District.

1.3. STUDY AIM AND OBJECTIVES

1.3.1 Aim of the study

The aim of the study was to explore patient-related factors associated with glycaemic control in T2DM patients attending Daveyton Main Clinic in the eastern sub-district of the Ekurhuleni health district, Gauteng Province.

1.3.2 Study objectives

1. To determine the socio-demographic characteristics of T2DM patients attending Daveyton Main Clinic;
2. To describe patient-related factors associated with good glycaemic control in T2DM patients attending Daveyton Main Clinic; and
3. To describe patient-related factors prevailing in poor glycaemic control in T2DM patients attending Daveyton Main Clinic; and
4. To describe the association of various factors with glycaemic control in T2DM patients attending Daveyton Main Clinic.

1.4 ORGANIZATIONAL REPORT

The research report has five central chapters. Chapter 2 is a literature review, Chapter 3 is methodology, Chapter 4 is results, Chapter 5 is discussion, and Chapter 6 is conclusions and recommendations. These chapters are followed by references and appendices. The next chapter reviewed the literature related to the study.

CHAPTER 2: LITERATURE REVIEW

2.1. INTRODUCTION

The largest clinical study on Diabetes Mellitus, the United Kingdom Prospective Diabetes Study (UKPDS), has provided evidence that serious complications of T2DM can be reduced through a combination of good blood glucose and blood pressure.[10] The Diabetes Control and Complications Trial (DCCT) and KUMAMOTO studies show that intensive management of T2DM can reduce chronic complications, and that early and aggressive glucose control aids in the prevention or development of complications.[5] In 2008, the International Expert Committee, with members representing the American Diabetes Association (ADA), the European Association for Study of Diabetes (EASD) and the International Diabetes Foundation (IDF) recommended that the HBA_1C test be used as a diagnostic tool of T2DM and the value for diagnostic being 6.5 % or higher.[11, 12] This has been supported internationally by WHO[2] (WHO 2011) and locally by SEMDSA who has also has validated HBA_{1C} for diagnostic.

In SA the value of 6.1% has been recommended for screening and diagnostic amongst the colour ethnic groups because of the possibility of organ dysfunction with HBA_1C of 6.5%.[4] Currently HBA_1C is the gold standard tool for management of DM. The American Diabetes Association recommends a target HBA_1C of 7% or less to achieve glycaemic control in most patients with T2DM. However, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) research, which has the objective of reducing cardiovascular diseases (CVD) with interventions aimed at achieving an HBA_1C of less than 6.0%, has had results indicative of excess death in the intensive treatment group. Therefore, intensive or aggressive intervention with a goal of lowering HBA_1C to 6% is not recommended especially for elderly patients.

The *Journal of Endocrinology, Metabolism and Diabetes of South Africa* (JEMDSA) recommended diabetes mellitus education as the cornerstone of care for DM patients.[13] Major factors that increase the risk of T2DM are: over-nutrition and a sedentary lifestyle, smoking with consequent overweight, obesity [14]and high cholesterol and other NCD. Therefore, managing T2DM without clear monitoring of lifestyle modification is inappropriate, as the T2DM complications of peripheral neuropathy and retinopathy occur

because of poor glycaemic control. Recommending patient goals of care is an important process in the management of T2DM.[7] The achievement of recommended clinical goals substantially reduces the risk of illness and death. In addition, this achievement in primary health care facilities cannot be possible without the appropriate assessment of the glycaemic control required and the contextual factors associated with the glycaemic control.

There is a robust epidemiological indication base for selecting a target glycosylated haemoglobin A_1C (HBA_1C) level of 7 % as a good glycaemic control level, because patients with T2DM with levels above 7.5% have a relative risk of developing microvascular complications that are 2.5- to five-fold greater, as well as a five-fold bigger danger of emerging peripheral artery disease.[11] The HBA_1C level of a patient is now well accepted internationally and is a widely standardised test for glycaemic control (WHO, IDF).[2,6]

Some misconceptions about NCD, especially DM, include a common belief that NCD[8] affects mainly rich people or high income countries but the truth according to the evidence of IDF and WHO[8] is that less affluent people mainly low and middle income countries are much more likely to be affected than the wealthy to develop NCD. As a result NCD causes a substantial financial burden and pushes an individual and a household into poverty (WHO, IDF).

A second misconception is that DM and other NCDs affect mainly people older than 60 years of age whereas the current evidence from WHO[8], IDF[6] and SANHANES-1[4] is that the prevalence of DM and other NCD for 45 to 60 years of age has reached alarming proportions causing premature death in people younger than 60 years of age therefore causing a severe financial burden in many countries because of loss to the economy of an economically active population. (IDF, WHO, SANHANES). A systematic review of T2DM studies conducted in Sub-Saharan Africa from 1999-2011 found the prevalence of DM increasing with the highest estimate of 12 % with the total annual cost of diabetes in the region of an estimated US$ 67.03 billion, or US$ 8 836.00 per diabetic patient[15].

Another misconception of NCD such as DM is that they are too expensive to prevent and to control for low and middle income countries but the truth is that the cost of not

preventing and not controlling is premature death and severe complications with a severe burden to the family and countries[8]; while a full range of cost effective interventions for NCD such as DM are available in all countries. According to the evidence of WHO[8], IDF[6], and SANHANES[4], the risk factors of Non-communicable diseases such as DM are well known and preventive interventions are effective.

2.2 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS

The prevalence of DM varies between 6- 20% in adult population, according to a recent IDF[6] Sub-Saharan Africa has 22 million people with DM and 62% undiagnosed Diabetics. Currently, Sub-Saharan Africa has the lowest DM population by number but the trend is changing with rapid development and westernisation of society. The IDF[6] estimates that the DM population of Sub-Saharan Africa will increase by 110% by 2035. DM in Africa affects mostly the economically active population between 40 and 59 years of age, therefore having the potential to adversely affect economic development in the region if the challenge is not tackled head on.

A South African study[16] of the black population with DM in peri-urban clinics found the mean age of the study population to be 56, 3 years that was comparable with the 58 years of age in a recent Johannesburg study[17]. A SANHANES-1[4] study found that amongst the SA population, the prevalence of DM was higher for the Coloured and Indian population. There were no gender related differences between the two studies.[16,17]

However, the mean age of the patients was 41.37 years, 58.5% were male and the mean duration of insulin treatment was 4.9 (±5.1) years in the Ethiopian study[19] , a lower mean age of DM patients seems to be the current trend in Sub-Saharan Africa considering the evidence of IDF[6]. The Al-lawati[21] study in the Middle-East and Malaysia[22] found the mean age to be 53.3 and 55.9 years of age respectively which was comparable with South-Africans studies.[16,17] Studies done in the higher income countries[,23,24,25] have a mean age above 60 years which confirms the higher risk of an economically active population in Sub-Saharan Africa comparable with other regions.

Obesity was present in 562 patients (79.4%)[16], in black peri-urban clinics. Another study in Mamelodi, Primary Health Care (PHC) (SA) among DM patients found that 71% were obese and 15 % morbidly obese.[20] Obesity and overweight prevalence was also found by

SANHANES-1[4] to be significantly higher at 56 % for black female South Africans (SANHANES-1). According to a Canadian Agency, 14.7% of obese Canadian patients of 18 years and older were reported to have DM while African studies report more than 50 % of obese as having DM. Clearly being overweight and obesity are major risks factors but the impact seems to be less in high income countries compared with low or middle income countries. Target values of HBA_1C were only achieved in 16.4% of obese and 21% of non-obese diabetics, with mean HBA_1C levels being significantly higher ($p<0.05$) in the former group.[16] These results would most likely be similar to our results, as a similar population is being dealt with in this study. However, this study[16] was done 15 years ago in a peri-urban setting, and with advances in the understanding of DM and improved availability of drugs better results are anticipated.

African studies[16,17] indicated that poor social status and poor education were associated with poor glycaemic control as also found by a Nigerian study[18] that level of education, income level and short duration of diabetes were in relation to good glycaemic control. The short duration of DM and obesity were associated with poor glycaemic control in a study in Oman.[21]

2.3 PATIENT-RELATED FACTORS WITH GOOD GLYCAEMIC CONTROL

Below are good glycaemic control studies conducted in different parts of the world:

2.3.1 AFRICAN STUDIES

Erasmus[16] *et al*, in their study of assessing glycaemic control among stable black South Africans T2DM patients attending peri-urban clinics, found that from 708 patients, good glycaemic control (with $HbA_1C \leq 7\%$) was achieved in only 20.1 % of patients (142), which was similar to the result of a Johannesburg study, which found 16 % to have good glycaemic control.[17] In addition, 14.7% were insulin-treated patients and 85.3% were non-insulin-treated patients, and there was a non-gender-related difference in glycaemic control, which is the same case as in the Johannesburg study.[17] Patients whose HBA_1C levels fell within the target values had diabetes of a significantly shorter duration than those displaying poor control (5.0+0.2 vs 7.03+0.5 years). Level of education, income level and short duration was also found in relation to good glycaemic control in the Nigerian study.[18]

In an Ethiopian study, Angamo *et al*[19] found that from the sampled 284 insulin-treated diabetic patients with regular follow-ups, only 18.3% achieved good glycaemic control. The study was a cross-sectional hospital-based survey of patients on insulin therapy, and the result of 18.3 % of the patients having good glycaemic control is indicative of poor glycaemic control, which is similar to Erasmus' findings[16] and the Johannesburg study's[17] results. However, previous studies and a recent systematic review for the use of insulin in out-patients at PHC, indicate insulin to be safe and effective in reducing HBA_1C [20]. The researcher speculates that poor glycaemic control might be linked to advanced disease compared to the effectiveness of insulin. The mean age of 41.37 (± 15.08) in the study[19] was lower than that of Erasmus[16] and the Johannesburg[17] studies, which may be an indication of earlier Diabetes Mellitus occurrences in the Ethiopian population, the trend also reported in many low and middle income countries by WHO[2] and IDF[6]. The researcher considers this study's[19] findings of poor glycaemic control to be expected, as insulin-treated diabetes patients are often more advanced in the disease process than patients on an oral regimen. Furthermore, the good glycaemic control level of 18 % is in line with other African studies.[16,17]

2.3.2 MIDDLE- EASTERN STUDIES

A poor glycaemic control rate of 68 % was also found in the younger age group by Al-Lawati *et al*[21] in their study of primary health care in Oman where mean HBA_1C levels were 8.9, 8.3, and 7.8 in the age groups 20–39, 40–59 and 60+ years respectively. A proportion of 32 % (405) of patients had good glycaemic control with a target of $HBA_1C \leq 7\%$. Similar results were obtained in a Jordanian study with 65 % of poor glycaemic control amongst 917 patients with T2DM[22] and 67.9% in Saudi Arabia within the PHC.[23] The researcher notes that this result is better than in the previous African studies[16.17,18,19], which reported a poor glycaemic control range of 80 – 84 %. In the Al-Lawati study[21], the mean age was 53.3 ±11.5, which is similar to that of Erasmus[16] and closer to the result of 58.2 ±12.2 years in the Johannesburg study[17].

2.3.3 FAR-EASTERN STUDIES

The Quah *et al*[24] study conducted in Singapore indicated that 35.3% of the sample of 688 T2DM patients had good glycaemic control ($HBA_1C \leq 7\%$), which is similar to Al-Lawati's[21] and other Middle-Eastern studies[22,23] but better than the African studies[16, 17, 18] quoted earlier. To the contrary, a Malaysian study found that only 23 % of 557 T2DM

patients had good glycaemic control in PHC[25] which was similar to the aforementioned African studies.[16,17, 19] In the Malaysian study[25], the patients were more likely to have good glycaemic control if they were female, Chinese, elderly and had a shorter length of Diabetes Mellitus. While most other studies did not find the female gender to be associated with good glycaemic control.

2.3.4 AMERICAN STUDIES

In a Brazilian public health study by Viana *et al*,[26] from a total of 5750 patients only 26 % achieved good glycaemic control ($HBA_1C \leq 7\%$), similar to the 23 % of good glycaemic control in the Malaysian study[25] and closer to the African studies[16,17,19] quoted earlier but below the 35.3 % in the Quah study[24] and 32 % in the Al-Lawati study.[21] Considering that Brazil is a middle-income country with huge inequality, much like South Africa, the researcher surmises that the factors associated with good glycaemic control may be similar to those in the South African context. This result of the Brazilian study is slightly better than the study by Erasmus[16] (20 %), the Johannesburg study[17] (16 %) and Angano's study[19] (18 %), but is lower than those in the Middle Eastern[21] and Singapore[22] studies, which found good glycaemic control of around 35 %.

However, the Viana study[26] was a survey, based on self-reporting surveillance within the public health system only; therefore the results need to be taken with caution, because a cross-sectional study can only identify associations between several factors and glycaemic control, but is unable to pinpoint risk factors.[24] The researcher noticed the trend of the results indicating that the African[16, 17, 19] and South-American[24] studies' populations had the worst glycaemic control (around 20 %). In contrast, the Middle-Eastern[21] and Asian[22,23] studies had far better glycaemic control (an average of 25 - 35 %), which is probably related to their countries' income level. Therefore, the researcher is of the opinion that the income level of a country can determine the level of glycaemic control.

In an American study by Otiniano *et al*[27] conducted among older Mexican–Americans, of the 209 T2DM patients, 34.9 % (73) achieved good glycaemic control with an $HBA_{1C} \leq 7\%$, and 136 (65.1%) had poor glycaemic control ($HBA_1C > 7\%$). These results are in line with the findings of the study by Quah[22] in Singapore and are better than the African studies[16, 17,19.] However the study was a survey of the very old, with an average age of 70

years, a stage of life that most African populations do not reach. This result also indicated a similar trend in a country's income level.

Despite the fact that Otiniano's[27] study was done on Mexican–Americans, who could be considered as the group with the lowest income according to USA standards, the glycaemic control was far better than in African studies.[16,17,19] Contrary to the HAWAI study of the 2970 DM patients with poor glycaemic control, only 5,9 % patients were able to achieve and maintain a good glycaemic control with a mean HBA_1C of less than 7% for the 3 years[28] of the follow up.

2.3.5 EUROPEAN STUDIES

In a German study, Rothenbacher[29] *et al* found that of 845 patients with T2DM in 12 PHC general practices surveys, 78.9 % (667) had good glycaemic control with an HBA_1C value of $\leq$ 8% and younger patients had an increased risk for poor glycaemic control with high HBA_1C values. This is similar to the Al-Lawati[17] study in Oman with a younger age group of 20-39 years having poor glycaemic control. The researcher considers that this finding may be misleading, as the level of glycaemic control was set at HBA_1C above 8 % and not above 7 % like most of the studies quoted. Despite the level of glycaemic control HBA_1C set above 8% for poor control, to have 78 % of the sample achieve good glycaemic control, is indicative of the trend of a country's high income level being a major protective factor with an exception of the HAWAI study.[26]

Another cross-sectional survey of 373 T2DM patients in PHC treated by General Practitioners in Augsburg, Germany found 45 % of patients achieved good glycaemic control with $HBA_1C < 7$ which is still a high level of glycaemic control compared with the African, Middle-Eastern and Far-Eastern studies.[30] A Japanese cross-sectional survey of more than 15 000 DM patients treated by GPs and Specialists found 65 % of good glycaemic control with $HBA_1C < 7$.[31] The aforementioned two studies[30,31] confirms the fact as the researcher indicated earlier in relation to Viana's[26] finding that white ethnicity, high income country predicted better glycaemic control.

2.4 PATIENT-RELATED FACTORS ASSOCIATION WITH POOR GLYCAEMIC CONTROL

The study by Al-Lawati[21] in OMAN PHC found a statistically significant difference in the mean HBA_{1C} between three age groups of 20-39, 40- 59 and above 60 years in; subjects with ≥5 years of diabetes, subjects on oral agents, and subjects with a BMI in the range of overweight or obese. Obesity, longer duration of DM, use of insulin and lower age group were also connected with poor glycaemic control in Africans studies.[16,17,19]

The factors connected with poor glycaemic control in a Saudi Arabian study[22] were: female gender, level of education, urban population, non-adherence, treatment regimen with insulin therapy or combination of insulin and oral therapy. The researcher considers the above results surprising that younger adults in the 20–39 age groups were found to have worse HBA_1C than the older age groups, because the expectation is that with the progress of the disease the older age groups would do worse. However, one positive finding for the researcher is that these studies were conducted in low- and middle-income countries similar to South Africa and in a PHC setting, therefore making the results comparable.

In a study by Quah[24] in Singapore, the percentage of patients with poor glycaemic control increased with the duration of diabetes by more than 10 years, similar to the Johannesburg study,[17] relating to the ethnic group (Malay and Indian), use of insulin (53.4%) and obesity (30.0%). Ethnic group or race might be an important factor to consider as also the SAHANNES-1[4] study in SA found that Coloureds and Indians have higher prevalence of DM than any other SA ethnic group despite the fact that all our participants were Black Africans. Other factors, such as gender, marital status, smoking history, household income, education level, satisfaction with clinic and confidence in the doctor were not associated with glycaemic control[26] ($HBA_1C \geq 7\%$).

However, the UGANDA study[32] found that the risk factors of poor glycaemic control were age, gender, family history of DM, smoking and alcohol use. The researcher found these results from the Singapore study[24] surprising, as the African studies[16,17,19] indicate that poor social status and education level are often associated with poor glycaemic control. The other factors such as duration of diabetes, use of insulin regimen and obesity appear similar to other studies.

In a Brazilian study by Viana[26] white ethnicity and being from the Midwest region of Brazil were protective factors connected with good glycaemic control. In contrast, diabetes duration, obesity, use of insulin and living in the Northeast region of Brazil were connected with poor glycaemic control. Unfortunately, in our study the population group is black South Africans and are located in a single low-income setting. In a Cape Town qualitative study[33] in Primary Health care among DM patients attending CHC, the DM patients self-reported that financial constraints, challenges with physical activities and challenges with a healthy eating plan were major factors contributing to poor control of DM. The researcher concurs with other studies that not only socio-economic factors and poor lifestyle are contributing to the rise of NCD such as DM but are also a poor marker of glycaemic control.

In the Otiniano[27] study among Mexican Americans, an analysis revealed that patients with poor glycaemic control had a longer disease period and inferior level of education, which are findings that are similar to other studies.[16,17,19] These patients also used a glucometer more often and had additional diabetes-related complications when matched with those in the group with good glycaemic control. Multivariable logistic regression analysis found the following factors were connected with poor glycaemic control: less than eight years of education, being foreign-born, smoking, obesity, lengthier disease duration, daily glucometer use and macrovascular complications.[27] Most of these factors as education level, longer duration of DM, obesity, use of insulin are similar factors as indicated by Viana[26] and others studies[16,17,19]

In the Hawai study[28] of 2970 DM patients, independent variables that were assessed as possible forecasters of glycaemic control were age, sex, type of insurance cover, illness level, diabetes length, history of cardiovascular disease, and amount of medications, which were similar to the factors associated with glycaemic control from most of the studies[16,17,19,21,22,25] quoted but the low level of glycaemic control was surprising for a high income country such as the USA. The type of medical cover is a new factor which the researcher is not considering as all participants in this study are state patients.

However, it may be a factor to consider in future studies of DM in SA, comparing the level of control between state patients and medical aid patients. The researcher can only speculate that this result may not be comparable because the study considers merely DM

patients ($HBA_1C > 9$) with very poor glycaemic control which may be a category that is even more difficult to manage. Despite this speculation, to have less than six percent of good glycaemic control for a large population of 2970 DM patients is an indication of how challenging DM management may be, even in a high income country.

A German study[29] of DM in PHC found no significant connection in multiple regression analysis among HBA_1C level and gender, level of education, family status, occupational status, level of social support, smoking, alcohol consumption, physical leisure activity, obesity, and patients' self-rating of health condition. The researcher can merely speculate that these factors, such as education level, social status and occupation have less of an impact in Germany and other high income countries because: the level of education and income status are far higher than in lower and middle income countries and social support provided by the state almost eliminates the level of poverty found in lower and middle-income countries.

Therefore, these factors have a lesser impact on glycaemic control in Germany. There was, however, a connection between HBA_1C level and age, duration of diabetes, diabetic medication and physicians' assessment of compliance[27], which were similar to other studies.[16,17,19,21,22,25] Surprisingly, obesity had no significant association with poor glycaemic control in the German study[29], contrary to many other studies in Africa[16,17,19] and the Middle-East.[21,23]

2.5 ASSOCIATION OF OTHER FACTORS WITH GLYCAEMIC CONTROL

2.5.1 DEPRESSION AND GLYCAEMIC CONTROL

Depression is one of the co-morbidity factors which might badly affect a patient with DM. Currently, evidence available is unclear. An Australian study[34] reported that men with DM had a higher prevalence of depressive moods than non DM. Similarly a report on Pima Indian (American Native Indian)[35] found the prevalence of depression to be higher in DM and depression to be associated with poor glycaemic control (HBA_1C).

Therefore the relationship between depression and DM is bidirectional; up to a point the severity of either seems to be associated with chronicity of the other. A meta-analysis of the Literature by Lustman[36] of cross-sectional studies and Randomized Control Trials (RCT) between 1976 and 1999 found depression to be connected with poor glycaemic

control, with treatment of the depression having the potential of improving the glycaemic control.

More recently, a study[37] in India found a higher prevalence of depression amongst DM patients and treatment of depression with an anti-depressant such as Serotonin Selective Re-uptake Inhibitors (SSRI) improving glycaemic control. To the contrary another study[38] among Mexican Americans found that depression was connected with higher HBA_1C among participants born in the USA, who had greater education, and those who completed the study evaluation in English.

Conversely, depression was not connected with HBA_1C among those born in Mexico, those who were poorly educated, and those who completed the study evaluation in Spanish. This result is contrary to the expectation. In an unpublished study done in the Daveyton Main Clinic[39] among the patients attending the chronic clinic, they found a very low prevalence of depression amongst DM patients but higher amongst epileptics. There is less evidence in Africans studies for the association between depression and DM; therefore the researcher would like to assess this type of association in this study.

2.5.2 PHYSICAL ACTIVITY AND GLYCAEMIC CONTROL

Physical activity is one of the major recommendations of life style change for newly diagnosed DM. According to a SEMDSA[13] report that randomised control trials have demonstrated that consistent physical activity improves glycaemic control and decreases cardiovascular risk factors for DM patients. In a systematic review[40] of 26 randomised control trials with 2253 T2DM patients, volume or frequency of exercises were the most important factors associated with reduction of HBA_1C in all types of exercises compared to the intensity of the exercises.

A randomised study in Iran found also that physical training such as aerobics or resistance training improves glycaemic control[41] In a study in India[42]on the effects of exercises on peripheral neuropathy in T2DM, it was reported that moderate intensity exercises can alter progression of diabetic neuropathy. In another review, it was reported that exercise decreases cholesterol and improves blood pressure in T2DM[43]. Therefore the researcher would like to assess the impact of physical activity on T2DM attending the DMC.

All the above mentioned studies indicate poor glycaemic control ranging from 64% to 94%, depending on whether participants are from highly resourced or poorly resourced countries, with the exception of the German[33] and Japanese studies'[35], with 78% and 65% good glycaemic control respectively. It is an indication of how difficult a condition such as DM is to manage, as it requires a multifaceted and multidisciplinary approach. There is an expectation of increasing global burden of DM and particularly in low and middle income countries such as SA, understanding the patient-related factors associated with glycaemic control in the researcher's practice is critical in developing strategies to improve clinical outcomes of DM. Therefore, this study aims to explore patient-related factors associated with the glycaemic control of T2DM patients attending the Daveyton Main Clinic (DMC). The research question is: what are the patient-related factors associated with glycaemic control of T2DM patients attending DMC?

2.6 DEFINITION OF TERMS

2.6.1 Type-2 Diabetes Mellitus

A metabolic disease characterised by chronic hyperglycaemia and disturbances of carbohydrate, fat and protein metabolism resulting from predominantly insulin resistance with relative insulin deficiency, to predominantly secretory defect with insulin resistance.[13]

2.6.2 Glycosylated haemoglobin test (HBA_1C)

The glycosylated haemoglobin test is a blood investigation used to diagnose diabetes and to measure the level of glycaemic control of diabetes. It goes by many names, including glycated haemoglobin, glycosylated haemoglobin, and haemoglobin A1C. The HBA_1C test result indicate the average blood glucose measurement for the past two to three months.[13]

2.6.3 Glycaemic control

Glycaemia is the level of glucose in the bloodstream. The level of control is determined by the level considered to be normal. The level determined in our study for good glycaemic control is $HBA_1C \leq 7\%$ for the majority of patients and $HbA_{1C} < 7.5\ \%$ for elderly patients (older than 60 years)[8]. Therefore, the range of glycaemic control will be an HBA_1C between 7 – 7.5%

2.6.4 Socio-demographic characteristics

These are socio-demographics characteristics of T2DM patients including age, gender, housing, education level, employment status, duration of diabetes, type of treatment and social habits.[16,17]

CHAPTER 3: METHODOLOGY

3.1. INTRODUCTION

This chapter describes the methodology of the study. It includes the study design, setting, population, sampling, data collection process, data analysis, ethical considerations and limitations of the study.

3.2 STUDY DESIGN

The researcher conducted a cross-sectional descriptive study of T2DM patients attending the chronic disease clinic of DMC.

3.3 STUDY SETTING

The research was conducted at Daveyton Main Clinic (DMC), eastern sub-district, Ekurhuleni health district, Gauteng Province. It is one of the oldest clinics in Daveyton Township in Ekurhuleni. The community served consists mainly of four-roomed houses and informal settlements with a ratio of 70 % and 30 % respectively. This ratio is lower than the ratio in Ekurhuleni according to a recent survey by Statistics South Africa. The DMC is the first clinic in Daveyton built in 1957 and officially opened on the 31st of January 1958. It is situated in the heart of Daveyton customer care centre in Ward 70 of the Ekurhuleni Metropolitan Council. Daveyton Civic Centre, the Daveyton Mall, Daveyton Magistrate's Court and a taxi rank are within walking distance from the clinic. DMC services an estimated population of 150.000.

The clinic provides a comprehensive primary care service for; curative and chronic, family planning, child health, sexually transmitted infection, antenatal and post-natal with Prevention of Mother to Child Transmission (PMTCT), an HIV clinic one of the first sites in Primary care with a head count of more than 6 000 patients. DMC also has specialised services such as rehabilitation services (physiotherapy, occupational therapy, and speech therapy), oral health, school health, optometry service, social worker, dietician, medico-legal or rape crisis centre and mental health services.

Like most community health centres (CHC) of Ekurhuleni, DMC is supported by the University of Witwatersrand Family Medicine Department and the district Family Medicine Unit, made of Family Physicians, registrars and medical officers. The clinic is a major public health care facility, as there is no hospital in Daveyton Township. Therefore,

for the Daveyton population, the clinic is an important facility for their chronic and acute care.

3.4 STUDY POPULATION

The study population was all T2DM patients willing to participate in the study attending the Daveyton Main Clinic during the period from March 2015 to June 2015.

3.5 SAMPLING

3.5.1 Sampling and sample size

The sampling technique was a convenience sampling. During the recruitment period all T2DM patients attending the chronic diseases clinic in the DMC were informed about the study on a daily basis. The sample size was 200 T2DM patients attending the chronic diseases clinic in Daveyton (DMC). The sample choice was the first 200 consenting T2DM patients who were recruited. The glycaemic control was determined by doing an HBA_{1C} blood test on the date of recruitment for all participants on T2DM treatment for at least a year.

3.6 INCLUSION AND EXCLUSION CRITERIA

3.6.1 Inclusion criteria were

- Adults (older than 18 years old) with T2DM attending the chronic disease clinic in Daveyton (DMC) during the period of recruitment from March 2015 to the saturation of sample size.

- Patients with T2DM who had attended the DMC for at least a year.

3.6.2 Exclusion criteria were

- Critically ill patients
- Minor patients (younger than 18 years old);
- Haemoglobinopathies
- Pregnant women

3.7 DATA COLLECTION TOOL OR INSTRUMENT

- Chronic disease attendance register;
- Patient clinical record review; and

- Patient questionnaire administered by the researcher or two assistants.

The patient questionnaire is made of eight parts, the general socio-demographics, general diabetics, clinic accessibility, treatment compliance, association with hypertension, depression screening, global physical activity and lastly the patient clinical measurement. The process was to cater for most socio-demographics factors, diabetes related factors and treatment compliance. We considered also the accessibility to facility and hypertension association. During the assessor group process, it was recommended ~~to us~~ to consider other factors such as depression and physical activity. Therefore we added the WHO validated depression screening questionnaire (PHQ2) and validated global physical activity questionnaire (GPAQ) in the data tool for the study.

3.8 DATA COLLECTION PROCESS

During a three-month period from April 2015 (to June 2015) a sample of 200 T2DM patients attending the Daveyton Main chronic disease clinic for at least a year were enrolled in the study with their consent. The glycaemic control was determined by the level of HBA_1C. All participants underwent a blood test for HBA_1C and the following were administered to them: a patient questionnaire including socio-demographic, diabetes information, co-morbidities, a global physical activity questionnaire (GPAQ) and a depression screening questionnaire PHQ 2.

The initial information about the study was provided by a professional nurse or a PHC nurse managing the chronic disease clinic in the DMC during a routine consultation. The willing participants were referred to the study team. The latter was comprised of the researcher and two trained assistants. The study team explained the details of the study to all willing participants; assessed the suitability of the patient and obtained their consent. Finally, on the day of recruitment or consultation the study team; administered the questionnaire, took blood for HBA_1C and anthromethric measures needed.

Patients attending the chronic disease clinic three times per week on Mondays, Tuesdays and Wednesdays were recruited by the team. A convenience sampling method was used. The first successive 200 T2DM patients attending the DMC and willing to participate in the study were enrolled. The sample was divided into two arms according to their level of glycaemic control. Poor glycaemic control was considered to be $HBA_1C > 7$ % and > 7.5

% for age groups below 60 and above 65 years respectively. The group with an HBA_1C above 7 or 7.5 (poor glycaemic control) did form the study arm. The group with an HBA_{1C} below or equal to 7 or good glycaemic control was the control case. The number of participants for each group was determined by the results of HBA_1C of the blood test done during recruitment. The study team used a DMC lecture room to complete the process.

The expectation of recruiting 30 patients every week during the recruitment period was reached. The questionnaire was in English only; it was made of socio-demographic, diabetes general information and compliance. The World Health Organisation (WHO) validated Patient Health Questionnaire (PHQ) 2 for screening of depression and WHO validated Global Physical Activity Questionnaire (GPAQ). The process of completing the questionnaire, anthropometric measures and collecting blood took more and less thirty minutes for each participant.

Collection of data from patients' clinical records was done using a template attached to the questionnaire. Identification of the patients was done by a coding number allocated by the study team. The factors considered were gender, age, housing, education level, employment, means of transport, distance to the clinic, duration of diabetes, treatment regimen, compliance level, body mass index, physical activities, co-morbidities, complications and depression screening.

3.9 DATA ANALYSIS

Microsoft Excel was used to capture data and Stata13 was used for data management and analysis. Selected predictors included socio-demographic variables (sex, age, education, housing, employment status …) and some comorbidities (depression, hypertension, HIV, etc.)

The main outcome of interest glycaemic control was defined as HBA_1C (glycosylate Haemoglobin) ≤ 7. It was coded as controlled '$\leq 7\%$ for patients younger than 60 years of age and ≤ 7.5 for patients older than 65 years' and uncontrolled '>7% or 7.5% respectively for patients younger and older than 60.

Physical activity was also investigated as one of potential confounders. Categorical variables were described using frequency tables and percentages, whereas continuous

variables were described using mean and standard deviation or median and inter quartile range depending on the underlying distribution.

The first objective was achieved using frequency tables and percentages for categorical covariates and mean and standard deviation (median and inter quartile range) for continuous variables. Pie charts were used to portray the distribution of categorical factors and histograms were used for continuous factors.

The second objective was achieved using the Pearson chi-square test of association for categorical variables and an independent t-test (Mann Whitney test) for equality of means were used for continuous variables.
The third objective was met by fitting a logistic regression model to investigate the magnitude of the association between significant predictors and the outcome of interest. The final logistic model was tested for lack of fit by using the Hosmer Lemeshow test for goodness of fit.

Primarily, the independent or input variables are socio-demographic characteristics. The dependent, output or outcome variables includes HBA_1C, body mass index, duration of diabetes, treatment regimen, blood pressure, co-morbidities, complications and adherence levels. Data were captured on Excel spreadsheets and imported into Stata 9 software. With the help of a statistician, descriptive statistics and frequency distributions were analysed through means, standard deviations of means, proportions, comparisons and correlations. A Pearson correlation coefficient (***r***) was expressed when the relationship between two categorical variables. Correlation used in this way did mean association and not necessarily causation. Analysis of the association between two numerical variables such as the participants' age was done using a student t-test. Statistical significance was considered at a 5% level and denoted p value < 0.05.

3.10 ETHICAL CONSIDERATIONS

Initial approval to conduct the study was sought and obtained from the Human Research Ethics Committee (HREC), University of the Witwatersrand, Johannesburg (Appendix A). Secondly from the Ekurhuleni health district, Daveyton Main Clinic management (Appendix B). The HREC ethical clearance number is 150269. Consent (Appendix C) was

obtained from all participants before being interviewed by the researcher and the team using a structured questionnaire (Appendix D). Patients' information was kept strictly confidential by the research team. Data records were securely kept and only accessed by the research team. No harm was done to the participants, the benefits of the study for the participants include the possibility of improving their medical conditions.

3.11 FUNDING

The study was funded by the researcher

3.12 STUDY LIMITATIONS

Due to the geographical and cultural variations, the study cannot be generalised to all CHC facilities in South Africa. The sampling methods used in the study may be prone to the influence of selection, information or communication biases by the researcher and research assistants. The convenience sampling method is not the best method, but because of time constraints of the study, it may still be appropriate. Furthermore, the fact that participants joined the study at different times may compromise the study's findings.

CHAPTER 4: STUDY RESULTS

4.1 INTRODUCTION

This chapter describes the findings of the study. It includes the following results: description of the socio-demographic characteristics of the study participants**,** Patient-related factors associated with glycaemic control and Logistic Regression Model.

4.2 PARTICIPANTS' SOCIO-DEMOGRAPHIC CHARACTERISTICS

Table 1: Baseline Socio-demographic characteristics of participants

Characteristics	Frequency, % (n=200)
Sex	
Male	**46 (23.00)**
Female	**154 (77.00)**
Age (mean, std)	**58.72 (11.7)**
Education Level	
None	**18 (9.00)**
Primary	**80 (40.00)**
Secondary	**91 (45.50)**
Tertiary	**11 (5.50)**
Housing Type	
Formal	**167 (83.50)**
Informal	**33 (16.50)**
Employment Status	
Unemployed	**45 (22.50)**
Employed	**56 (28.00)**
Pensioner	**99 (49.50)**
Height (mean, std) in m	**17.67 (7.01)**
Weight (mean, std) in Kg	**85.98 (17.49)**
BMI Categories	
Normal	**18 (9.28)**
Overweight	**49 (25.26)**
Obese	**56 (28.87)**
Moderate Obesity	**37 (19.07)**
Severe Obesity	**34 (17.53)**
Type of transport to the Clinic	
Taxi	**113 (56.50)**
Private	**10 (5.00)**
Walk	**77 (38.50)**

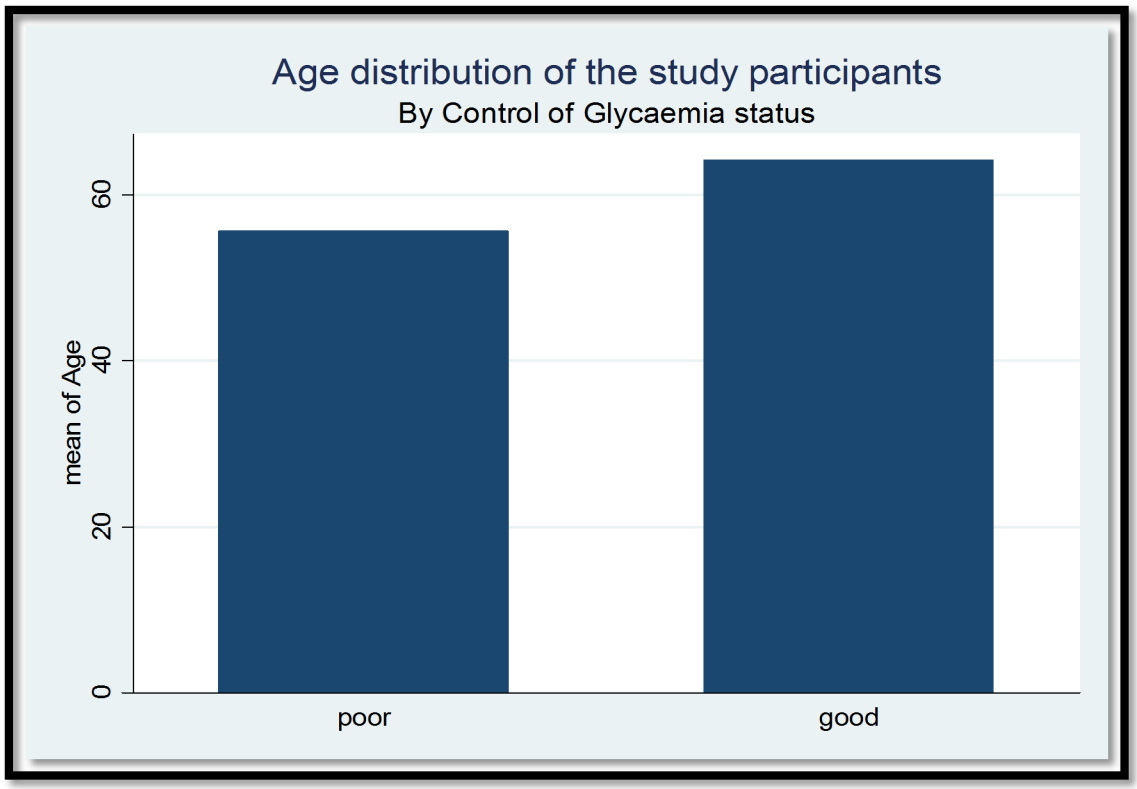
The above table shows that majority of participants (84% n=167) were living in formal housing and 10% of the participants were commuting by private transport to reach the Daveyton Main Clinic.

4.3 PARTIIPANTS' GENDER DISTRIBUTION

From the 200 participants, more than three quarters and less than a quarter were females (77.00% n=154) and males (23% n=46) respectively.

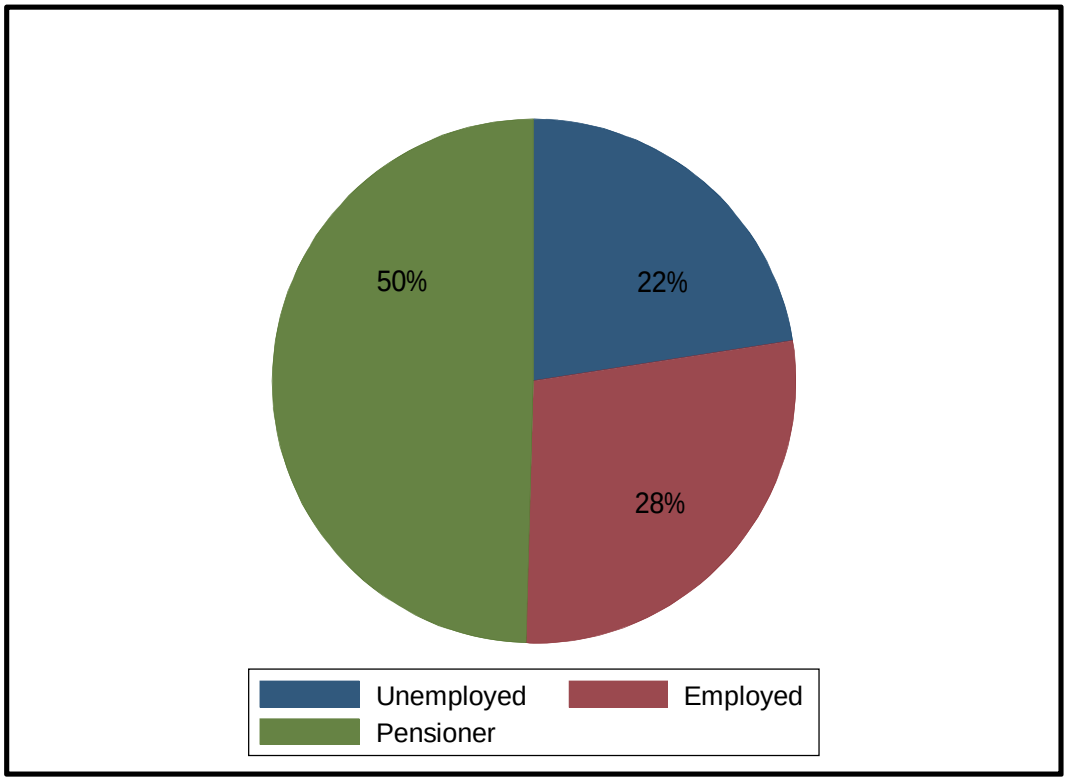
4.4 AGE DISTRIBUTION OF PARTICIPANTS BY GLYCAEMIC CONTROL

Figure 1: Age distribution of participants by glycaemic control



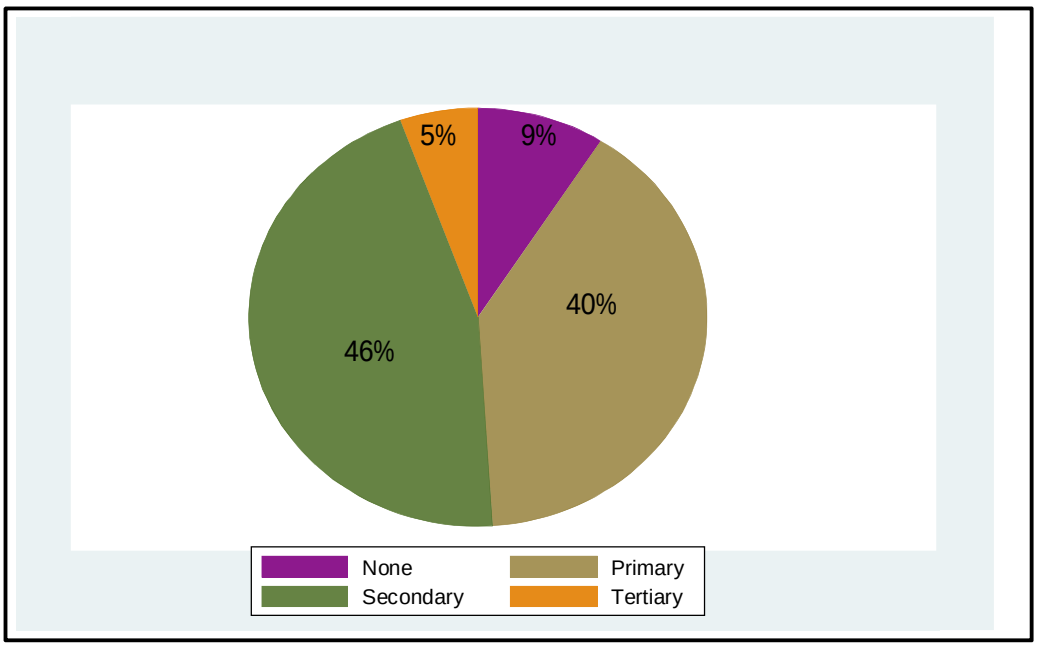
- The above figure shows that participants with good glycaemic control tend to be older (mean age: 64.17; standard deviation: 11.61) compared to those with poor glycaemic control who tend to be younger (mean age: 55.66; standard deviation: 10.62).

Figure 2: Distribution of participants' employment status



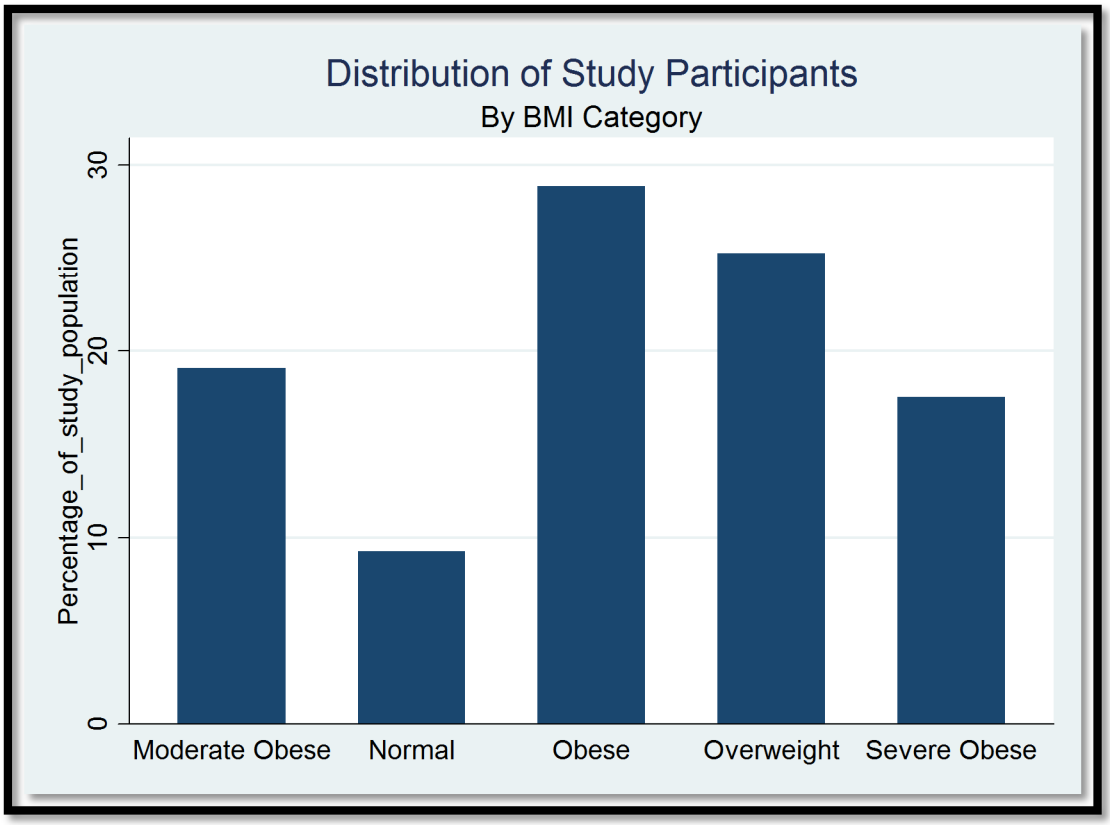
The above figure shows that 50% of participants were pensioners with only 28% of participants being employed.

Figure 3: Distribution of participants by educational level



The above figure shows that a great majority of the participants (86% n=171) have completed some primary or secondary education but only 5% (n=11) have tertiary education with 9% (n=18) without any education.

Figure 4. Distribution of patients by body mass index category



The above figure shows that eighty two percent (82 %, n=176) of participants were overweight or obese with only 18% with normal body mass index. Amongst the overweight and obese 17%(n=34) were severely obese.

4.5 PATIENT-RELATED FACTORS ASSOCIATED WITH GLYCAEMIC CONTROL

Table 2 (a): Patient-related factors associated with glycaemic control

Characteristics	Frequency, %
Systolic blood pressure (mean, std)	145.07 (16.54)
Diastolic blood pressure (mean, std)	84.35 (10.06)
Blood pressure Categories	
Normal	37 (18.50)
Hypertensive	163 (81.50)
HBA1C (mean, std) in %	8.65 (2.30)
Good control	72 (36)
Poor control	128 (64)
Comorbidities	
Hypertension	182 (91.92)
Others	16 (8.08)
HIV Status	
Positive	4 (2.01)
Negative	91 (45.73)
Unknown	104 (52.26)
Type of Treatment	
Oral	143 (71.50)
Injections	7 (3.50)
Combined	50 (25.00)
Duration of diabetes (mean, std) in years	7.32 (5.95)
Cost of transport to the Clinic (mean, std) in SA Rand	11.44 (11.46)
Clinic attended is the nearest	
Yes	197 (98.50)
No	3 (1.50)
Compliance	
Yes	157 (78.50)
No	43 (21.50)
Previous Admission to the hospital	
Yes	49 (24.50)
No	151 (75.50)
Known Hypertensive disease	
Yes	181 (90.50)
No	19 (9.50)
Under treatment for Hypertension	
Yes	181 (90.50)
No	19 (9.50)
PHQ2	
Without Depressive Symptoms	190 (95.00)
With Depressive symptoms	10 (5.00)

The above **Table 2 (a)** indicate that the mean glycaemic level as measured by HBA_{1C} was 8.65 with a standard deviation of 2.30, suggests that the average control of glycaemic level among the patients was poorly controlled 64 % n=128. The table 2a also shows the level of reported compliance by the participants to be 79% (n=157) compared to objective measurement of HBA_{1C} which was only 36% (n=72). More than 70% (n=143) of participants were on oral treatment with only 25% (n=50) on combined treatment.

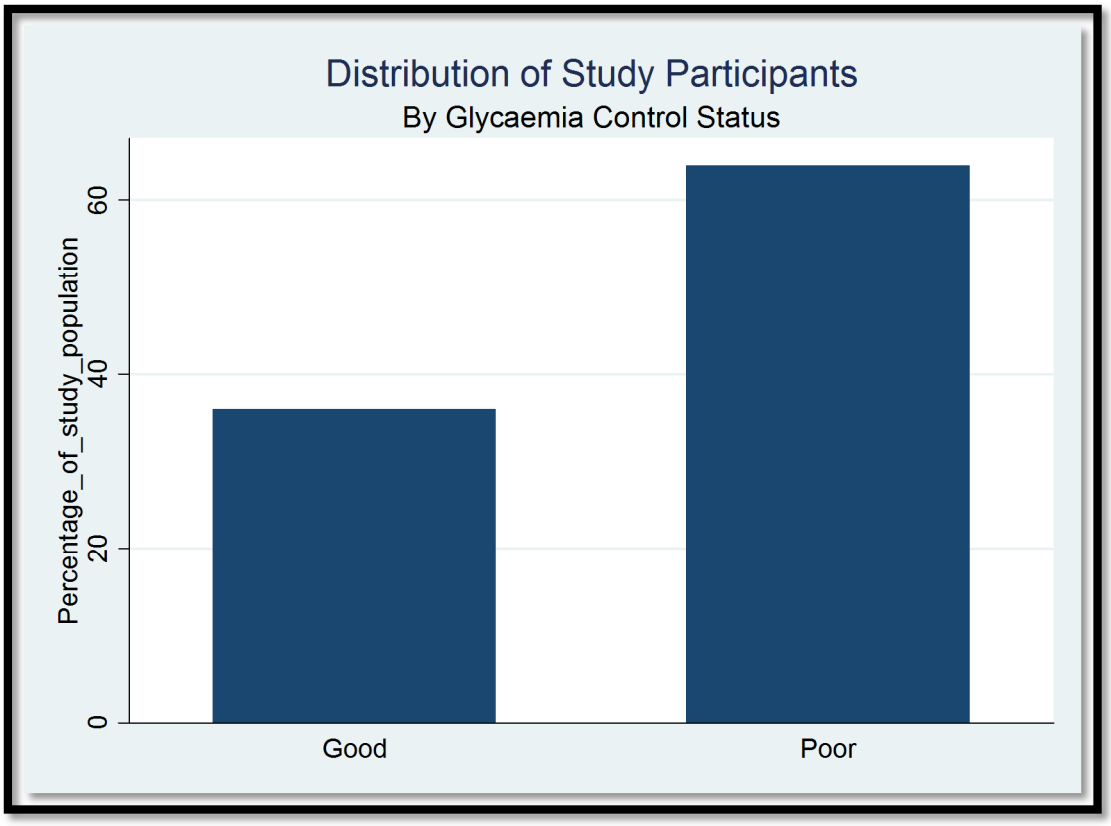
Table 2 (b): Patient-related factors associated with glycaemic control

Characteristics	Frequencies
Vigorous activities	
Yes	1 (0.50)
No	199 (99.50)
Moderate Activities	
Yes	7 (3.50)
No	193 (96.50)
Bicycle use	
Yes	166 (83.00)
No	34 (17.00)
Recreational Activities	
Yes	3 (1.50)
No	197 (98.50)
Activities that increase heart rate	
Yes	50 (25.00)
No	150 (75.00)
Sedentary duration in hours	
Moderate (1 – 4 hours)	33 (16.50)
Excessive (4 hours+)	167 (83.50)
Complications	
None	136 (68.34)
Retinopathy	5 (2.51)
Peripheral neuropathy	51 (25.63)
Stroke	6 (3.02)
Heart	1 (0.50)

The above Table 2 (b) shows that the majority of study participants were not participating in physical activities - only 25% participated in activities that raised the heart rate and 84

% (n=167) had sedentary duration of more than 4 hours. Most of the participants (68% n= 136) had no complications, only 26% (n=51) had peripheral neuropathy.

Figure 5. Distribution of participants by glycaemic control



- The above figure shows that majority of participants had poor glycaemic control (64% n=128)

4.6 ASSOCIATION WITH GOOD GLYCAEMIC CONTROL

Table 3 (a): Association of socio-demographic, patients-related factors and good glycaemic control

Characteristics	Good control (n=72)	Poor Control (n=128)	p-value
Sex			
Male	19 (41.30)	27 (58.70)	0.393
Female	53 (34.42)	101 (65.58)	
Age (mean, std)	64.17 (11.61)	55.66 (10.62)	0.001
Education Level			
None	9 (50.00)	9 (50.00)	
Primary	28 (35.00)	52 (65.00)	0.502
Secondary	30 (32.97)	61 (67.03)	
Tertiary	5 (45.45)	6 (54.55)	
Housing Type			
Formal	66 (39.52)	101 (60.48)	0.020
Informal	6 (18.18)	27 (81.82)	
Employment Status			
Unemployed	11 (24.44)	34 (75.56)	
Employed	11 (19.64)	45 (80.36)	0.001
Pensioner	50 (50.51)	49 (49.49)	
Height (mean, std) in m	18.54 (6.69)	17.18 (7.16)	0.194
Weight (mean, std) in Kg	82.80 (14.63)	87.77 (18.74)	0.056
BMI			
Normal	7 (38.89)	11 (61.11)	
Overweight	20 (40.82)	29 (59.18)	
Obese	21 (37.84)	35 (62.50)	0.360
Moderate Obesity	14 (37.84)	23 (62.16)	
Severe Obesity	7 (20.59)	27 (79.41)	
Systolic blood pressure (mean, std)	143.45 (16.94)	145.98 (16.30)	0.304
Diastolic blood pressure (mean, std)	82.35 (9.31)	85.21 (10.39)	0.108
Blood Pressure			
Normal	15 (40.54)	22 (59.46)	0.524
Hypertensive	57 (34.97)	106 (65.03)	
Comorbidities			
Hypertension	69 (37.91)	2 (12.50)	0.056[F]
Others	113 (62.09)	14 (87.50)	
HIV Status			
Negative	23 (25.27)	68 (74.73)	
Positive	2 (50.00)	2 (50.00)	0.011[F]
Unknown	46 (44.23)	58 (55.77)	
Type of Treatment			
Oral	56 (39.16)	87 (60.84)	
Injections	3 (42.86)	4 (57.14)	0.231
Combined	13 (26.00)	37 (74.00)	
Duration of diabetes (mean, std) in years	7.93 (7.01)	6.97 (5.27)	0.274

Tables 3a above shows that age was related to good glycaemic control with p=0.001 and formal housing related also to good glycaemic control with p=0.020

Table 3 (b): Association of socio-demographic, patients-related factors and good glycaemic control

Characteristics	Good control (n=72)	Poor Control (n=128)	p-value
Type of transport to the Clinic			
Taxi	43 (38.05)	70 (61.95)	
Private	4 (40.00)	6 (60.00)	0.707
Walk	25 (32.47)	52 (67.53)	
Cost of transport (mean, std) in SA Rand	12.06 (11.22)	11.09 (11.63)	0.570
Clinic attended is the nearest			
Yes	72 (36.55)	125 (63.45)	0.191
No	0 (0.00	3 (100.00)	
Compliance			
Yes	54 (34.39)	103 (65.61)	0.366
No	18 (41.86)	25 (58.14)	
Previous Admission to the hospital			
Yes	19 (38.78)	30 (61.22)	0.641
No	53 (35.100	98 (64.90)	
Known Hypertensive disease			
Yes	69 (38.12)	112 (61.88)	0.054
No	3 (15.79)	16 (84.21)	
Under treatment for Hypertension			
Yes	68 (37.57)	113 (62.43)	0.154
No	4 (21.05)	15 (78.95)	
PHQ2			
Without Depressive Symptoms	69 (36.32)	121 (63.68)	1.000
With Depressive symptoms	3 (30.00)	7 (70.00)	

The table 3b above shows that being hypertensive was not related to good glycaemic control with p=0.054, reported good compliance by participants was not related to good glycaemic control p=0.366 and lastly depressive symptoms was not related to good glycaemic control p=1.000

Table 3 (c): Association of socio-demographic, patients-related factors and good glycaemic control

Characteristics	Good control (n=72)	Poor Control (n=128)	p-value
Physical Activities			
Vigorous Activities			
Yes	72 (36.18)	0 (0.00)	1.00[F]
No	0 (0.00)	127 (63.82)	
Moderate Activities			
Yes	69 (35.75)	124 (64.25)	0.704[F]
No	3 (42.86)	4 (57.14)	
Bicycle use			
Yes	16 (47.06)	18 (52.94)	0.140
No	56 (33.73)	110 (66.27)	
Recreational Activities			
Yes	70 (35.53)	127 (64.47)	0.295
No	2 (66.67)	1 (33.33)	
Sedentary hours			
Mild (1- 3 hours)	9 (27.27	24 (72.73)	0.253
Excessive (4hours+)	63 (37.72)	104 (62.28)	
Activities that increase heart rate			
Yes	50 (33.33)	100 (66.67)	0.179[F]
No	22 (44.00)	28 (56.00)	
Complications			
Retinopathy	3 (60.00)	2 (40.00)	
Peripheral neuropathy	15 (29.41)	36 (70.59)	
Stroke	3 (50.00)	3 (50.00)	0.486[F]
Heart	0 (0.00)	1 (100.00)	
None	50 (36.76)	86 (63.24)	

Tables 3c: Pearson Chi Square test was used for the above p-value, unless otherwise indicated. Independent t-test was used for equality of means between good control and poor control.

F: p-value from Fisher exact test.

- Of all the factors (socio-demographic, and patient-related), age, type of housing, employment status, weight, HIV and comorbidity were significantly associated with the control of glycaemic level.

However, the extent of such a relationship could not be obtained using simple tests of associations as from the above table. Thus, we fitted a simple logistic regression model and results of the final model are displayed on the table below.

Table 4: Logistic Regression Model

Characteristics	OR & 95% C.I.	p-value
Age (mean, std)	1.08 (1.05 – 1.12)	0.001
Height (mean, std) in m	1.06 (1.01 – 1.11)	0.031
Weight (mean, std) in Kg	0.98 (0.96 – 1.00)	0.095
HIV Status		
Negative	1	
Positive	5.46 (0.53 – 56.13)	0.153
Unknown	1.94 (0.96 – 3.93)	0.065
Activities that increase heart rate		
No	1	
Yes	2.14 (0.97 – 4.70)	0.059

The Table 4 shows that the odds of having a good glycaemic control level increased with **age** (OR: 1.08 (1.05 – 1.12). The likelihood of having good glycaemic control increased also with height (OR: 1.06; 95% C.I: 1.01 – 1.11) and not weight (OR: 0.98; 95% 0.96 – 1.00).

Across the spectrum of socio-demographic and patients-related factors, the final logistic regression model contained age, height and HIV status.

CHAPTER 5: DISCUSSION

5.1 INTRODUCTION

The aim of the study was to assess patient-related factors associated with glycaemic control on T2DM patients attending the DMC. The factors that influence glycaemic controls are multiple and complex. In this chapter the results obtained in the study are discussed and interpreted in relation to literature.

This study shows that T2DM patients: aged ≥ 65 years, pensioners, living in formal housing, being hypertensive, and doing physical activities that increased heart rate, were more likely to have good glycaemic control. The study did not attempt to explore systems-related factors or health care-related factors that influenced glycaemic control.

The methodology used in this study being descriptive cross-sectional could provide only the association between factors without inference on causation. There was a higher possibility of selection and information biases and the sample size used may not be adequate.

5.2 SOCIO-DEMOGRAPHICS CHARACTERISTICS

All participants of the study were black Africans (n=200) which is normal because previously Daveyton was a racially demarcated area for black Africans and is still inhabited by black Africans only. This result is similar to the Johannesburg[17] study where all the participants of a Community Health Centre in Soweto were black Africans for historical reasons. Another study[16] in a peri-urban population in the Eastern-Cape had also as all of its participants, black Africans.

The study indicated that more than three quarters of the participants were female with less than one quarter male; results similar to other studies[16,17] with a high representation of the female gender among the participants. Higher female gender participation may be explained because more men are at work during that time of the day when most chronic patients attend the clinic. Higher female participation gives rise to a higher possibility that these results could be bias to the female gender. However this trend is not unique to this study, as a convenience sampling method was used. Previously, other studies in PHC revealed a majority of female participants. The researcher can speculate that the female

gender has more help seeking behaviour than the male gender. Therefore, it is not surprising, to have more female than male participants.

Patients included in the study varied between the ages of 26 to 91 years old, as adults only were considered for the study. The study mean age was 58 years old with a standard deviation of 12 years. These results were comparable with other SA studies[16,17] and Middle-Eastern studies[21,22,23]but better than others Africans studies.[16,17,19] This level of mean age may be considered as a positive trend because the lesser the mean age, the worse glycaemic control. The researcher can speculate that this mean age which is higher than most Africans studies may be explained by the fact that SA is a middle income country comparable with many Middle-Eastern countries and better than many African countries in the level of development, and as a result the occurrence of T2DM is closer to other middle income countries than Africans countries.

In terms of the education level of the participants, 50% (n=102) had a good educational level (secondary and tertiary), and only 10% (n=18) had no education. These results are similar to another study in Daveyton that found approximately one twentieth (5%, n=200) of participants without any education.[37] Contrary to the Johannesburg study[17] with more than three quarters of the participants never having completed secondary school. These results were better than many Africans studies with a lower level of education. However, these results have to be taken into consideration with caution because it was a self-reporting survey and participants have a tendency to exaggerate their answers. Therefore, the findings may not be a true reflection of the picture.

Regarding the employment level of the participants; nearly half (49%, n=99) were pensioners, more than a quarter were employed, and less than a quarter of participants were unemployed which is better than the level of unemployment in the general population in SA which is considered to be very high i.e. between a quarter and a third of the population. (Stats SA). The study results indicated a larger number of participants living in formal housing (85% n=167), and less than a twentieth (16%, n=33) living in informal housing that is close with the Ekurhuleni urbanisation level of 90% according to Stats SA.

The above may be a positive factor for good glycaemic control because the SANHANES reports that the urban population of formal housing have good glycaemic control contrary to the informal settlement which is associated with poor glycaemic control. The researcher can speculate that formal housing associated with good glycaemic control can be explained by the fact that formal housing has basic amenities such as running water, toilet, electricity that may facilitate compliance to treatment of chronic conditions.

5.3 PATIENT-RELATED FACTORS WITH POOR GLYCAEMIC CONTROL

The study results indicated more than a third of the participants had a good glycaemic control of $HBA_1C \leq 7\%$, which is better than previous South African[16,17] and African studies[18,19] but that is in line with the Middle-Eastern studies[21.22,23] and American studies.[25,26] The factors associated with poor glycaemic control were age and informal housing. The younger the age of participants the risk of poor glycaemic control mean age 55.66 (10.62) with p= 0.001. Informal housing was associated with poor glycaemic control p=0.020.

The researcher can speculate that this result 64% (n=128) poor glycaemic control may be an indication of the level of economic development in SA as a middle income country compare to others Africans study. Another factor to take into consideration of this result is that the previous SA studies were done a long time ago, more than 10 years. This result may also be an indication of a level of improvement in managing DM in the DMC. Previously the researcher undertook a quality improvement study on the process of care of DM in the DMC: the audit results indicated poor monitoring glycaemic control with less than a quarter of participants with HBA_1C being assessed regularly which was in line with other SA studies[16,17] but the intervention improved monitoring of glycaemic control considerably.

This result may be due also to the impact of the Family Medicine Unit in the Ekurhuleni Health District and particularly in DMC. The Family Medicine Unit brings skills and knowledge for clinical improvement of PHC services. This level of glycaemic control is still below half, and therefore below the goal of Diabetes Mellitus management but may be also related to the nature of the condition which is difficult to manage even in higher income countries when considering the level of control in many studies.

5.4 PATIENT-RELATED FACTORS OF GOOD GLYCAEMIC CONTROL

The age of participants was significantly connected with good glycaemic control, the older the participants were, the better their glycaemic control with 66 years as the mean age (p-value: 0.001). This result is similar to other African studies[16,17,19] and other studies.[21,22,23] Contrary to the researcher's initial expectation, believing that with the progress of DM, the older patients would have most of the worse outcome. It is common knowledge that the worsening of glycaemic control over time is linked to the reduction of pancreatic beta cells leading to greater insulin resistance associated with the ageing process. This can also be explained by the fact that in Africa the undiagnosed population of DM is more than half according to the IDF[6], therefore with late diagnosis of DM, the DM patients are already in very poor shape when they are diagnosed as a result of the progression of the disease.

The HIV status was a controversial factor, the result indicates that HIV positive patients were five times more likely to have good glycaemic control compared to HIV negative patients. Yet, such a difference was not statistically significant (p-value: 0.153). The researcher can speculate that most probably this association was only an incidental finding without bearing on the management of DM, therefore not to be taken seriously.

The study also indicated Height (p-value: 0.031), weight (p-value: 0.095), formal housing (p-value: 0.020), employment status (p-value: 0.001) were associated with good glycaemic control but hypertension was not statistically significant (p-value: 0.054). Weight being associated with glycaemic control is in line with current evidence, as T2DM is influenced by nutritional factors, therefore weight control is imperative for good glycaemic control.

Exercising that increases the heart rate was also one of the relevant factors affecting a good glycaemic control level. Those undergoing such exercises were twice (OR: 2.14) more likely to have a good glycaemic level compared with those who do not. However, such a difference was not statistically significant (p-value: 0.059).

Formal housing in the study was associated with good glycaemic control which is in line with the results of the finding by SANHANNES[4] that urban formal housing was associated with good glycaemic control. This result can also indicate that a house with basic amenities

which is an indication of the level of development or income level is a positive factor for glycaemic control.

The factors associated with glycaemic control have been difficult to elucidate from study to study, sometimes even contradictory. Otiniano[27] in an American study found that longer duration of the disease, lower level of education, frequent use of glucometer, being foreign-born, smoking and obesity were associated with poor glycaemic control while a systematic review by Sanal[44] could not find an association of smoking, duration of diseases with poor glycaemic control. A study in Mamelodi (SA) found that obesity associated with poor glycaemic control which was similar to our finding and also with others SA studies[16,17]. A lower level of education associated with good glycaemic control is controversial. In our study we did not find any association of glycaemic control with level of education but studies done by Van de Sande in the Free State (SA) and Khan (Saudi Arabia) found level of education to be associated with good glycaemic control similar also to other SA study[16].[17]

This study could not establish the association between duration of the diseases and glycaemic control but the Hawaiian study[28], Johannesburg study[17] as well as the study by Otiniano[27] have established that longer duration of diseases is associated with poor glycaemic control which is in line with the current evidence by IDF or WHO. Another controversial factor in relation to glycaemic control was unemployment status, this study could not establish any association with glycaemic control but the Johannesburg[17] study found unemployment to be associated with good glycaemic control. The level of reported compliance by participants was not related to glycaemic control.

5.5 DEPRESSION AND GLYCAEMIC CONTROL

The result indicates that there is no association between depressive symptoms and glycaemic control. This is similar to other African studies[16,17] where there was no association between depressive symptoms and glycaemic control. Depression was not a major co-morbidity of DM contrary to others studies[34,35] where depressive symptoms were associated with poor glycaemic control and depression was always a major co-morbidity. This result has to be taken into consideration with caution because in a self-reporting study participants have a tendency to underestimate or overestimate according to the situation.

Furthermore the study used only PHQ-2 which helped to screen for depressive symptoms but is not an appropriate tool for diagnosis of depression. Therefore it may be not an appropriate tool to determine an association between depressive symptoms and glycaemic control. Hence this part of the study might need further research with more details on tools according to DSM-V such as PHQ-9, and the Hamilton Depression scale.

5.6 PHYSICAL ACTIVITIES AND GLYCAEMIC CONTROL

Results indicate that moderate physical activities which increase the heart rate was also one of the relevant factors affecting the good glycaemic control level but not statistically significant p-value: 0.059. This result is similar to the Africans studies[16,17], that is in line with the evidence-based recommendations of SEMDSA[11], ADA or IDF[6]. Participants undergoing such physical activities were twice (OR: 2.14) more likely to have a good glycaemic control level compared with those who do not. This result is in line with many studies that have demonstrated that regular physical activity and moderate cardiorespiratory fitness are associated with a reduction in cardiovascular and overall mortality of T2DM patients[11].

Therefore, counselling for physical activity is mandatory for appropriate management of T2DM. However, results are to be taken in consideration with caution as the difference was only marginally significant (p-value: 0.059). Results indicated a high level of sedentary amongst the participants which might contribute to poor glycaemic control even if the regression model could not establish a direct association. The researcher can speculate that a higher level of sedentary among participants was associated with a high level of obesity, both factors being associated with poor glycaemic control.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 INTRODUCTION

In the following chapter, the researcher will provide the study conclusion and make recommendations**.**

6.2 CONCLUSION

The majority of participants in this study had poor glycaemic control. That was to be expected considering the results of previous studies of glycaemic control done globally[16,17,19, 21,22,23,24,25,26,] . Nonetheless, the results of this study were far better than .previous study results in terms of glycaemic control in SA[16,17]. The level of good glycaemic control found in this study was comparable with many middle income countries such as Saudi Arabia[23], Oman[21], in the Middle East and Brazil in South America.[26]

The factors which influenced glycaemic control were multiple, complex, variable and sometimes contradictory. The patient-related-factors which were associated with good glycaemic control were age, formal housing, earning an income, normal weight and physically active. Depression or depressive symptoms were not found to be associated with glycaemic control in this study. Therefore elderly patients living in formal housing, earning an income, with normal weight and physically active were more likely to have good glycaemic control. The study has shown that improvement of glycaemic control amongst T2DM patients attending the DMC is possible.

6.3 RECOMMENDATIONS

Addressing the growing DM epidemic in the clinic and the district is challenging. Therefore the results of this study could contribute to the strategic planning of DM management in the Ekurhuleni health district taking into consideration the fact that this study is one of the first in Ekurhuleni primary health care. The researcher wishes to propose the following recommendations:

6.3.1. Focus on younger T2DM patients attending DMC as the target for intensive management to prevent poor glycaemic control and early complications of DM. In this study the younger T2DM patients were classified as any patient below 50 years

old attending the DMC. Therefore the researcher recommends that all patients within this target group be routinely screened for DM and receive close monitoring of the condition.

6.3.2. Encourage diabetes support group meetings where education on the condition and sharing of experience with other T2DM patients is an ongoing process. Health promoters, professional nurses, and PHC doctors should be involved. Every contact with a target group would be an opportunity for education and health promotion. From the waiting area to all steps of consultation there are multiple opportunities for staff to be involved. It would be desirable to address the problem within a year.

6.3.3. Ensure regular monitoring of T2DM patients attending PHC according to the National Department of Health (NDOH) guidelines and SEMDSA guidelines that recommend at least one HBA_{1C} blood test every six months or yearly for the control T2DM. The guidelines should be communicated to all staff and made available in each consulting room.

6.3.4. Further study of depression and glycaemic control using appropriate tools for diagnosis of depression such the Hamilton depression scale or the WHO Patient health information questionnaire 9 (PHQ-9), which are more comprehensive for diagnosis of depression, can be considered in future to provide in-depth information.

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R14/49 Dr Bakatuamba Pab...

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150269

NAME: (Principal Investigator)	Dr Bakatuamba Pabu
DEPARTMENT:	Family Medicine Daveyton Main Clinic, Ekurhuleni Health District, Gauteng District
PROJECT TITLE:	Patient-Related Factors Associated with Glycaemic Control in Type-2 Diabetes Mellitus Patients Attending Daveyton Main Clinic in the Eastern Sub-District of Ekurhuleni Health District, Gauteng Province
DATE CONSIDERED:	27/02/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	John Musonda
APPROVED BY:	Professor P Cleaton-Jones, Chairperson HREC (Medical)
DATE OF APPROVAL:	15/04/2015

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

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.**

Principal Investigator Signature

Date 25/04/2015

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

PROTOCOL NO: M150269

Patient Information Sheet

Study Title: Patient-related factors associated with glycaemic control of type-2 diabetes mellitus attending Daveyton Main Clinic in Eastern sub-district of Ekurhuleni health district, Gauteng Province.

Good day Sir/Madam
Introduction:
My name is Dr B. Pabu, a family physician registrar in Ekurhuleni health district and at the University of Witwatersrand's Department of Family Medicine. I am doing a study looking at people who have blood sugar disease or diabetes at Daveyton Main Clinic for my Family Medicine degree.

Invitation to participate:
We would like to invite you to take part in a research study about blood sugar disease or diabetes in Daveyton Main Clinic.

What is involved in the study:
The researcher's opinion is that understanding factors which influence control of adult blood sugar disease is very useful. The study will provide information which will assist to improve the management of type-2 diabetes at our clinic. The study will also assess the relationship of factors such as depression, physical activities and other diseases like hypertension.

During a three-month period, some 200 type-2 diabetes mellitus patients who have attended the clinic for at least one year will be enrolled in the study after obtaining consent. The average level of sugar in the blood (also called glycaemic control) will be determined by the value of HbA1C which is a blood sugar test which indicates level of blood sugar for the last three months.

All participants will undergo blood test for HBA1C and a patient questionnaire including socio-demographic, diabetes information, co-morbidities, global physical activity questionnaire (GPAQ) and depression screening questionnaire PHQ 2 will be administered to them. From March 2015, patients' willing to participate will be included in the study till total of 200 is reached. There will be two professional nurses who are part of the team and helping in the study to attend to any problems.

Risks:
There is no harm to you as participants. The study has minimal risk such as discomfort or pain during the collection of blood for investigation.

Benefits:
The study will provide information about how patients with blood sugar disease and attending Daveyton Main Clinic are controlled. This benefit will apply to the Daveyton community rather than to individual patient.

Participation is voluntary:
The participation is voluntary and non-participation will not impact you negatively in any way. Even withdrawing your participation from the study after initial consent would not affect anyone negatively.

Reimbursements:
There is no reimbursement for participation in the study and there is no cost also to the participants. There would tea and refreshments for participants.

Confidentiality:
Your information will be kept strictly confidential by researchers. Data records will be kept secured and will only be accessed by the research team, supervisor of the study and Human Research Ethics Committee. Researchers will not tell anybody that you are in this study and we won't share information about you to anyone who is not involved. After the study is over, you will be told about the outcome individually during your normal monthly visit to the clinic.

Time
The process of answering this questionnaire will take about half an hour. You are not going to lose your place in the queue, all necessary routine assessments will be done by the team and you would receive your medications as required.

Contact details of researcher/s:
You can contact me for further questions about any part of the study. I am available at any time of the day and I can be contacted on telephone number 011 424 8741 (during office hours) and mobile number 083 928 1091 or 084 989 0400 (anytime).

Contact details of REC Administrator and Chair:
In case you are not satisfied with answers provided by the researcher, or if you have a complaint, you are allowed to report that to the Human Research Ethics Committee board. Here are contact details:
Prof Cleaton-Jones, chairperson of the Human Research Ethics Committee (medical): telephone number 011 717 2301, email: peter.cleaton-jones1@wits.ac.za. Secretariat: Ms. Zanele Ndlovu and Mr. Langutani Masingi, zanele.ndlovu@wits.ac.za , langutani.masingi@wits.ac.za, telephone 011 717 1052 /2700/ 1234/ 2656.
The research ethics committee administrator and chair can be contacted on telephone number 011 717 1234 for the reporting of complaints and any problems regarding the study.

Consent Form: Use of Clinical Information for Research

Dear Patient,

You are currently being follow- up at Daveyton Main Clinic (DMC) for treatment of sugar disease or diabetes you are currently experiencing. The DMC not only renders treatment but is also actively involved in conducting research aimed at improving the quality of care that we deliver. We would like to request your permission to participate in the interview about your sugar disease or diabetes and use your clinical records (files) from which information would be extracted. The use of such information is subject to the following:

1. Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.

2. Identity of a patient from whose file information is extracted is never revealed to anyone but the researcher unless specific consent is obtained to do so. The information gathered does not contain the name of the patient but only a coded number so as to maintain anonymity.

We would like to obtain your consent for participation in the study of factors associated with blood sugar control and to use information from your file for the purpose of research, subject to the aforementioned conditions. If you choose not to give consent, this will not compromise your treatment in any way. If at any time you choose to withdraw consent you are free to do so and will not be prejudiced in any way.
Should you wish to contact us at any stage regarding consent, contact Dr B. Pabu at (011) 424 8741 or 0839281091

A. Consent Given

I_____ hereby give consent to participate in the interview and for my records to be used as per the above mentioned conditions for the purposes of research:

PATIENT: _____
DATE: _____

B. Consent Not Given

I _____ do not give consent to participate in the interview and for my records to be used:

PATIENT: _____
DATE: _____

EKURHULENI METFCPOLiTAN MUNICIPALITY

2014 -10- 2 8

DAVEYTON MAN CLIN I C
HEALTH SOCIAL DEVELOPMENT
DE-NONI S O C

Daveyton Main Clinic 9307 Empilweni St

Daveyton
1520

TEL: 011 424 8741

RE: APPLICATION FOR CONDUCTING A RESEARCH AT DAVEYTON MAIN CLINIC

TITLE: PATIENT-RELATED FACTORS ASSOCIATED WITH GLYCAEMIC CONTROL IN TYPE-2 DIABETES MELLITUS PATIENTS ATTENDING DAVEYTON MAIN CLINIC IN THE EASTERN SUB-DISTRICT, EKURHULENI HEALTH DISTRICT, GAUTENG PROVINCE.

Dear Dr B. Pabu Persal 52537382

We have a pleasure in advising you that your application for conducting the above mentioned study for the purpose of your post graduate degree in Family medicine at Daveyton Main Clinic has been approved as long as you have the approval of the Wits Human Research Ethic Committee (HREC).

Yours sincerely M. NYAKATYA

EKURHULENI METROPOLITAN MUNICIPALITY

2014 -10- 2 8

DAVEYTON MAIN CLINIC
HEALTH & SOCIAL DEVELOPMENT

IURSE CHIEF PROFESSIONAL N R E

OPERATION MANAGER

24.10.2014

Patient Questionnaire Protocol number M 150269

Interviewer: _____

Date of Interview: Reference:

1. Socio-demography

1.1 Sex:

□ M

□ F

1.2 Age: _____

1.3 How much schooling have you completed?

□ None

□ Less than primary school

□ Primary school completed

□ Some high school

□ High school completed

□ Tertiary education

1.4 Which of the following best describes your work status over the past year?

□ Unemployed

□ Employed

□ Retired/pensioner

□ Homemaker

□ Self-employed

□ Student

Please specify (others)_____

_

1.5 Where do you live?

□ Informal settlement

□ Back yard dwellers

□ Formal Brick house/ RDP house

□ Rental Flat

□ Formal house

□ Others

2. General diabetes information

2.1 How many years have you been living with Diabetes?

2.2 What type of treatment are you currently on?

□ Oral

□ Injectable
□ Combination of both
□ Others

3. Clinic accessibility

3.1 What means of transport do you use to get here?
□ Walk
□ Car
□ Taxi
□ Bus
Please specify(others)_____

3.2 How long does it take you to get here? _____ Hrs_____ min

3.3 How much does it cost you to get here and then home again?_____
3.4 Is this your nearest clinic/CHC?
□ Yes
□ No
□ Don't know

If not, why do you come here?_____

4. Treatment Compliance

4.1 Have you ever missed your medications? ☐ Yes ☐ No
Is there anything stopping you from taking your medications?□ Yes
□ No
□ Unsure

4.1.1 If yes, how often does this happen?
□ Every day
□ At least once a week
□ 2-3 times a week
□ >3 times a week
□ A few times a month
□ Very rarely
4.1.2Have-you-taken-your-medication-today?_____

4.2 Have you ever been hospitalised for diabetes problems? (e.g. for high or low glucose levels.)

□ Yes
□ No

4.3 Do you think you have received enough information to manage you diabetes well?

 Yes

 No

5. Hypertension

5.1 Are you having high blood pressure?

 Yes

 No

 Don't know

5.2 Are you currently receiving treatment for blood pressure?

 Yes

 No

6. Depression screening Questionnaire WHO PHQ2

Over the past 2 weeks how often have you been bothered by the following problem	Not at all	Several days	More than half The days	Nearly every day
1. Little interest or pleasure on doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

Patient screened positive for depression would be referred to Daveyton Main Clinic mental health section which is run by mental health nurses, psychologists and visiting psychiatry registrars form University of Witwatersrand.

7. Global Physical Activity Questionnaires (GPAQ)

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. [Insert other examples if needed]. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Questions	Responses	Code
1. Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?	Yes 1 No 2 If No, go to P 4	P1
2. In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days	P2
3. How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes	P3
4. Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?	Yes 1 No 2 If No, go to P 7	P4
5. In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days	P5
6. How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes	P6
Travel to and from places		
Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship.		
7. Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 If No, go to P 10	P7
8. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days	P8
9. How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes	P9
Recreational activities		
Now I would like to ask you about sports, fitness and recreational activities		
10. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football,] for at least 10 minutes continuously?	Yes 1 No 2 If No, go to P 13	P10
11. In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?	Number of days	P11
12. How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : minutes	P12
13. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that causes a small increase in breathing or heart rate such as brisk walking,(cycling, swimming, volleyball)for at least 10 minutes continuously?	Yes 1 No 2 If No, go to P16	P13
14. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?	Number of days	P14
15. How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?	Hours : minutes	P15
Sedentary behaviour		
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping.		
16. How much time do you usually spend sitting or reclining on a typical	Hours: minutes	P16

PATIENT MEASUREMENTS

1. Height (cm) ----------

2. Weight (kg) ----------

3. Blood pressure (mmhg) ----------

4. Urine analysis----------

5. HBA_{1C}----------

6. Co-morbidities----------

7. HIV Status ----------

8. Target organ damaged ----------

	Yes	No
Diabetes Retinopathy (Eyes)		
Peripheral Neuropathy (Feet)		
Heart Condition		
Stroke		